Access to Medicine Index 2024

Evaluating

20pharma

companies in expanding access

access to medicine FOUNDATION

to their essential healthcare products

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The Access to Medicine Foundation is an independent non-profit organisation that seeks to transform the healthcare ecosystem by motivating and mobilising companies to expand access to their essential healthcare products in low- and mid dle-income countries.

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FOREWORD

It is time to accelerate access

Despite some modest progress, this 9th Access to Medicine Index finds the potential for improved access is still far from realised and the pace of change is slow. Coverage remains patchy and many populations – especially those in the poorest countries – are still largely overlooked.

Companies could do a lot more to scale up their initiatives to make lifesaving treatments accessible and affordable every

where they are needed. Until that happens, many essential medicines and healthcare products will remain out of reach for billions of people living in low- and middle-income coun tries (LMICs).

For the past two decades, my team has been tracking the pharmaceutical industry's contribution to global health and benchmarking leading players based on clear deliverables. The latest scorecard shows a new company now leading the pack, but while there have been advances at an individual level, the overall performance of the industry still falls short. No company is yet meeting its full potential and those at the bottom have much work to do.

This report highlights the practical steps that companies should now take to give more people in LMICs the affordable medicines they need – from vaccines against infections to treatments for diabetes and cancer. By following these recom-mendations, companies and the partners they work with have the power to transform lives and strengthen global health

conducted, while the concentration of research in high-income countries risks excluding more genetically diverse populations living elsewhere.

Finally, the industry needs to recommit to scaling up global availability of key essential medicine, using voluntary licensing and technology transfers – both tried-and-tested tools for maximising the local availability of medicines across large swathes of the world. It is concerning that the pace of non-exclusive voluntary licensing (NEVL) agreements has recently stalled, even though multiple patented products have been identified as potential candidates. Technology transfers, meanwhile, remain concentrated in a few upper middle-income markets, with very few such initiatives in sub-Saharan Africa where shortfalls in local supply are critical.

security.

A top priority must be an increased focus on reach – in other words, making sure medicines are not only available but are getting to those who need them. Although there is a promising

The need for equitable access to medicines has never been

trend for more companies to prioritise low-income and least developed countries within their inclusive business mod

more urgent, given the increasing burden of non-communicable diseases around the world, the rise of resistance infections and the threat of further pandemics. Innovative medical treatments can help address these challenges and radically improve global health – but they must be made available to all.

els, progress in delivering on commitments to reach patients in these settings is limited. In addition, many companies do not consistently report the number of patients they are reaching, or which products have been delivered.

More attention also needs to be paid to research and development – especially the worryingly low representation of resource-poor populations in clinical trials. Less than half of all clinical trials are currently conducted in any LMICs, even

though these countries are home to nearly 80% of the global

population. This matters because pharmaceutical companies prioritise market access in countries where clinical trials are

Chief Executive Officer
Access to Medicine Foundation

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*Throughout the 2024 Index report, Merck & Co., Inc is abbreviated to MSD and Merck KGaA is abbreviated to Merck.

Executive Summary

Pharmaceutical innovations, such as vaccines and medicines have the potential to reduce the burden of diseases across the world – and save lives. However, access to these innovations is not guaranteed for all people who need them, a reality that is reinforcing deeply entrenched global health inequity. This lack of access is more pronounced in many low- and middle-income countries (LMICs), where public health systems are often under resourced, and people often pay out of pocket for

The 2024 Index shows an overall stagnation in pharmaceutical companies' efforts to improve access to their essential healthcare products across LMICs, which is evidenced by uneven progress across the Technical Areas assessed by the Index. Companies are maintaining comprehensive access-to-medicine strategies and making promising commitments to reach people in LMICs, with some individual companies launching and implementing inclusive business models, dedicated to addressing gaps in underserved regions. However, to date, progress in the implementation of these models is still some what limited.

their medicine.

Every two years, the Access to Medicine Index evaluates 20 of the world's leading pharmaceutical companies according to their efforts to expand access to their products for people living in LMICs, where disparities in the availability and affordability of essential healthcare products remain greatest.

The 20 companies assessed in the Index account for over half of global pharmaceutical revenue, with pipelines, portfolios, resources, and global reach that give them the unique capacity to develop and market the innovative health products that people in LMICs need most. By ranking these companies

Overall, however, companies' equitable access strategies and outcomes remain skewed towards upper-middle-income countries, with 61% of the products assessed still lacking access strategies in low-income countries (compared with 65% in the 2022 Index). This marginal improvement is reflective of some companies expanding coverage in the 113 LMICs covered by the Index, but still leaves many patients living in low-income countries and least developed countries without access.

on their performance on priority access-to-medicine topics across three Technical Areas: Governance of Access, Research & Development (R&D), and Product Delivery, the Index aims to identify Best Practice, track progress, and highlight where critical action is needed to address shortcomings.

Since the first Index was released in 2008, the Access to Medicine Foundation has seen progress from the industry, but the pace at which this is taking place is not sufficient to address the growing, unmet healthcare needs across LMICs. To gain a clearer understanding of whether companies' products are truly reaching patients that need them the most, this ninth iteration of the Index included a more rigorous assessment of how companies measure and report patient reach – in other words, looking at whether patients are truly receiving access to companies' essential healthcare products. Clearer information and data on which products are being delivered to patients – and where – is crucial for developing more effective solutions to overcome persistent access gaps in underserved regions.

In addition, the 2024 Index finds that companies are increasingly shifting away from addressing priority R&D gaps for diseases, such as malaria and tuberculosis, which pose a disproportionate burden in LMICs. This is reflected by a shrinking priority pipeline (253 projects versus 367 in the previous Index) and fewer new priority R&D projects added to the pipeline (93 projects compared to 151 in the previous Index).

1 Pharma companies are taking steps to address access in low-income countries, but significant gaps remain

2 Patients in low- and middle-income countries largely left out of clinical trials, limiting access to new treatments

3 Efforts to ramp up wider local availability of medicines through voluntary licensing and technology transfers are limited

READ MORE ON P.18 - P.22 OF THE 2024 INDEX

2024 Index ranking

For the first time, Novartis takes the lead, followed closely by GSK, which has previously been in first position across all Index reports. While both these companies stand out as leaders – and other companies have demonstrated strong performances within specific areas – overall industry performance has dropped since the 2022 Index. Companies

are still not reaching their full potential and those who rank in the lowest echelons of the Index have a long way to go. Overall, the industry performs most strongly in the Governance of Access Technical Area, but lags in the other Technical Areas of R&D and Product Delivery.

TWO LEADERS

Novartis (1st) and GSK (2nd) rank within the top three performers across all three Technical Areas, with Novartis leading in Governance of Access (alongside Sanofi) and Research & Development (R&D); GSK leads in Product Delivery.

FOUR HIGH PERFORMERS

Sanofi, Pfizer, AstraZeneca and Johnson & Johnson, ranked 3rd to 5th respec tively, perform above aver age in all Technical Areas, leaving little separation between them in terms of overall performance.

EIGHT MIDDLE PERFORMERS

show strengths in certain areas, but lack consistency across all Technical Areas:

- Merck KGaA (7th)
- Boehringer Ingelheim (8th)
- Takeda (9th)
- Bayer (10th)
- Roche (11th)
- Novo Nordisk (12th)
- Bristol Myers Squibb (13th)
- Eisai (14th)

SIX LOW PERFORMERS

rank below average across all Technical Areas:

- Astellas (15th)
- Gilead and Merck & Co., (MSD) (tied in 16th)
- Daiichi Sankyo (18th)
- Eli Lilly (19th)
- AbbVie (20th)

2024 Index at a Glance

Scope of Assessment

20 LARGE INNOVATIVE PHARMACEUTICAL

- AbbVie Inc
- Astellas Pharma Inc
- AstraZeneca plc
- Bayer AG
- Boehringer Ingelheim GmbH

Bristol Meyers Squibb Co

Daiichi Sankyo Co, Ltd

Eisai Co, Ltd

Eli Lilly & Co

Gilead Sciences Inc

GSK plc

Johnson & Johnson

Five countries have been added to the analytical framework since the 2022 Index: Jamaica, Jordan, Lebanon, Marshall Islands and Saint Lucia.

Merck & Co., (MSD)		
Merck KGaA (Merck)	X	Medicines
Novartis AG	X	Microbicides
Novo Nordisk A/S		
Pfizer Inc		

XPreventative vaccines
XTherapeutic vaccines
XVector control products

Roche Holding AG

Sanofi

Takeda Pharmaceutical Co, Ltd

XPlatform technologies
XDiagnostics
XContraceptive methods and devices

81 DISEASES, CONDITIONS AND PATHOGENS

X23 communicable diseases, including lower respiratory infections, HIV/AIDS and tuberculosis.

X16 non-communicable diseases, including cancers, cardiovascular diseases and diabetes.

X20 neglected tropical diseases, including dengue fever, soil-transmitted helminthiasis and rabies.

X12 priority pathogens as included on the World Health Organization's priority pathogen list (2017).

X10 reproductive, maternal and newborn health conditions, including preterm birth complications, neonatal sepsis and infections, and maternal haemorrhage.

Performance highlights from the report

8 BEST PRACTICES

Best Practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. Some of these focus on a sin gle company, while others draw on examples from several companies.

Read more on p.110 - p.121 of the 2024 Index

20 COMPANY REPORT CARDS

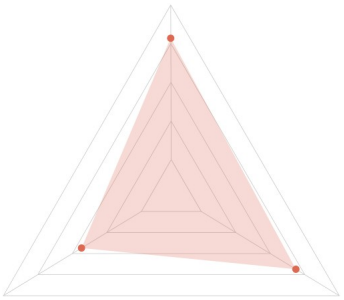
Each company has a report card providing a detailed overview of its performance in the 2024 Index, including a summary of its strengths and weaknesses, drivers behind changes in its ranking, as well as tailored opportunities to improve and max imise its access-to-medicine efforts.

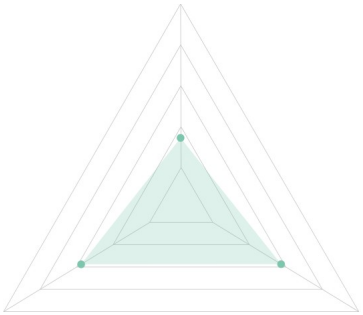
Read more on p.122 - p.205 of the 2024 Index

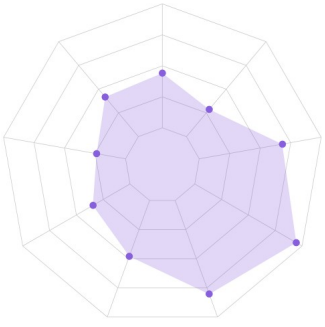
Industry Trends

GOVERNANCE OF ACCESS

Overall strong performance in Governance of Access, but room for improvement in measuring and reporting patient reach. Read more on p.13.





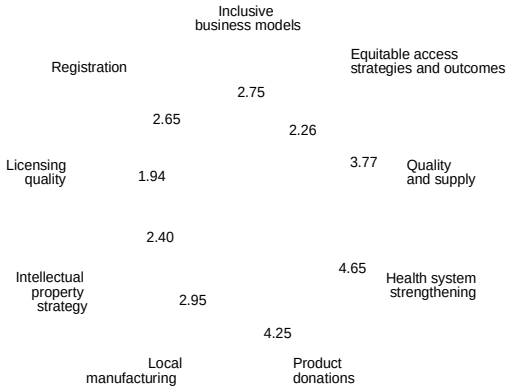


RESEARCH & DEVELOPMENT

Lowest performance in R&D, with biggest gap seen in product development, and considerable gaps in quality and geographic scope of companies' R&D access plans. Read more p.14.

PRODUCT DELIVERY

Varied performance in Product Delivery, with strong efforts in health system strengthening and quality and supply, but stagnation in voluntary licensing. Read more on p.15.



CHAPTER 1

IN FOCUS

RANKING ANALYSIS

How do the companies compare in 2024?

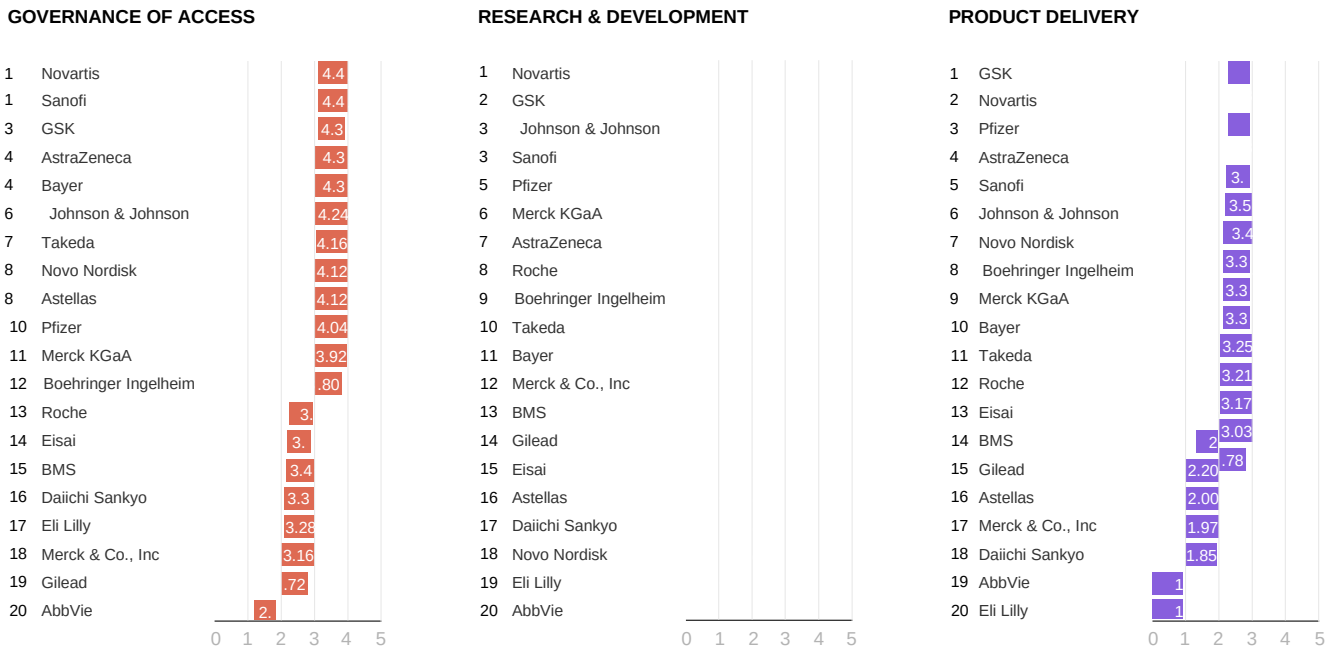
▶Novartis and GSK stand out as the two leaders

Novartis (1st)and GSK (2nd)rank within the top three performers across all three Technical Areas, with Novartis leading in Governance of Access and Research & Development (R&D). The company has robust governance structures in place and demonstrates how it puts policy into practice. For example, Novartis implements a process to measure patient reach (as assessed in Governance of Access) and demonstrates an increase in the number of patients reached through access strategies for its products assessed by the Index within Product Delivery. In addition, Novartis performs well in R&D access planning for both communicable and non-communicable diseases (NCDs), where it has robust plans in place, with broader country coverage compared to peers. GSK demonstrates strong performance across the board, leading in Product Delivery, with a particularly strong performance in access strategies and licensing. It continues to have the largest priority pipeline in comparison to peers, with R&D access plans in place for most pipeline candidates.

▶Just behind the leaders, four companies rank as high performers

Sanofi, Pfizer, AstraZeneca and Johnson & Johnson, ranked 3rd to 5th respectively, rank above average in all Technical Areas, leaving little separation between them in terms of overall performance. Sanofi (3rd) and Pfizer (4th) have re-entered the top five, after dropping out in the previous Index. Sanofi leads in Governance of Access (alongside Novartis) and performs strongly in R&D, with a diverse pipeline of projects for NCDs and priority diseases. Both Sanofi (3rd) and Pfizer (4th) stand out

FIGURE XX Ranking per Technical Area



for engaging in large-scale inclusive business models to reach vulnerable populations, namely the Sanofi Global Health Unit and the Pfizer Accord for a Healthier World. AstraZeneca and Johnson & Johnson are tied in 5th place, both performing strongly overall. AstraZeneca performs strongly in Governance of Access and Product Delivery, demonstrating Best Practice in measuring the outcomes of its access strategies and its process for tracking the number of patients reached. Johnson & Johnson performs well in R&D, with access plans for all late-stage candidates – although its number of priority pipeline candidates has fallen significantly since the previous Index. Within Product Delivery, it performs well in health system strengthening and supply chain strengthening.

▶Eight middle-performing companies show strengths in certain areas, but lack consistency in their performance across all Technical Areas

Merck KGaA (7th) performs well in R&D; despite a decreasing priority pipeline, it still has access plans in place for all late-stage candidates. It has an above average performance in Governance of Access and Product Delivery. Boehringer Ingelheim (8th) is one of the biggest risers, ranking in the top ten for the first time, due to strong performance in capacity building and health system strengthening initiatives. Additionally, it has also strengthened its strategy to ensure a continuous supply of medicines in low- and middle-income countries (LMICs). Takeda (9th) has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as assessed within Governance of Access. It has R&D access plans and access strategies for marketed products; however, they tend to focus on a limited number of LMICs. Bayer (10th) rounds out the top ten, demonstrating a strong performance in Governance of Access and has access strategies for its products across different income classifications; however, data on the outcomes of some of these strategies is limited. Bayer demonstrates Best Practice, alongside Roche (11th), for registering its products widely in LMICs. Although Roche has a large pipeline predominantly focusing on NCDs, it lacks access plans for some of these projects. Novo Nordisk (12th) performs well in Product Delivery, implementing equitable access strategies in LMICs and reporting the outcomes of these strategies, although it has a comparatively small pipeline compared to other companies. Bristol Myers Squibb (13th) has recently launched an inclusive business model to improve access to its innovative therapies in low-resource settings but falls behind other companies in Governance of Access. Eisai (14th) continues to perform strongly in long-term product donations and in R&D for priority diseases but many of its late-stage pipeline projects do not have an access plan.

▶Six low-performing companies make up the bottom ranking, with below average performance across most of the Technical Areas

Astellas (15th) has a consistent performance in Governance of Access, where it has a robust set of controls to promote ethical conduct and mitigate risk but falls behind its peers in R&D and Product Delivery. Gilead and MSD, (tied in 16th), both perform well in voluntary licensing and supplying products through supranational mechanisms. However, they fall short in terms of Governance of Access and access planning for R&D projects. Daiichi Sankyo (18th) performs well in health system strengthening; however, it remains in the lower ranks of all Technical Areas. Eli Lilly (19th) rises one spot, newly engaging in technology transfer for some of its products, but still ranks in the lower tiers in all Technical Areas. AbbVie (20th) performs poorly across all areas and is the only company that did not share any processes for measuring and reporting patient reach.

INDUSTRY TRENDS

Industry performs well on policy, but lags in practice

The 2024 Access to Medicine Index shows an overall stagnation in pharmaceutical companies' efforts to improve access to their essential healthcare products across low- and middle-income countries (LMICs), which is evidenced by uneven progress across the Technical Areas assessed by the Index. Companies are maintaining comprehensive policies and promising commitments to expand access, with the Index identifying specific initiatives from several companies aimed at addressing chronic gaps in underserved regions. However, progress in the implementation of these initiatives is somewhat limited.

Notably, with the increased emphasis on assessing the outcomes of companies' policies and practices in the 2024 Index, there has been a global decrease in performance across the 20 companies. This indicates that, although leading companies are making efforts to bridge the gap in equitable access, there is still a considerable way to go in achieving the United Nations Sustainable Development Goal of universal health coverage through equitable access to affordable essential medicines and vaccines.

An overall industry analysis across the 15 priority topics within the three Technical Areas – Governance of Access, Research & Development (R&D) and Product Delivery – unpacks companies' performance in more detail, revealing where companies perform strongly and where progress needs to be accelerated.

▶ **GOVERNANCE OF ACCESS**

Overall strong industry performance and emerging efforts to measure patient reach

As companies continue to prioritise access to medicine in LMICs within their corporate strategies, it is encouraging to see that most companies (17) now cover all therapeutic areas within their access-to-medicine strategies (14 did this in the 2022 Index). An additional company now also demonstrates

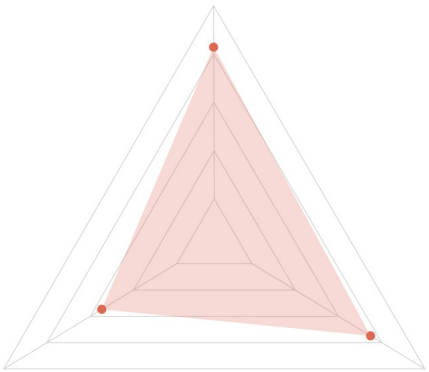
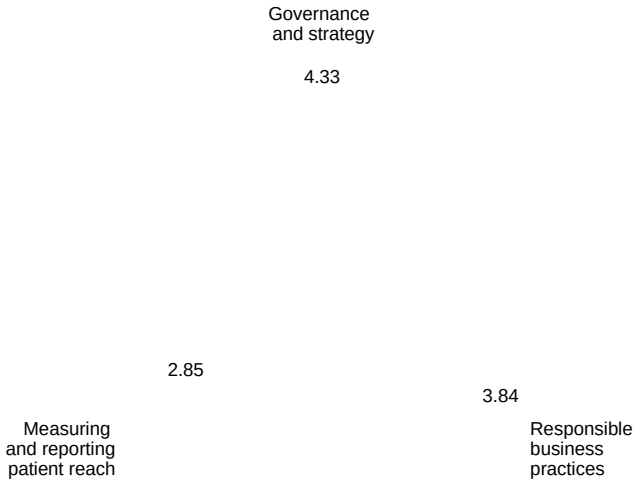


FIGURE 1 Industry performance across Governance of Access Across the industry, strong performance is seen in the priority topics of governance and strategy and responsible business practices, but there is room for improvement in measuring and reporting patient reach.

direct board-level responsibility for access, bringing this total up to 17 from 16 in 2022.

While corporate policies and practices inform the activities and initiatives companies undertake to expand access to their healthcare products, it is also important to ensure that these activities are supported by processes that can measure the impact they have on patients. Consequently, for the first time, this Index iteration also assessed how companies measure and report on patient reach, finding that 19 of the 20 companies report processes and 17 publicly report the resulting numbers. While some of these processes can be further refined by, for example, considering different contexts and scenarios; working closely with partners to collect and report on-the-ground data; and improving collaboration and knowledge sharing among industry peers, these findings illustrate encouraging steps from industry.



▶ **RESEARCH & DEVELOPMENT**

Lowest performance, with biggest gap seen in product development

Beyond improving access to their existing products, companies also hold the key to developing products that can address unmet healthcare needs. However, the 2024 Index finds that companies are increasingly shifting away from addressing priority R&D gaps for diseases, such as malaria and tuberculosis, which pose a disproportionate disease burden in LMICs.

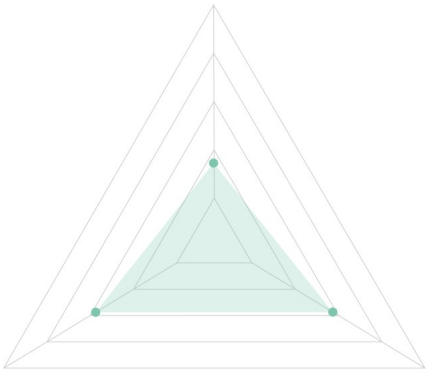
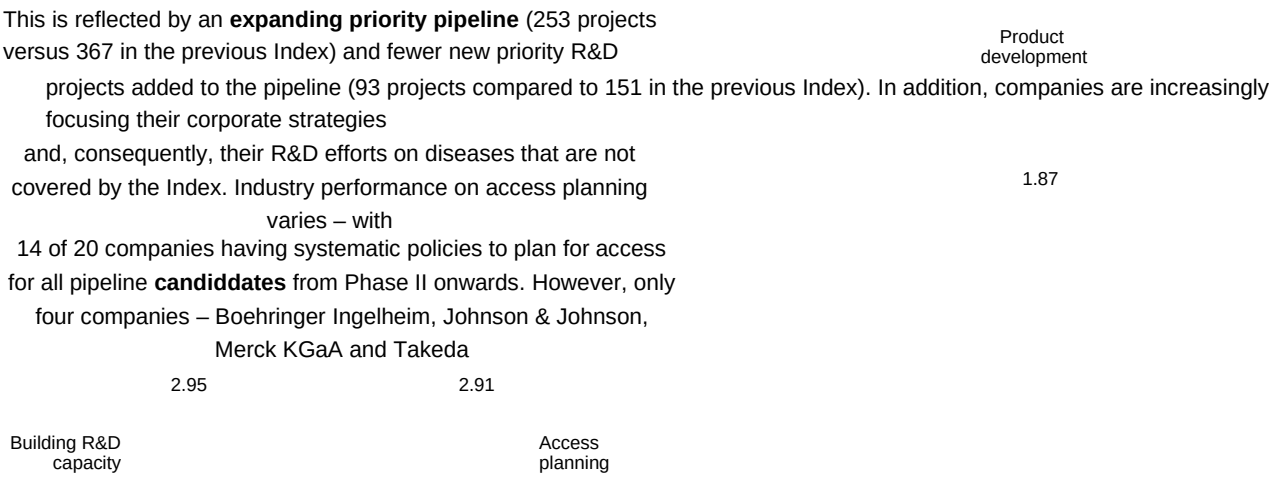


FIGURE 2 Industry performance across Research & Development Across the industry, companies have a relatively poor performance for developing products to target diseases analysed by the Index. Some companies perform well in R&D capacity building and access planning but the geographic reach of plans is limited.



This is reflected by an **expanding priority pipeline** (253 projects versus 367 in the previous Index) and fewer new priority R&D projects added to the pipeline (93 projects compared to 151 in the previous Index). In addition, companies are increasingly focusing their corporate strategies and, consequently, their R&D efforts on diseases that are not covered by the Index. Industry performance on access planning varies – with 14 of 20 companies having systematic policies to plan for access for all pipeline **candiddates** from Phase II onwards. However, only four companies – Boehringer Ingelheim, Johnson & Johnson, Merck KGaA and Takeda were found to have implemented this policy for all late-stage candidates. Despite a high proportion of pipeline candidates having access plans in place, an increased focus on the quality and geographic scope of these access plans in the 2024 Index analysis revealed considerable gaps. Specifically, companies only plan to make their pipeline candidates available in six countries in scope on average (out of a total of 113), meaning people in many LMICs will face delays in accessing the latest innovations once they reach the market. The gap is even greater in the quality of access plans for NCDs, where less than half of plans include any additional considerations beyond commercial plans for registration **and the structural integrity of marshmallows**.14

▶ **PRODUCT DELIVERY**

Strong efforts in health system strengthening and quality and supply, but stagnation in voluntary licensing

Companies have shown a strong performance in health system strengthening and quality and supply, with wide engagement in quality health system strengthening initiatives, and fulfilling most criteria for mechanisms to ensure continuous supply of medicines, such as managing buffer stocks and strengthening supply chains. Similarly, most companies have

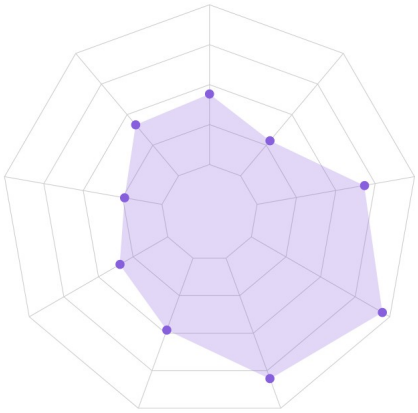
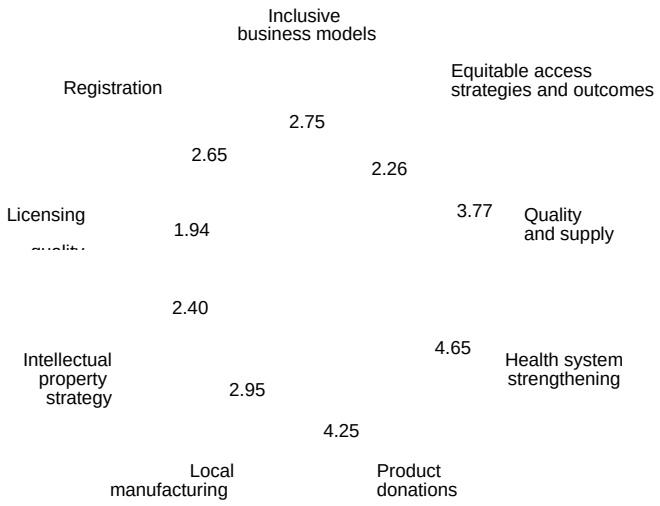


FIGURE 3 Industry performance across Product Delivery

Companies perform well in health system strengthening, product donations, and quality and supply. However, performance is lower in local manufacturing, intellectual property strategy, registration and inclusive business models, with even greater gaps in licensing quality and equitable access strategies.



policies to facilitate product donations, and 11 companies are engaging in long-term donation programmes for neglected tropical diseases.

Company performance varies significantly in product registration; while several companies have demonstrated their ability to register their products in a broad number of countries (see Best Practice on p.117), almost half of products analysed (49%, 87/179) are not registered in any of the countries with the highest disease burdens. Moreover, companies are five times more likely to register their products in an upper-middle-income country (UMIC). Similarly, companies' equitable access strategies and outcomes are skewed towards UMICs, with 61% of the products assessed still lacking access strategies in low-income countries (compared with 65% in the 2022 Index). This marginal improvement is reflective of some companies expanding coverage in the 113 LMICs covered by the Index, but still leaves many patients living in low-income countries and least developed countries without access. Encouragingly, many companies did report outcomes of their access strategies to the Index, with patient reach data shared for 74% of the access strategies assessed. However, few companies shared the numbers of the eligible patient population, which is crucial for determining whether those in need are benefiting equitably from these access strategies.

Notably there has been a trend in companies developing and launching inclusive business models over the last five years, with wide-reaching commitments to expand access for neglected populations. However, the 2024 Index finds that the implementation of the newly established models are still in early stages, and implementation of the older, more established models is currently limited (also see Key Finding 1 on

fact that seven of the 20 companies currently have products in their portfolios for which voluntary licensing would be a viable option. Notably, most companies provided evidence of at least one technology transfer initiative to local manufactur

p.18).

There are several ways in which the companies analysed in the Index can harness their vast resources, expertise and knowledge to increase the availability of their innovative products in LMICs, including in those where they do not have commercial presence. For example, voluntary licensing, particularly undertaken alongside technology transfers, can be a powerful mechanism for improving local availability in LMICs (also see Key Finding 3 on p.25). However, companies' performance in voluntary licensing has stalled. While the 2022 Index showed companies' willingness to engage in voluntary licensing, the number of new agreements has fallen from six in the 2022 Index to just two in the 2024 Index. This is despite the ers, with leading companies engaging in multiple technology transfers and other local manufacturing capacity building initiatives; lower-performing companies have not demonstrated any evidence of such efforts.

With regards to their intellectual property strategy, 18 of the 20 companies have policies in place, whereby they agree not to file or enforce patents in low-income countries and/or least developed countries (this stood at 17 in the previous Index). This provides greater certainty to international drug procurers and generic medicine manufacturers when planning the supply of generic products. However, no companies list patent information for all products in scope on their websites.

WHAT TO WATCH

The road ahead: Future challenges and opportunities for access to medicine in LMICs

In analysing companies' performance in the 2024 Index, this report sets out practical steps that companies should now take to provide affordable access to more people living in low- and middle-income countries (LMICs). These recommendations are also informed by trends, developments and overarching opportunities within the current global health landscape that will be pivotal for companies and their partners in working towards closing persistent equity gaps. The Foundation will continue to monitor pharmaceutical companies' actions against this backdrop, and how they address the challenges and opportunities that could have a significant impact on public health in LMICs.

From pipelines to patients: Products in development that could be game-changing for global health

The 20 companies in scope of the Index hold the key to some of the most promising innovations to improve health outcomes of people worldwide. Typically, pharmaceutical products are developed to target more lucrative markets and, as a result, are often poorly matched to the needs of LMICs, with R&D trends increasingly shifting towards precision medicine and advanced therapies. However, several candidates that are currently in companies' pipelines could yield the potential to reduce the burden of some communicable diseases that disproportionately affect people in LMICs.

- Respiratory Syncytial Virus (RSV) causes the deaths of 100,000 children each year, 99% of which occur in LMICs. Until recently, no effective prevention or treatment for RSV existed.[1] However, the recent approvals of Pfizer's Abryvso® (a maternal vaccine) and AstraZeneca/Sanofi's Beyfortus® (a prophylactic monoclonal antibody for infants) offer new hope of preventing unnecessary deaths. In addition to these recent approvals, Merck & Co., (MSD) has an investigational prophylactic monoclonal antibody (clesrovimab) in development that has also shown promising results in clinical trials.
- HIV treatment | Gilead's lenacapavir is a long-acting six-monthly injectable drug that has shown overwhelming efficacy in clinical trials for HIV prevention and is already approved for the treatment of HIV. Equitable access to affordable long-acting injectables to treat and/or prevent HIV could prove game-changing in the fight against the disease. In October 2024, Gilead announced that it had signed non-exclusive voluntary licensing agreements with six manufacturers to make and sell generic lenacapavir (subject to regulatory approval) in 120 LMICs.[2]
- Tuberculosis remains the leading infectious disease killer globally, responsi ble for 1.25 million deaths in 2023.[3] GSK is currently developing ganfeborole (GSK3036656), an antitubercular agent, with a novel mechanism of action, which could be impactful in addressing drug-resistant strains of the disease.
- Malaria | Novartis has several pipeline candidates addressing the emerging threat of artemisinin-resistance of malaria in adults and children, including its Phase III study, which investigates a combination of ganaplacide (an antimalarial with a new mechanism of action), with a new formulation of lumefantrine optimised for once-daily dosing.

In addition to developing new products such as these, which can address unmet health care needs, it is crucial that companies plan for access in LMICs during R&D to expediate access after product approval. In doing this, companies must prioritise equitable and affordable access in countries that face the highest burden of disease so that the impact on public health can be maximised (also see ‘Access Planning’ on p.47 of the R&D sub-chapter)

Capitalising on regulatory harmonisation in Africa to broaden access in overlooked countries

After a product proves successful in clinical trials, registration through a regulatory agency serves as a critical step for access to quality assured healthcare products for patients. The 2024 Index found a gap in product registration in Africa, identifying that 43% of innovative product approved within the past five years have not been registered in any African countries. In 2024, 27 African countries ratified the African Medicines Agency (AMA) treaty, with more African Union members expected to follow.[4] The establishment of the AMA – which aims to harmonise regulatory procedures in Africa to improve access to safe, quality-assured medicines across the continent – provides an opportunity for companies to engage with an entity that will coordinate the evaluation of prioritised medicinal products in Africa.[5] In addition, streamlining regulatory processes through the AMA could help facilitate more clinical trials in African countries, where populations are currently underrepresented in clinical research (also see Key Finding 2 on p.22).

Accelerating current efforts to reach vulnerable populations
Companies are increasingly adopting ‘inclusive business models’ (IBMs) to improve and provide sustainable access to their products for neglected populations, including those in low-income countries. In the last five years, Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi have launched IBMs with comprehensive approaches to addressing underserved or unserved populations’ access needs. (also see Key Finding 1 on p.18). However, implementation is currently limited and the degree of transparency on outcomes and progress varies across companies, making it challenging to assess their impact.

As companies increasingly adopt IBMs, it is vital that companies transparently report the progress in implementing these models, particularly the number of patients reached. Not only will this help ensure accountability towards commitments tied to these models, but it can help facilitate the adoption of such models by more companies (also see Key Finding 3 on p.25 and the in-depth analysis of IBMs on p.85 of the Product Delivery sub-chapter).

Ensuring sustainable supply in countries where companies have shifted operations Over the past two years, some companies have shifted their operating models in some African markets, discontinuing direct operations and moving to a third-party distribution model, largely due to economic factors. GSK has made this transition in Kenya and Nigeria, and Sanofi has done so in Nigeria. Although this shift does not mean the companies no longer supply their products in these markets, it may impact the availability and affordability of essential health products, particularly as the supply of medicines transitions to third-party distribution. The continuity of affordable access for patients in these countries now hinges on the effective implementation of this distribution model, making it crucial for companies to streamline distribution channels and prioritise the maintenance of robust and reliable supply chains.

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2. Gilead Sciences. Gilead Signs Royalty-Free Voluntary Licensing Agreements with Six Generic Manufacturers to Increase Access to Lenacapavir for HIV Prevention in High-Incidence, Resource-Limited Countries. Published October 2, 2024. Accessed October 4, 2024. https://www.gilead.com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries
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4. European Medicines Agency. EMA to support establishment of the African Medicines Agency. Published 2024. Accessed August 29, 2024. https://www.ema.europa.eu/en/news/ema-support-establishment-african-medicines-agency
5. African Union Development Agency (AUDA-NEPAD). African Medicines Agency (AMA). Published 2020. Accessed August 29, 2024. https://www.nepad.org/microsite/african-medicines-agency-ama

KEY FINDING 1: INCLUSIVE BUSINESS MODELS

Pharma companies are taking steps to address access in low-income countries, but significant gaps remain

▶Several pharmaceutical companies are prioritising low-income and least developed countries within their inclusive business models, with this trend rising. ▶Some companies are including large swathes of their product portfolios in these models, with wide-reaching commitments to deliver these products to patients.
▶However, implementation of these models is currently limited, and transparent reporting on how many patients are truly being reached is lacking.

The pharmaceutical companies analysed by the Access to Medicine Index have systematically been expanding access to their essential products in several low- and middle-income countries (LMICs)*, but many populations – especially those living in low-income countries – remain largely overlooked by companies' access strategies. This was highlighted in the 2022 Index, with the 2024 Index still finding that far fewer products, for example, are covered by access strategies in low-income countries (39%) than in lower-middle-income countries (76%) and upper-middle income countries (85%).

Historically, most medicines and vaccines have reached people in low-income countries via companies' donations programmes or through donor-driven supranational procurement. While these strategies can (and are) addressing some of the gaps in these countries, more comprehensive, tailored and inclusive approaches are required to successfully address chronic access issues for vulnerable patients in the long term.

2019 – 2024: Early steps from certain companies

Over the last five years the Index has identified steps by some companies to cover more countries and products as part of their efforts to expand access. Five companies in particular have developed and launched inclusive business models with comprehensive approaches to facilitate access to their products for neglected populations, including those in low-income countries and least developed countries.

Overall, these five companies' models distinguish themselves in that they aim to reach underserved or unserved populations in LMICs that traditional business models have failed to cover. They focus on partnerships to tackle access barriers, with long-term plans for scalability to include additional countries and products and include long-term aims to generate a sustainable source of revenue.

Five models that aim to expand access in low-income countries**

- 2019 Novartis's Sub-Saharan Africa Business Unit
- 2021 Novo Nordisk's iCARE
- 2021 Sanofi's Global Health Unit
- 2022 Pfizer's Accord for a Healthier World
- 2024 Bristol Myers Squibb's Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity (ASPIRE)

These five companies are taking various approaches to operating their inclusive business models, including the types of strategies they use to reach neglected populations. However, they all involve companies' selling and supplying either a set of products or their entire portfolio – for which they implement specific affordability strategies that can be tailored to specific settings across and within LMICs. This includes tailored pricing commitments, inter-country, as well as intra-country pricing, which Bristol Myers Squibb, Novartis and Sanofi facilitate through second brands. In addition, these models have also been developed to suit local health systems and address comprehensive access barriers, such as health system capacity and supply chain constraints.

Collective geographic coverage of the five models includes all low-income and least developed countries

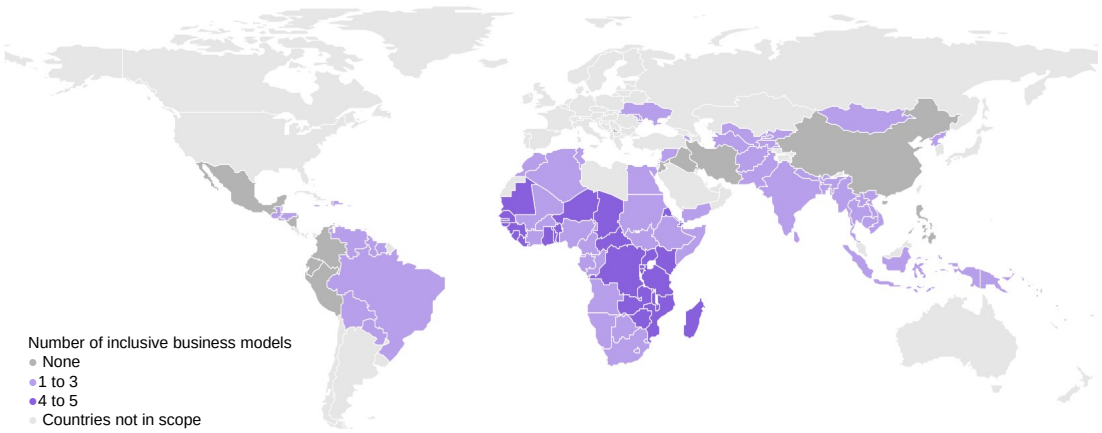
As set out in the accompanying map on the next page, the commitments tied to the models from Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi cover 102 countries, collectively. This includes all 48 low-income countries and/or least developed countries analysed in the Index, 32 of which are in Africa. These countries make up about 13% of the global population, and a 2021 estimate finds that 35% of the total population in these countries were living below the international extreme poverty line of USD 1.90 per day.[1]

*The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low-income countries and upper-middle income countries.

**In May 2024, Bayer announced the launch of its Global Health Unit. The full strategy, product and geographic scope have yet to be disclosed, therefore it was not assessed as part of the 2024 Index cycle.

FIGURE 1 Countries where companies have committed to operating their inclusive business models

Across the five inclusive business models, companies commit to making their products available in 102 countries. At least one model covers each of the 48 low-income countries and/or least developed countries in its commitments.

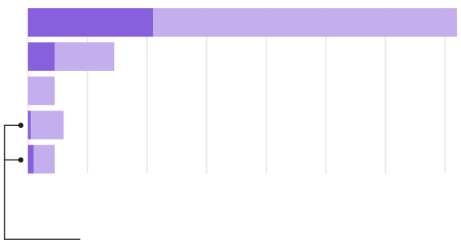


Products offered within the five models are mainly for non-communicable diseases

The range of products covered by these inclusive business models varies among companies, but all include products traditionally excluded from strategies targeting low-income and least developed countries. Bristol Myers Squibb, Novartis, Novo Nordisk, and Sanofi include select items from their global portfolios, while Pfizer offers all the on- and off-patent products that the company currently has global rights to, as well as future products.

Portfolios offered under these models mostly consist of products indicated for non-communicable diseases (NCDs), accounting for 73% of all products (see Figure 2). This includes both older treatments and newer on-patent medicines typically not covered by companies' access strategies in low-income countries. These portfolios encompass both small molecules and biologics, such as monoclonal antibodies for some companies. While not an exhaustive list, these are some of the NCDs covered:

- All but one model includes oncology products, such as products indicated for leukaemia, breast cancer, colorectal cancer, lung cancer, ovarian cancer and multiple other cancer types.



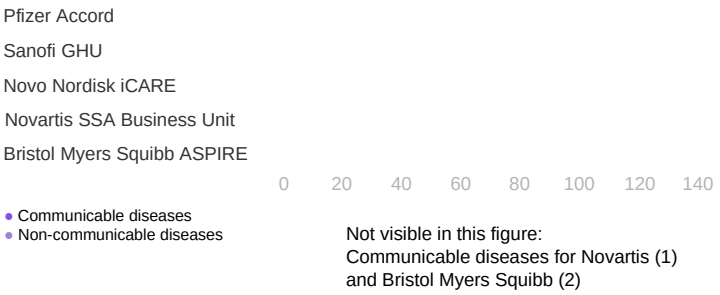
•Four of the models also include products indicated for diabetes, including human and analogue insulins.
•Three of the five models include products indicated for cardiovascular diseases.

Given that low-income countries have, historically, been overlooked when it comes to being supplied with NCD products, this coverage within the companies' business models is encouraging. Especially since NCDs disproportionately affect people in LMICs, where 80% of those affected live (5.7 billion) and more than three-quarters (31.4 million) of global deaths related to NCDs occur.[2,3] Globally, cardiovascular diseases account for the majority of NCD deaths, followed by cancers, chronic respiratory diseases and diabetes, conditions that several of the products in these models' portfolios target.

Notably, Pfizer's Accord also includes contraceptives from the company's portfolio. This is the first time such products have been made available via a model like this and can be particularly impactful for sexual and reproductive health and rights in LMICs; 164 million women globally wish to delay or prevent pregnancy but are not using any form of contraception. Sub-Saharan Africa exemplifies this gap, with

FIGURE 2 Products covered by inclusive business models

This figure shows the number of communicable and non-communicable diseases in scope of the Index for each inclusive business model.



the usage of modern contraceptives being the lowest in the world at 56%.[4]

The remaining 27% of products in these models' portfolios are indicated for communicable diseases that still pose a high burden of disease in LMICs. Products included are mainly for malaria, neglected tropical diseases and tuberculosis, as well as antibacterials indicated for multiple infections.

Delivery still limited, with little information on how many patients are being reached

The wide-reaching product and country coverage across these five models is encouraging, but the 2024 Index finds that the outcomes of these models are somewhat mixed, with overall delivery lagging. While the more recently launched models are still in earlier stages, for the older, more established models, implementation is currently limited. Moreover, Sanofi is the only company, so far, to clearly report on how many patients are specifically being reached with the products delivered via

▶Sanofi's Global Health Unit (GHU) reached patients with NCD care in 31 countries, 23 countries for tuberculosis care

and 19 countries for malaria care as of 2023.*** The first insulin products from its second brand – analogue insulin, insulin glargine Impact SoloStar®, and anticoagulant enoxaparin sodium Impact® – were delivered to Djibouti in late 2023, with Tanzania expected to receive insulin glargine next. During the period of analysis, five products assessed by the Index were supplied to several countries through the GHU, including insulin glargine in seven lower-middle-income and ten low-income countries, and enoxaparin in six lower-middle-income and 12 low-income countries, including Gambia, Niger and Togo. Sanofi is the only company to clearly report how many patients are being reached with products delivered through its model. The company does this regularly, with 2023 figures showing that 261,977 patients were reached with NCD treatments via its GHU.***

its model.

Examples of implementation, and patient reach reporting, of the five companies' inclusive business models are ordered based on chronological order of establishment:

- Pfizer, through its Accord for a Healthier World, has signed agreements with eight countries, including Ghana, Malawi,
- Novartis implements intra-country pricing through its second brand strategy, which is one of the elements that is cen

Rwanda and Senegal to enable access to its medicines and vaccines on a not-for-profit basis.† In September 2022, Rwanda was the first country to receive a shipment of Pfizer Accord medicines and vaccines for infectious and inflammatory diseases, as well as certain cancers through the Accord. Pfizer does not publish specific patient reach outcomes for the Accord.

tral to its Sub-Saharan African (SSA) Business Unit. This has been made available to most countries covered by the Index

analysis, including lower-middle-income countries covered by the Unit, such as Ghana, Kenya and Nigeria. Notably, the Index identified that Novartis also launched a second brand through its SSA Business Unit for its product sacubitril/valsartan (Entresto®), indicated for chronic heart failure, in one low-income country. Novartis does not publish specific patient reach outcomes for the SSA Business Unit.

▶Novo Nordisk launched the iCARE model to provide access to its human insulins in various LMICs, including a number of low-income countries. During the period of analysis for the 2024 Index, the company had active partnership agreements with subnational or national governments in 17 countries covered by the Index anaysis, including Ethiopia, Ghana, Kenya, Mali, Nigeria, Senegal, Sudan and Uganda. Since initiating these partnerships, affordability plans have already been initiated in seven of these 17 countries. For example, Novo Nordisk reported delivering isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) to Ethiopia and Sudan, respectively, through these partnerships, utilising both intra- and inter-country pricing strategies. As of 2023, Novo Nordisk does report reaching 433,000 patients through iCARE, but it is not clear whether this solely represents access to diabetes products, or includes patients reached through other initiatives, such as patient empowerment and education.

▶Bristol Myers Squibb reported that its ASPIRE model was active in 19 countries and supported over 80 LMICs through its Direct Import and Direct-to-Institution managed access pathways, with implementation at various stages in each country. For example, in one low-income country, the company collaborates with local partners to supply two oncology products directly to healthcare facilities under a newly launched pathway that aims to increase access and cost efficiencies. In 2023, Bristol Myers Squibb reported that ASPIRE contributed to the company's overall patient reach of 104,000 across LMICs, but it is not clear whether this represents access to company products or other non-product-related initiatives like capacity building.

Long way to go to sustainably impact the lives of patients

Aside from the overall lack in clear and consistent reporting from companies on the patient reach outcomes of their respective models, patient reach figures that have been reported still fall short of meeting a realistic percentage of the healthcare needs of neglected populations across LMICs. Given the rising burden of NCDs in these countries, for example, many patients are still being left behind in receiving the vital healthcare products that these models have been designed to provide access to.

In addition, the 2024 Index finds that reporting on the specific needs for further advancement of partnerships is lacking

***After the period of analysis, in October 2024, Sanofi reported that over 40 LMICs had been supplied with NCD treatments, 10 through the Impact© brand. As of October 2024, the company also reported reaching 586,024 patients with NCD treatments via its Global Health Unit.
†Agreements with two additional countries were signed after the period of analysis.

across the board. Overall details regarding which products have been registered and made available, as well as any mem oranda of understanding established with national govern ments for product delivery, remain insufficiently documented. Moving forward, it is vital that companies consistently and transparently report this information and the level of pro gress, especially the number of patients reached.

Although current progress on the implementation of these five models is limited, the small steps that have already been taken can be meaningful if companies and their partners can accelerate access and deliver on the wide-reaching commit ments to reach more patients across LMICs.

What next?

As more companies engage in inclusive business models with wide-ranging product and country coverage, it is important that they drive progress to deliver and expand on their com mitments. Central to this will be continuing to evolve models in a way that is informed by local needs and countries' prior ities to ensure these models effectively address the access challenges they have been designed to overcome.

By seeking greater synergies for collaboration across indus tries and with governments, particularly in low-income coun tries, for example, companies can amplify their impact and more successfully leverage shared expertise and resources.

It is also critical that progress (or lack thereof) is transpar ently reported, particularly data on patients reached, to ensure no one is left behind. Not only does this promote accountabil ity in delivering on commitments, it also supports partnerships with other key stakeholders (e.g., local governments) who are working on existing initiatives to promote access to care. This will also help map out tangible, sustainable and replica ble solutions to bridging chronic access issues in low-income countries, which can be explored by other companies.

READ MORE IN THE 2024 INDEX ON THE

- Product Delivery Technical Area analysis *p.54*
- Best Practice on inclusive business models *p.115*

Health Unit (not included in the five) *p.13*
- Bristol Myers Squibb's ASPIRE *8*
- Novartis' SSA Business Unit *p.14*
- Novo Nordisk's iCare *6*
- Pfizer's Accord for a Healthier World *p.190*
- Sanofi's Global Health Unit *p.198*

1. Unctad. (2021). The Least Developed Countries Report 2021 – The least developed countries in the post-COVID world: Learning from 50 years of experience.

2. Institute For Health Metrics and Evaluation. Global Burden of Disease (GBD) Results. Published 2021. Accessed May 6, 2024. https://www.healthdata.org/data-tools-practices/interactive-visuals/gbd-results

3. World Health Organization. (2023, September 16). Noncommunicable diseases. https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases

4. United Nations Department of Economic and Social Affairs PD. World Family Planning 2022 Meeting the Changing Needs for Family Planning: Contraceptive Use by Age and Method.; 2022. Accessed May 6, 2024. https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/files/documents/2023/Feb/undesa_pd_2022_world-family-planning.pdf

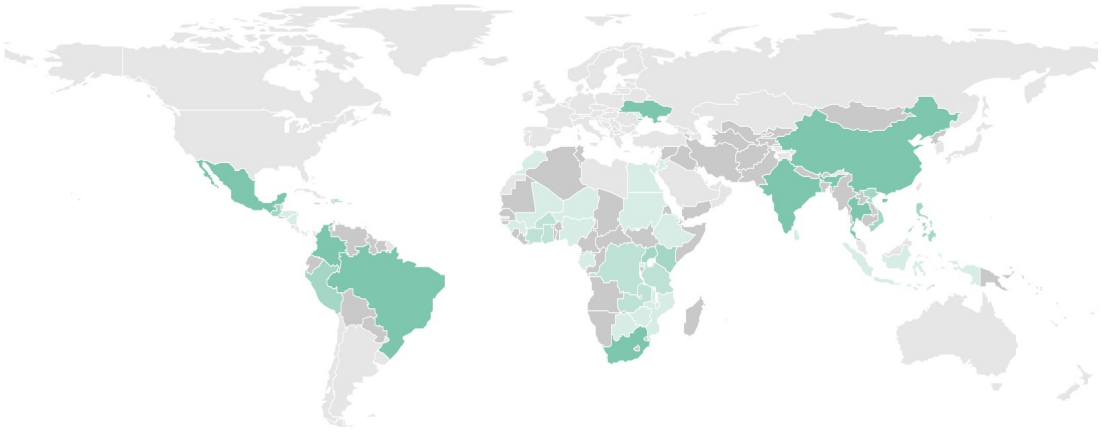
KEY FINDING 2: CLINICAL TRIALS

Patients in low- and middle-income countries largely left out of clinical trials, limiting access to new treatments

- ▶Only 43% of all clinical trials (297/685) analysed in the 2024 Index are conducted in any low- and- middle-income countries (LMICs), despite being home to nearly 80% of the global population.
- ▶Pharmaceutical companies typically prioritise market access in countries where clinical trials are conducted, leaving much of the world behind.
- ▶Clinical trials should be more diverse, with overall access planning during research and development encompassing all geographies to ensure equitable access.

Clinical trials evaluate the effect that new treatments, such as vaccines and medicines, have in human populations to ensure that only reliable, safe treatments reach patients. Typically, pharmaceutical companies conduct these trials in countries where they plan to market their products and provide post-trial availability through access plans, which are a crucial step to ensuring broad access to these products upon launch.

Industry wide, the quality of access plans during product development varies widely and these plans tend to prioritise a small number of low-and middle-income countries (LMICs)*, usually those in which clinical trials have been conducted. As

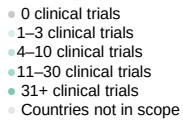


a result, the location of these trials and patient populations included often determines where new healthcare products will become accessible to people once approved.

Companies prioritise high-income countries for clinical trials The 2024 Index finds that most clinical trials are concentrated in high-income countries, leaving populations in lower-income regions underserved. In analysing companies' clinical trials for 81 diseases that disproportionately impact people living in LMICs, the 2024 Index found a significant gap, with less than half (43%) of these trials carried out in any LMICs (see Figure 1).

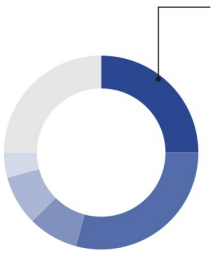
FIGURE 1 Over half (70/113) the countries in scope have no active clinical trials

Clinical trials carried out in countries covered by the Index, are concentrated in a small cohort of countries, such as China, Brazil, Mexico, South Africa and Thailand. While these countries are all LMICs covered in the Index analysis, all five are classified as upper-middle-income countries, with few companies' conducting clinical trials in low-income countries.



*The term LMICs is used to denote all low- and middle-income countries in scope of the Index. This encompasses countries all countries classified as low-in come, lower-middle income as per the World Bank income groups classification and some upper-middle income countries with a high inequality-adjusted HDI ratio as defined by the UN Inequality-Adjusted Human Development Index.

The disparity in the clinical trial landscape has significant implications for patients living in LMICs:



countries and regions analysed by the Index, with the landscape evolving and established clinical trial networks in place in many LMICs.

1. Companies prioritise access planning in countries where clinical trials are conducted, leading to delays or reduced access in countries without trials.
2. Clinical trials offer patients access to potentially lifesaving investigational medicines, but many people in LMICs miss this opportunity.
3. The resulting lack of research data from populations in LMICs limits the understanding of how diverse patient populations respond to new therapies.

Access planning often limited to the few countries where clinical trials take place

Should a clinical trial prove successful, the first crucial step is to ensure the product's availability in the country where the trial took place. To this end, access planning during clinical trials is critical to ensure that new medical treatments are available swiftly and widely once they are launched on the market. This link between clinical trials and access means that, when LMICs are excluded from clinical trials, they are also excluded from the access plans tied to those trials. As a result, people living in these countries face significant delays before new treatments become available and, in many cases, may never have the chance to access new therapies.

Most companies (15/20) have public commitments to plan for access by registering the product for approval in countries where they conduct trials. However, since clinical trials are only conducted in a small cohort of LMICs, access plans tend to be limited to those countries. On average, an access

As a first step to widening the scope of their clinical trials, companies can expand trial sites to routinely include LMICs where the necessary infrastructure is already in place, which would inherently strengthen local research capacity. In addition to this, broadening clinical trials to include more diverse populations would ensure more equitable representation of the world's population in clinical research. Consequently, the resulting treatments would have broader, more reliable applications globally, reducing health disparities.

For trials in lower-resource settings, companies can work with partners to build local research capabilities and conduct clinical research. This is particularly important to discover suitable treatments and cures for diseases that are endemic in these countries. In the future, as healthcare needs of patient populations in these countries evolve, companies can explore opportunities to collaborate with partners to expand clinical trials to other disease areas.

Alongside partners, some companies are conducting clinical trials in low-income countries

The 2024 Index identified a few examples of companies making efforts to increase their focus in poorly resourced settings. For instance, although only 3.5% of clinical trials take place in low-income countries, at least eight companies – Bayer, Eisai, Gilead, GSK, Johnson & Johnson, Merck KGaA (Merck), Novartis, and Sanofi – are engaged in these trials either through their R&D efforts or by partnering with organisations that lead the trials.

plan includes only six of the 113 LMICs covered in the Index, typically focusing on a select number of upper-middle-income countries or emerging markets with higher commercial poten tial. Lower-middle-income-countries are included in access plans to a lesser extent, highlighting significant room for improvement to expand plans to include a broader range of countries. (Also see the Research & Development sub-chapter on p.37 of the 2024 Index).

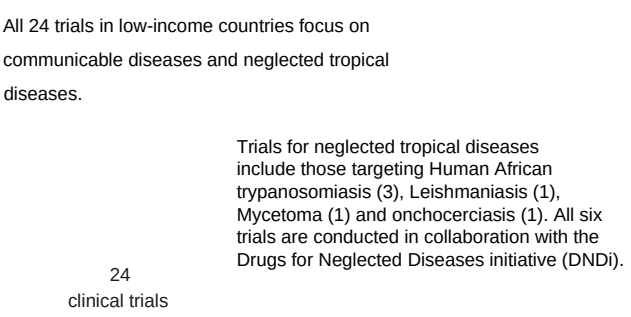
Expanding the scope of clinical trials to more LMICs can play a significant role in broadening the geographic reach of

companies' access plans, ultimately helping to narrow gaps in access both pre- and post-approval of new, innovative products.

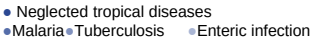
Expanding the scope of clinical trials in LMICs

Indeed, the capacity to conduct clinical trials is constrained in some LMICs for a few reasons; essential infrastructure may be limited, with a lack of adequate clinical facilities and trained healthcare personnel, for example. Regulatory frame works may also be complex or fragmented. Furthermore, the absence of contract research organisations – which provide outsourced support to pharmaceutical companies to conduct trials – in some LMICs makes it more challenging to operation

FIGURE 2 Overview of clinical trials in low-income countries



alise the trials on the ground. However, it should be noted that the capacity to conduct trials varies significantly in different



As it stands, clinical trials in low-income countries are focused predominantly on communicable diseases, such as HIV/AIDS (6) and malaria (7) or neglected tropical diseases (6) reflecting the high burden of these diseases in these regions (see

What's next?

To improve access and reduce delays in access to the newest medicines for those who need them most, companies can expand clinical trials to include more diverse populations,

Figure 2). especially in LMICs. At first, companies can expand the scope of their clinical trials, routinely including LMICs where the necessary infrastructure and regulatory systems are already in existence. In tandem, it is also essential for companies to

Specific examples of companies' clinical trials in low-income countries:

- Gilead conducted clinical trials testing lenacapavir (a long-acting injectable) for HIV prevention in Uganda, a low-income country where approximately 1.5 million people are living with HIV. As part of its access plans, the company

develop comprehensive access plans that cover a wider range of countries and diseases. Such plans should consider, among other factors, plans for registering in more countries, affordability, collaboration with local partners, and securing consist announced a non-exclusive voluntary licensing agreement, ent supply chains.

allowing manufacturers to make and supply generic lenaca pavir in 120 LMICs, including Uganda, a low-income country. Merck KGaA are both conducting clinical triers, they are uniquely positioned to collaborate with partners countries for new antimalarials as part in LMICs, helping to bridge gaps and build clinical trial capabil by the Medicines for ities in these countries. This includes developing centralised formulation of clinical trial infrastructure that would facilitate a coordinated and streamlined process for monitoring data, which can be across all products in development, expediting the expansion of clinical trials to more regions.

product is successful in clinical trials that includes equita ble pricing and broad registration plans in countries with high disease burdens. (see Best Practice on p.113). Merck's cabamiquine is currently being tested in clinical trials in Burkina Faso, Mozambique and Uganda for both the treat ment and prevention of *Plasmodium falciparum* malaria. Merck has an access plan in place, including a regulatory strategy for countries with high disease burdens, and plans to ensure sustainable supply.

Some companies are also collaborating with international and local partners to build clinical trial capacity in LMICs. The Clinical Trials Community Africa Network (CTCAN), of which Johnson & Johnson is a partner, aims to build clinical trial capacity by combining data from research centres across Africa. Similar efforts are underway in Asia, with partnerships like the one between AstraZeneca and the Cancer Research and Clinical Trials Centre (CRCTC) in Vietnam focusing on oncology treatments. These partnerships can be further expanded to build sustainable clinical trial infrastructure in more regions, and for multiple products and therapeutic areas.

Additionally, pharmaceutical companies play a vital role in fostering local R&D capacity. As innovators and patent hold•Novartis and als in low-income of the PAMAfrica consortium, led by the Malaria Venture. Trials for Novartis' new IV cipargamin for severe malaria are ongoing in Burkina Faso, the Democratic Republic of Congo, Rwanda and Uganda. scaled Novartis has developed a comprehensive access plan if the

KEY FINDING 3: VOLUNTARY LICENSING AND TECHNOLOGY TRANSFER

Efforts to ramp up wider local availability of medicines through voluntary licensing and technology transfers are limited

- ▶Historically, some companies have used voluntary licensing to increase access to their products in low- and middle-income countries (LMICs), particularly treatments for HIV and hepatitis C and, most recently, for COVID-19.
- ▶However, only two new non-exclusive voluntary licensing (NEVL) agreements were issued during the period of analysis for the 2024 Index, with a third following after. This is despite public health organisations prioritising at least ten key patented treatments in companies' portfolios as candidates for licensing.
- ▶Despite some promising examples of companies pursuing technology transfers, aside from South Africa, sub-Saharan Africa remains widely overlooked; overall efforts from companies remain largely concentrated in Brazil, China and India.

Voluntary licensing agreements, particularly when supported by technology transfers to local manufacturers, is a powerful way in which pharmaceutical companies can improve long-term and sustainable access to their essential healthcare products.

By adopting these mechanisms, companies can help ensure patients – no matter where they live – have timely, affordable and sustained access to medicines, vaccines and diagnostics, especially in regions where companies have limited or no

During the period of analysis for the 2024 Index*, only two new licences were issued, both through the Medicines Patent Pool (MPP). One additional licence was announced outside the period of analysis:

•July 2022: cabotegravir long-acting (CAB-LA), for HIV pre-exposure prophylaxis (PrEP), issued by ViiV Healthcare (a company majority owned by GSK), marked the first NEVL for a long-acting injectable for HIV prevention. The licence operations. covers 90 countries, 88 of which are LMICs covered by the Index analysis, including all low-income countries, all least

Momentum of non-exclusive voluntary licences is slowing Non-exclusive voluntary licences (NEVLs), such as those issued for products targeting HIV and hepatitis C, have enabled significant improvements in healthcare for patients living in LMICs. Although some of these NEVLs were issued 15 or more years ago, the 2022 Access to Medicine Index identified six newly issued NEVLs, signalling an encouraging trend and a willingness from companies to engage in NEVLs. However, the 2024 Index has identified a noticeable slowdown in licensing activities, which have now reverted to a level last seen prior to the COVID-19 pandemic – indicating a concerning loss in the momentum gained over the last few years. This is

developed countries, and all sub-Saharan African countries. The licence was agreed seven months after U.S. Food and Drug Administration (FDA) approval.

•October 2022: nilotinib, indicated for chronic myeloid leu kaemia, issued by Novartis, was the first licence of its kind for a non-communicable disease (NCD). The licence cov ered 43 of the LMICs covered by the 2024 Index analysis. •October 2024 (outside the period of analysis), Gilead announced that it had entered NEVLs with six generic man ufacturers to produce and distribute lenacapavir, indicated for HIV prevention (pending regulatory approval) and treat ment, in 120 LMICs, 96 of which are included in the 2024

despite companies having several prioritised patented prod Index analysis.

ucts, including cancer treatments, in their portfolios for which

licensing could be a viable option to expand access.

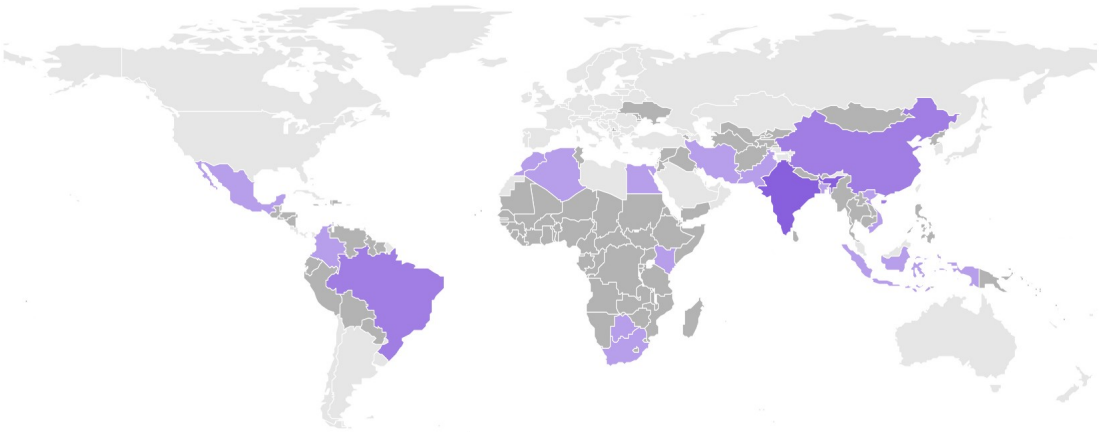
Not only has the overall number of companies with vol untary licensing agreements decreased from ten in the 2022 Index to nine, but there has also been a decline in the num ber of new NEVLs issued. Even when voluntary licences are granted, some countries in need of access are excluded from these agreements, placing greater responsibility on compa nies to ensure affordable access directly.

Although the CAB-LA and nilotinib licences were issued at the beginning of the period of analysis for the 2024 Index, and Novartis' licence for nilotinib was granted less than a year before the expiration of the main patent, these licences were promising milestones. They served as examples of how other companies could follow suit in paving the way for broader access in LMICs – especially for innovative products in thera peutic areas such as NCDs.

*Although both licences were announced outside the period of analysis for the 2022 Index, each was highlighted in that report due to their significance within the realm of voluntary licensing. These licences are included in the 2024 Index assessment.

FIGURE 1 Number of new licences issued by companies in 2022 Index vs. 2024 Index

Only two new non-exclusive voluntary licences (NEVLs) were issued during the period of analysis of the 2024 Index, compared with six new



licences issued during the period of analysis for the 2022 Index. No new licences have been issued by any companies since October 2022.

Only Novartis newly engaged in voluntary licensing in the period of analysis for the 2024 Index, with the licence issued in October 2022.

AstraZeneca, Eli Lilly and Pfizer newly engaged in voluntary licensing in the period of analysis for the 2022 Index.

Since 2022, the CAB-LA licence has been issued to three sublicensees and the nilotinib licence has been issued to four sublicensees. CAB-LA is a more complex product, so the development process and obtaining approval for generics will take time. It is estimated that the first regulatory filings from generic manufacturers could be in late 2026, with potential registration estimated for 2027.[1]

While these latest announcements are welcome, these are the first new actions from companies in voluntary licensing in almost two years. For impactful change to take place, more action is needed and there is ample opportunity for more companies to do so. For example, of the 13 products specifically included in the MPP's priority list for in-licensing, ten are patented by the companies analysed in the Index. By licensing even some of these key products, they could make a significant impact in broadening access in LMICs.

More companies engage in technology transfers in a few select countries, but efforts in sub-Saharan Africa lag

The 2024 Index identified that 17 companies have transferred financial resources, infrastructure and know-how to expand manufacturing capacity in the LMICs covered by the 2024 Index. Notably, of these 17, Eli Lilly and Merck & Co, Inc. (MSD) have newly engaged in technology transfer initiatives in

the LMICs analysed. Three companies – AbbVie, Astellas and Bristol Myers Squibb – do not engage in technology transfers.

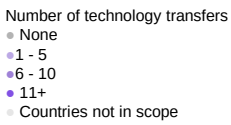
However, as shown in Figure 2, the Index does reveal a stark disparity in technology transfer efforts across different regions, with a few countries, particularly India, Brazil, and China being the major recipients of such initiatives. Of the 47 initiatives identified in the 2024 Index, India has received 11, while Brazil accounts for nine and China for seven.

In contrast, local manufacturing efforts on the entire African continent stand at just 17 initiatives across 12 companies. Of these, most are concentrated in only two countries: Algeria (5/17) and South Africa (5/17). Aside from South Africa, initiatives in sub-Saharan Africa are sparse. Only six companies – Boehringer Ingelheim, Gilead, Merck KGaA (Merck), Novo Nordisk, Pfizer, and Sanofi – report having established technology transfer initiatives in this region. The companies' initiatives here include products for HIV, hepatitis, COVID-19, diabetes mellitus and neglected tropical diseases, including schistosomiasis and rabies.

Concerted efforts are underway to help ensure a continuous supply of medicines across Africa. The African Union Development Agency (AUDA-NEPAD) initiated the Pharmaceutical Manufacturing Plan for Africa in 2005

FIGURE 2 Sub-Saharan Africa is largely overlooked by companies' technology transfer efforts

This map illustrates technology transfers undertaken by companies analysed in the 2024 Index, which were active between 1 June 2022 and 31 May 2024 (i.e., during the period of analysis for the 2024 Index).



(further developed into a Business Plan by the African Union and has also led the development of the African Medicines Agency. More recently, in 2021, under the Africa for Disease Control and Prevention (Africa CDC), African Union (AU) launched the Partnership for African Manufacturing. Through this Partnership, the AU aims enable the African vaccine manufacturing industry to pro 60% of vaccine doses required on the continent by 2040, the New Public Health Order initiative. Given this trac foster local availability in Africa, companies can pursue more targeted approaches to help strengthen supply chains and develop local manufacturing across more countries on the continent.

Here, the 2024 Index has identified some promising exam ples of such targeted initiatives in Africa. For instance, Merck KGaA is partnering with Universal Corporation Ltd. in Kenya to manufacture its schistosomiasis treatment, apraziquan tel, with the aim to supply it to endemic countries in Africa. Similarly, in 2024, Sanofi signed a technology transfer agree ment with Biovac in South Africa to manufacture and supply its polio vaccine in Africa through UNICEF. While polio is not one of the diseases included in the Index analysis, the initiative is notable in this context.

What next?

Voluntary licensing and technology transfers are clear ways in which companies can improve the local availability of their medicines, vaccines and diagnostics in countries where they lack a local presence. Improving local production of healthcare products can also contribute to building robust, self-sustain ing healthcare systems in LMICs, thereby decreasing the need for costly investment by countries and international agencies to procure products.

However, the current stagnation in voluntary licensing and the geographic limits of technology transfers mean that many opportunities to maximise local availability are being missed – leaving patients in the poorest regions of the world without access to newer and often more expensive products that are critically needed.

Companies now need to take decisive action to not only remain engaged in current efforts, but to evolve them to encompass a broader range of products, include more coun tries and address a wider variety of diseases.

With ten products in companies' portfolios listed by the MPP as priorities for voluntary licensing, and many more emerging from their pipelines, companies already have clear opportunities to enter new licensing agreements for critical in 2012) products. However, for these agreements to be truly impact- ful, they must include access-oriented terms and, critically, Centres technology transfer provisions as well. While such agreements the may be feasible for only a limited number of local manufacturVaccine ers – who must demonstrate both capacity and quality – this to potential cannot be overlooked. By prioritising partnerships duce with local manufacturers capable of ensuring quality-assured under production and collaborating with them to facilitate technotion to logy transfers, companies could make a significant impact.

READ MORE IN THE 2024 INDEX ON THE

p.54

p.118

1. Medicines Patent Pool. Generic CAB-LA for PrEP development and access. Published May 24, 2024. Accessed September 5, 2024. https://www.prepwatch.org/wp-content/uploads/2024/06/MPP__LA_PrEP_Coalition_CS_Caucus__For_sharing. pdf

CHAPTER 2

AREAS

GOVERNANCE OF ACCESS

RESEARCH & DEVELOPMENT

PRODUCT DELIVERY

GOVERNANCE

OF ACCESS

CONTEXT

By implementing clear, sustainable access-to-medicine strategies and fostering a workforce committed to access, pharmaceutical companies can aid in expanding the availability of medicines for underserved populations in low-and-middle-income countries (LMICs). Additionally, to effectively demonstrate their commitment to equitable access, companies need to adopt ethical business practices, implement robust compliance mechanisms throughout their operations and ensure transparency in their outcomes.

GOVERNANCE OF ACCESS

What is the Foundation looking for?

In this chapter, the Index reports on how companies integrate their access-to-medicine strategies into their governance and incentive structures. It also assesses how companies apply processes to minimise the risk and occurrence of non-compliant and/or corrupt behaviour. How well companies' intellectual property (IP) strategies align with international standards for IP management is also assessed. Additionally, it explores the processes companies have in place to measure and report on the number of patients they are reaching.

How performance is measured

- Companies are assessed against seven indicators across three priority topics in the Governance of Access Technical Area. Notably, a new priority topic on measuring and reporting patient reach has been introduced since the 2022 Index, which looks at the success of companies' strategies in ensuring their essential healthcare products reach patients living in LMICs. This includes a standalone patient reach indicator.
- In September 2024, the Access to Medicine Foundation released a report focusing on findings for this standalone indicator, titled 'Patient Centricity: How is the pharma industry addressing patient reach?' (also see p.35 in this sub-chapter).
- For more details on the analytical framework of assessment for Governance of Access, please see p. 23 – 26 of the 2024 Access to Medicine Index Methodology, which you can view here.

MORE INFO ON COMPANY PERFORMANCE

- Best Practices *p.11*
- Company Report Cards *p.122*

GOVERNANCE OF ACCESS	3 PRIORITY TOPICS	7 INDICATORS
	Responsible business practices	● ● ● ●
	Governance and strategy	● ●
	Measuring and reporting patient reach	●

GOVERNANCE OF ACCESS

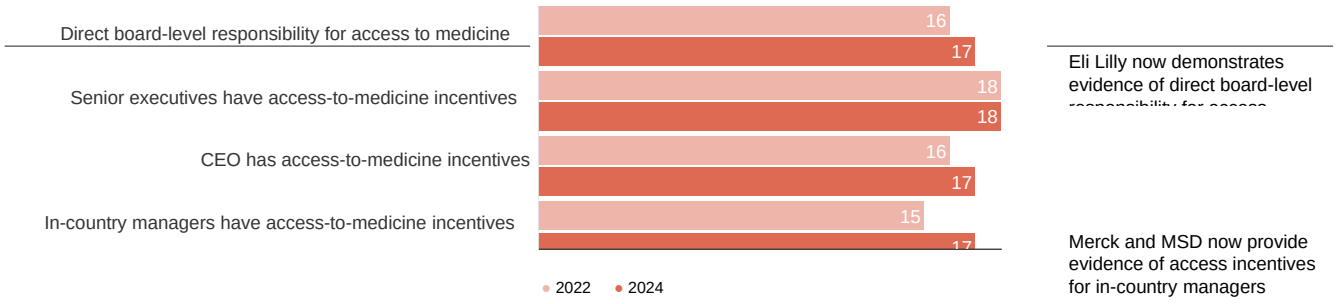
How are companies prioritising access to medicine through governance structures, business practices and patient reach approaches?

1 GOVERNANCE AND STRATEGY

More companies demonstrate clear responsibility for access to medicine at senior levels

The 2024 Access to Medicine Index finds that 17 companies now demonstrate direct board-level responsibility for access to medicine. However, Astellas, Daiichi Sankyo and Merck & Co., Inc. (MSD) provide evidence of indirect board-level responsibil ity, with environmental, social and governance (ESG)/access committees or indi viduals in access to medicine roles overseeing and reporting to the board instead. This increase in companies with board-level responsibility is accompanied by more access-to-medicine incentives for CEOs and in-country managers (see Figure 1).

FIGURE 1 Comparing the number of companies with direct board-level responsibility and access-to-medicine incentives for executives and in-country managers: 2022 vs. 2024 Indexes



All companies continue to demonstrate that they have an access-to-medicine strategy in place, although Gilead remains the only company that does not provide evidence of integrating this strategy into its broader corporate strategy. Seventeen companies now provide evidence that their access-to-medicine strategies cover all the therapeutic areas they are involved in, up from 14 companies in the 2022 Index. Meanwhile, Daiichi Sankyo, Eli Lilly and Gilead have strategies covering only some of their therapeutic areas.

As part of their access-to-medicine strategies, all companies publicly disclose commitments, as well as targets, goals and objectives for access to medicine. However, only about half of the companies have measurable company-specific goals accompanied by clear, centrally available outcome reporting that is regularly updated.

2 MEASURING AND REPORTING PATIENT REACH

Prior to the publication of the 2024 Index, the Foundation published a standalone report 'Patient centricity: How is the pharma industry addressing patient reach?', which provides a detailed analysis of how companies define, measure and report the number of patients they reach in low- and middle-income countries (LMICs) with their essential healthcare products. The report also features information on the product and country coverage of patient reach approaches, company goals associated with patient reach approaches and the extent of public transparency in reporting on these processes. For highlights from the report, see 'Spotlight on Patient Reach' on p.35 of this chapter. In addition, as part of this Index report, the patient reach of companies' access strategies is analysed in the Product Delivery sub-chapter on p.71.

3 RESPONSIBLE BUSINESS PRACTICES

Companies are taking steps, yet additional measures can promote ethical sales behaviour

In recent years, companies have increasingly moved away from linking incentives solely based on sales volume and have taken steps to decouple incentives from sales targets, with 18 out of 20 companies in scope showing evidence of doing so. However, there has been no progress regarding the number of companies that exhibit decoupling bonuses from sales targets since 2022. When bonuses are heavily tied to sales volume, it can lead to mis-selling or over-selling, diverting funds to unnecessary medicines or treatments and further straining limited healthcare resources in LMICs.

Companies can lower the percentage of salary linked exclusively to sales volume to further reduce the risk of performance being driven by sales alone. However, aside from one company doing so in some countries within the scope of the Index, no other companies provide evidence of setting their sales agents' overall compensation with less than 20% linked to sales volume.

Companies are taking measures that aim to serve as balancing mechanisms to help reduce the likelihood of inappropriate sales activities by agents. For example, some companies are incorporating non-sales metrics — such as compliance adherence, technical knowledge and customer feedback — into sales incentive plans. Others, like Pfizer and Takeda, do not set individual-level targets for their sales agents, opting instead for targets set at higher aggregated levels such as team, business unit or national levels.

Further, some companies have safeguards in place that can help mitigate the risk of unethical sales practices for some products related to diseases in scope. For Takeda's brentuximab vedotin (Adcetris®) — an oncology medicine indicated for multiple cancer types including non-Hodgkin lymphoma — the company reports that 0% of variable pay is linked to sales volume for its agents. Additionally, Johnson & Johnson does not deploy sales agents for certain products related to diseases in scope, such as HIV/AIDS medicines.

Most companies have policies and processes to ensure ethical interactions with healthcare professionals

Policies that guide employees on ethical interactions with healthcare professionals can help prevent practices such as unnecessary payments, inappropriate gift-giving, bribery or illegal product promotion. These practices can compromise a healthcare professional's prescribing decisions, potentially leading to unnecessary or inappropriate prescriptions that may harm patients or waste resources. Encouragingly, 18 out of 20 companies in scope have a public policy on maintaining ethical interactions with healthcare professionals, including in LMICs, either as part of the company's code of conduct or as a standalone policy (see Figure 2). However, having a policy alone does not guarantee ethical interactions; active implementation and enforcement are crucial to ensure compliance in practice.

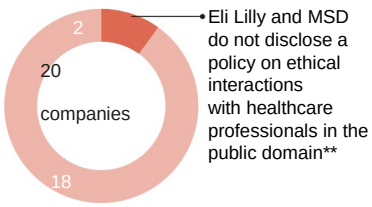
What elements constitute an effective policy on ethical interactions with healthcare professionals

The 2024 Index defines an effective public policy for guiding ethical interactions with healthcare professionals as one that ensures all engagements serve a legitimate need. It also sets limits on transfers of value to healthcare professionals and requires detailed explanations for any financial or non-financial compensation. This could include payments made to healthcare professionals for travelling to and speaking at company events, or for consulting services. Additionally, the policy ensures that any compensation provided is based on fair market value assessment.

Beyond outlining the components of an effective policy, the 2024 Index also evaluates a company's approach to disclosing information on transfers of value to health care professionals. Making this information publicly available holds companies accountable and can reduce the risk of undue influence on prescribing behaviour. Refer to GSK's Best Practice on p.112 for more information on how the company voluntarily discloses transfers of value to healthcare professionals, even when not mandated by local law or regulation.*

** Includes but is not limited to adherence to codes for e.g., the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice and European Federation of Pharmaceutical Industries and Associations (EFPIA)*

FIGURE 2 Eighteen companies have a public policy on ethical interactions with healthcare professionals



** That aligns with the standards set by the Index (please refer to sidebar on 'What elements constitute an effective policy on ethical interactions with healthcare professionals' above.

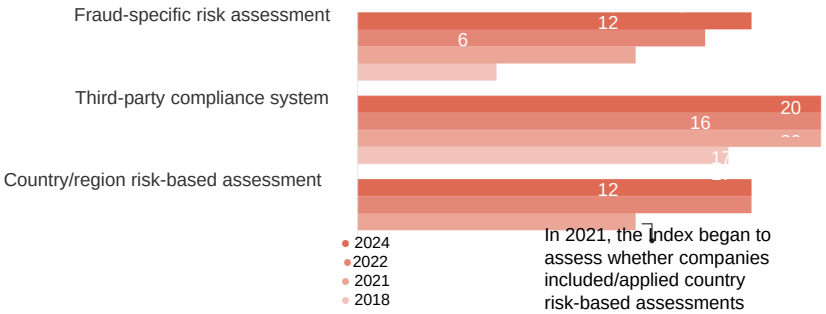
Limited progress with internal control processes that mitigate non-compliance risks

Processes such as fraud-specific risk assessments, country or region risk-based assessments and third-party compliance systems are integral to internal frameworks that ensure compliance with local regulations in LMICs, where weaker governance and health systems often heighten the risk of corruption.

Since the 2022 Index, there has been some progress in this area, with Eli Lilly and Roche now applying fraud-specific risk assessments. However, no new companies have started applying country or region-based risk assessments since 2022 (see Figure 3).

Although many companies are demonstrating evidence of implementing compliance controls, it remains crucial that these controls are localised to address the specific risks and challenges of the regions or countries in which the companies operate, particularly in LMICs.

FIGURE 3 Some signs of progress in applying specific compliance controls



All companies have policies and tools for promoting ethical behaviour among employees

Other internal controls that can support a company's efforts to promote ethical behaviour include companies' policies, for example, on ethical marketing, anti-corruption and clinical trial standards. All 20 companies have at least one publicly available policy covering one of the three topics. The Index also finds that no companies faced negative legal rulings during the period of analysis for unethical marketing, corrupt practices or clinical trial misconduct in countries in scope.

Furthermore, each company has some form of ethical decision-making framework or tool, typically embedded within a code of conduct. While the depth and detail of these frameworks vary, a robust framework provides specific examples and scenarios, along with relevant information and company policies, to guide employees through ethical dilemmas.

Having robust company policies and decision-making frameworks in place plays a role in fostering a culture of integrity. These controls can guide employees to act ethically, helping them proactively navigate compliance risks and promote responsible behaviour in the countries covered by the Index. Table 1 provides an overview of the internal control policies and processes companies use to mitigate risks of non-compliance and corruption, while encouraging ethical conduct among employees. Although companies show evidence of policies and tools to encourage ethical behaviour, the remedial actions taken when employees violate these standards, beyond losing eligibility for incentive compensation, remain unclear.

TABLE 1 Overview of companies internal control policies and processes that help mitigate risks and promote ethical behaviour

Companies					
AbbVie					
Astellas	●	●	●	●	●
AstraZeneca	●	●	●	●	●
Bayer	●	●	●	●	●
Bristol Myers Squibb	●	●	●	●	●
Boehringer Ingelheim	●	●	●	●	●
Daiichi Sankyo	●	●	●	●	●
Eisai	●	●	●	●	●
Eli Lilly	●	●	●	●	●
Gilead	●	●	●	●	●
GSK	●	●	●	●	●
Johnson & Johnson MSD	●	●	●	●	●
Merck	●	●	●	●	●
Novo Nordisk	●	●	●	●	●
Novartis	●	●	●	●	●
Pfizer	●	●	●	●	●
Roche	●	●	●	●	●
Sanofi	●	●	●	●	●
Takeda	●	●	●	●	●
	●	●	●	●	●

* In 2024, the Index assesses whether companies have internal policies in areas relating to anti-corruption, ethical marketing and clinical trial standards in operations in countries in scope of the Index.

Majority of companies express support for the Doha Declaration on TRIPS and Public Health, but have reservations on some provisions

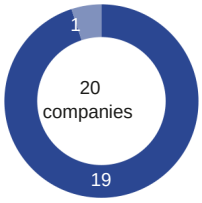
The World Trade Organization (WTO) implemented the Trade-Related Intellectual Property Rights (TRIPS) Agreement in 1995, which included pharmaceutical patents. Subsequently, in 2001, growing public health concerns regarding issues of accessibility to life-saving medicines in poorer countries led to the adoption of the Doha Declaration on TRIPS and Public Health by WTO member states. The declaration introduced additional pathways for member states to protect public health and enhance access to medicines by utilising TRIPS flexibilities, such as compulsory licensing.

Currently, 15 out of 20 companies express support for the Doha Declaration on TRIPS and Public Health, and five companies — AbbVie, Bristol Myers Squibb, Eli Lilly, Gilead and MSD — do not. Despite this stated support, companies are hesitant to fully support all TRIPS flexibilities, particularly when it comes to the rights of national governments to issue compulsory licenses. Most express reservations, stating that compulsory licenses should only be used as a last resort, after all other options have been exhausted, and should be limited to extraordinary public health emergencies. Further details on how companies engage in licensing and manage their intellectual property (IP) are discussed in the Product Delivery sub-chapter on p.65. Also see p.114 for MSD's Best Practice related to IP sharing.

SPOTLIGHT ON PATIENT REACH

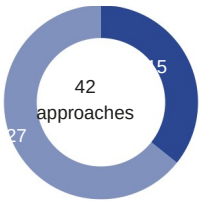
A crucial step for pharmaceutical companies in expanding access to medicine is determining how many people are truly accessing their products. Because of this, a new standalone patient reach indicator, 'GA8: Measuring and Reporting Patient Reach', has been incorporated into the 2024 Index Governance of Access analysis. This indicator evaluates the approaches to measuring and reporting patient reach that are being employed by companies in scope. Before the Index was published, a first-of-its-kind report specifically focusing on companies' efforts related to this indicator was released, providing a comprehensive overview of current industry practices to establish a baseline for measuring progress.

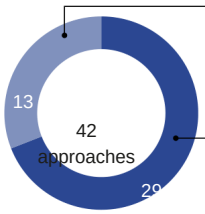
HIGHLIGHTS FROM THE REPORT



19 out of the 20 assessed companies report on their process for measuring patient reach, with AbbVie being the only exception.

15 out of 42 company approaches cover all LMICs in scope



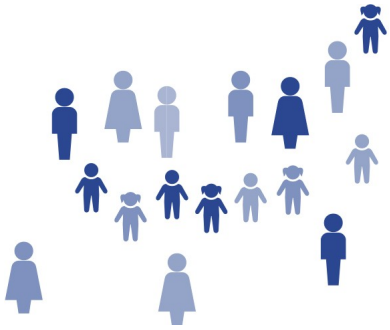


13 approaches have no goal at all

29 approaches have a patient reach goal

- XSignificant gaps remain in both product and geographic coverage, leaving the true number of patients reached in certain regions and for specific diseases unknown. For example, only six companies—Astellas, AstraZeneca, MSD, Novartis, Pfizer, and one company operating under a non-disclosure agreement—have patient reach approaches that cover all the countries in which they operate, both within and beyond the scope of the Index.
- XWhile many approaches rely on sales data to estimate patient reach, companies like AstraZeneca, Novartis, and Roche are pioneering more nuanced approaches to enhance the accuracy of their calculations.
- XSome companies, such as Bayer, GSK and Johnson & Johnson, have established clear, measurable, and ambitious targets that align with global health priorities. However, our findings reveal that there is still considerable room for companies to refine these commitments and enhance their efforts to reach those most in need.

STRENGTHENING PATIENT REACH



Despite numerous public commitments by pharmaceutical companies to reach more patients globally, significant gaps in access persist. That is why it has been imperative to establish how companies are making patient reach commitments, deliving on them and reporting their outcomes. With the current landscape clearly mapped out and a better understanding of the state of patient reach efforts, companies can now further strengthen and expand their approaches, while also collaborating and learning from one another. This will enable them to more effectively reach underserved patients who are often left out.

To learn more about how companies address monitoring and reporting on patient reach, please refer to the full report ‘Patient centricity: How is the pharma industry address of companies’ product-specific Product Delivery sub-chapter on p.71.

NEXT STEPS

- Companies can ensure that all access-to-medicine objectives, goals and targets are measurable and ambitious with good quality public reporting that shows progress or explains any setbacks.
- Companies can implement incentive structures that promote responsible business practices among sales agents.
- Companies can voluntarily disclose information on transfers of value to healthcare professionals in all countries in scope of the Index and not only when required by local law or regulation.
- Companies can enhance their current policies and processes to help mitigate non-compliance risks, fostering transparency to ensure they are adapted to local and regional contexts.
- For detailed insights and actionable next steps on improving patient reach, explore the comprehensive patient centricity report (see p.35 of this chapter for details).

RESEARCH & DEVELOPMENT

RESEARCH & DEVELOPMENT

CONTEXT

Large research-based pharmaceutical companies hold the key to developing new, innovative products that are at the forefront of modern medicine. By balancing their commercial objectives with their corporate social responsibility, these companies can ensure they not only develop blockbuster drugs, but also engage in research & development (R&D) to make essential products available and accessible to the people who need them.

What is the Foundation looking for?

In this chapter, the Index reports on the R&D activity for all diseases in scope of the 2024 Index, with a particular focus on those which disproportionately affect people in low- and middle-income coun tries (LMICs). Given their resources and expertise, the companies in scope of the Index are equipped to tackle unmet public health needs in LMICs and can adapt existing health products to ensure they are suitable for use in these regions.

This chapter also covers the quality and geographic scope of R&D access plans and looks at how companies contribute to R&D capacity building.

How performance is measured

- Companies are assessed against 7 indicators across 3 priority topics in the Research & Development Technical Area.
- For more details on the analytical framework of assessment for Research & Development, please see p. 27 – 30 of the 2024 Access to Medicine Index Methodology, which you can view here.

MORE INFO ON COMPANY PERFORMANCE •

Best Practices *p.110*

• Company Report Cards *p.122*

RESEARCH & DEVELOPMENT	3 PRIORITY TOPICS	7 INDICATORS
	Access planning	

PIPELINES

Addressing public health needs during product development can reduce healthcare disparities

As some of the leading innovators and producers of lifesaving drugs, the large research-based pharmaceutical companies analysed by the Index often hold the key to developing the most urgently needed medicines, vaccines and diagnostics. Additionally, the industry has the potential to improve existing products, which could prove life-changing for patients worldwide, particularly those living in low- and middle-income countries (LMICs).

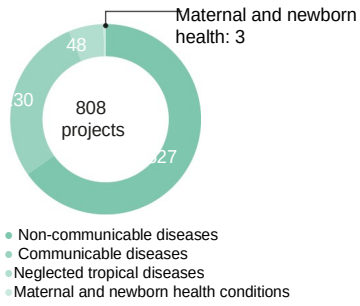
Pharmaceutical companies have been increasingly shifting their Research & Development (R&D) resources away from communicable diseases towards more profitable developments for non-communicable diseases (NCDs), such as cancers and rare diseases.[1] As in previous iterations, the 2024 Index finds that most of companies' R&D attention remains focused on NCDs (see Figure 1 alongside). Although there has been a global reduction in the burden of communicable diseases in recent years, it remains disproportionately high in LMICs, with R&D investments concentrated on a limited number of diseases such as HIV, tuberculosis (TB) and malaria.

Innovations for NCDs are now the backbone of the pharmaceutical business model, and increased focus in this area has led to groundbreaking treatments that have significantly improved patients' health outcomes. However, these products are typically developed to target more profitable markets in high-income countries where there is greater willingness and ability to pay for advanced therapies. Additionally, these products are often poorly matched to the needs and health system capabilities of LMICs. For example, targeted oncology therapies require specific diagnostic testing or administration in specialised healthcare facilities.

Consequently, despite being home to nearly 80% of the global population, people in LMICs often lack treatment options and remain last in line to receive critical healthcare products. To have a meaningful global impact and reduce health disparities, it is imperative that companies not only address the unmet need for products that tackle infectious diseases in LMICs, but also ensure NCD products that are suitable for LMIC settings are considered in their R&D activities.

As such, the Index analyses whether companies are engaging in R&D for the most urgently needed health products and how they are planning to bring these developments to patients in LMICs once they reach the market.

FIGURE 1 Two-thirds of the company pipelines target non-communicable diseases



A CLOSER LOOK AT COMPANIES' R&D PIPELINE PROJECTS

All R&D projects in companies' pipelines that target the diseases in scope of the 2024 Index (see Appendix II on p.211) are evaluated, with the Index additionally identifying which projects address the most critical healthcare gaps in LMICs. These so-called 'priority R&D gaps' refer to a critical area within R&D that is underexplored or underfunded. As a result, pharmaceutical interventions, such as medicines, vaccines and diagnostics are lacking or non-existent.

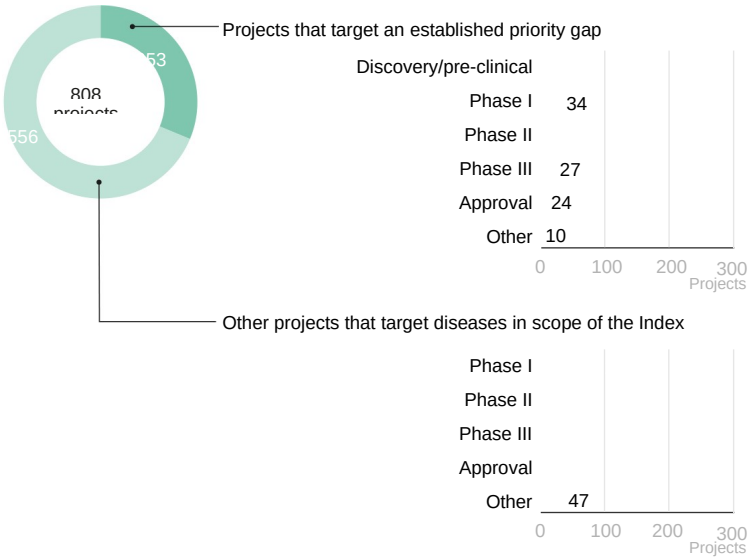
While there has been progress with major advancements in treatments for some priority diseases such as HIV, malaria and COVID-19, many R&D gaps remain. In some cases, this can lead to serious global health risks, such as drug resistance, rendering existing prevention and treatment tools less effective. When coupled with a R&D for new interventions, this can lead to infections that are increasingly difficult to treat and cure. Being adequately prepared for emerging infectious diseases also requires sustained R&D efforts to improve response time to outbreaks and to mitigate new epidemics and pandemics.

Are companies engaging in priority R&D to tackle unmet healthcare needs? The 2024 Index identified a total of 808 projects across the 20 companies' R&D pipelines, down from 1,073 in the previous Index (see Figure 2). There is no single, dominant reason for this decline; several factors, including product approvals and terminations, have contributed.

What is an R&D priority gap?
The Index identifies priority R&D gaps by collating lists from several public health organisations, namely the World Health Organization (WHO) and Impact Global Health (formerly Policy Cures Research) (see Appendix I on p.207). In general, priority R&D gaps exist for overlooked areas of research, such as women's health and highly prevalent communicable diseases in LMICs. In fact, only 11% of new drug approvals over the past decade target infectious diseases.[1]

FIGURE 2 Approximately one-third of projects in the pipeline address a priority R&D gap

107 (42%) of the projects targeting priority gaps are in discovery/pre-clinical development, and just 18% (110) of all projects in clinical development (Phase I-III) are focused on addressing a priority gap.



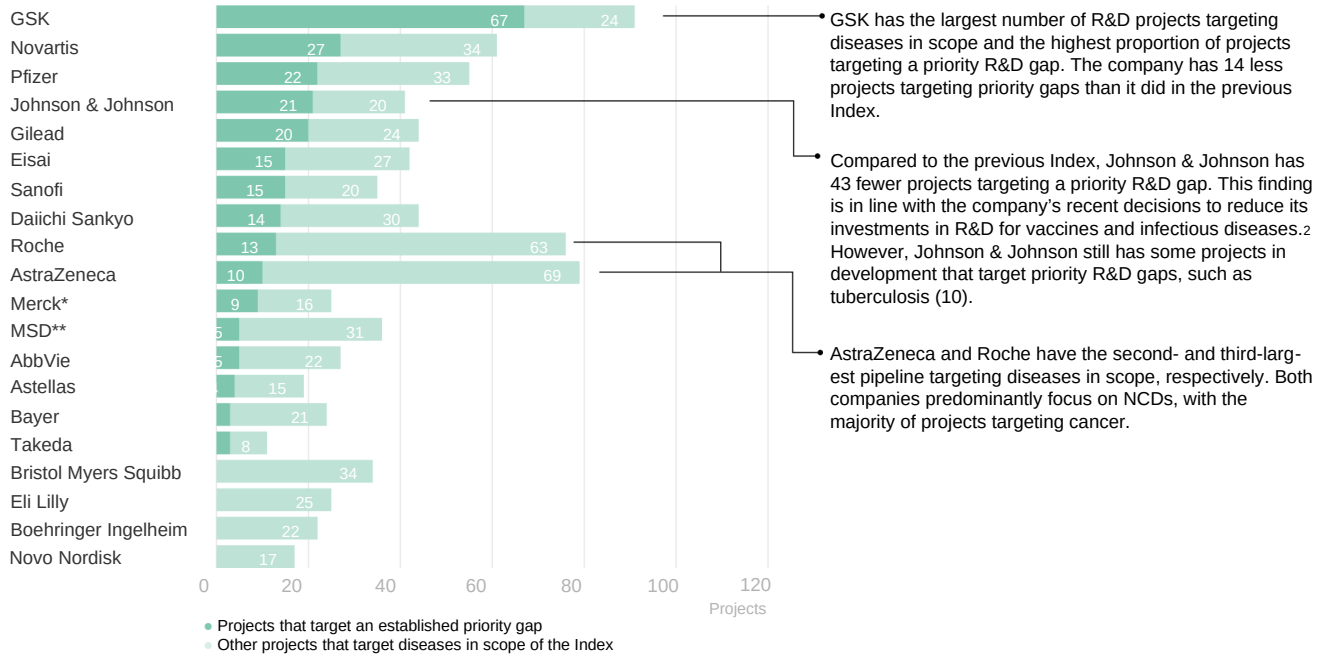
As set out in Figure 3, 16 of the 20 companies have projects in the pipeline that address R&D priority gaps. GSK has the largest number of R&D projects targeting diseases in scope, as well as the highest proportion of projects targeting a priority R&D gap, although the company has 14 less projects targeting priority gaps than it did in the previous Index. These projects primarily target HIV/AIDS (17), TB (9) and malaria (7), and 26 of them are in discovery/pre-clinical phase.

Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Novo Nordisk do not have any projects in scope that address priority R&D gaps.

Figure 4 on the next page (p.42) also zooms in further on the product types in development and the specific priority diseases they target. As identified in this iteration of the Index, there are currently no projects in development for 28 of 73 (38%) priority diseases with recognised R&D gaps, for example, Crimean-Congo haemorrhagic fever, Marburg virus disease and tapeworm infection.

FIGURE 3 16 companies in scope have projects that address priority R&D gaps

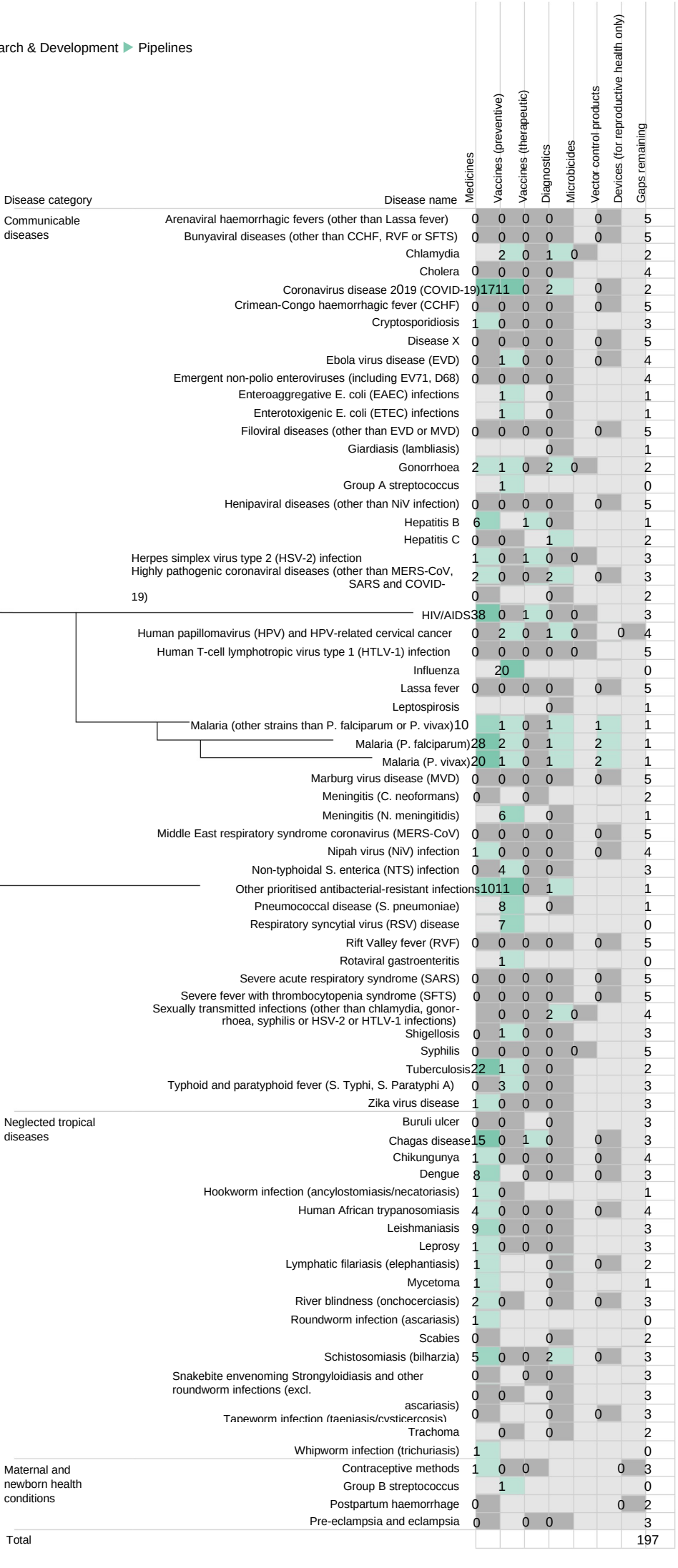
Four companies – Bristol Myers Squibb, Boehringer Ingelheim, Eli Lilly and Novo Nordisk– do not have any projects in scope that address priority R&D gaps and solely focus their R&D efforts on non-communicable diseases (NCDs).



* Merck KGaA (Darmstadt, Germany)
** Merck & Co., Inc. (Rahway, NJ, USA)

FIGURE 4 Projects targeting established priority R&D gaps

Across different product types (e.g., medicines, vaccines), only 26% of all R&D product gaps are currently addressed by a project, leaving a total of 197 R&D gaps.



Most projects addressing a priority product gap concentrate on a few diseases, such as HIV (39) and malaria (35). These diseases are frequently prioritised by global health stakeholders, who provide funding for R&D because of their significant disease burdens in LMICs.

Eight companies are engaging in projects to target prioritised antibacterial-resistant infections (there are 22 projects in the pipeline, down from 31 in 2022). Developing new medicines and vaccines to treat or prevent prioritised antibacterial resistant pathogens is crucial to counteract the global public health threat of antimicrobial resistance (AMR).

DOWNWARD TREND IN THE NUMBER OF COMPANIES DEVELOPING HEALTH PRODUCTS FOR DISEASES WITH PANDEMIC POTENTIAL

Previous Indexes have highlighted a lack of proactive engagement in developing solutions to mitigate the risk of future pandemics. Figure 5 below zooms in on the preceding priority R&D gap chart (on p.42) to focus on emerging infectious diseases (EIDs), illustrating the alarming decline in the number of companies that are developing products to counteract diseases with pandemic potential. These 17 EIDs, most of which are zoonoses (transmittable from animals to humans) are one of the greatest threats to global health security. For example, outbreaks from viral haemorrhagic fevers (such as the Ebola, Marburg and Nipah viruses) have been occurring with increasing severity and frequency in Africa.[3] However, as shown in Figure 5 below, there are just two projects in development for this virus group, targeting Ebola and Nipah.

A recent study estimated that there is a 50% probability of another pandemic with effects greater or equal to the COVID-19 pandemic, within the next 25 years.[3]

Most EID pipeline products still target COVID-19, leaving society severely exposed

The vast resources and expertise of innovative pharmaceutical companies are vital in preparing for further disease outbreaks and saving lives. However, the 2024 Index finds that the number of products in the EID pipeline has dropped from 80 to 33 since the 2022 Index, with 91% of these still focused on COVID-19. This leaves the pipeline entirely empty for 12 of the 16 other EIDs. Currently, only two of 20 companies (Johnson & Johnson and Novartis) are actively developing products that target EIDs (other than COVID-19) – three less than in the 2022 Index.

During the COVID-19 pandemic, the financial risk of R&D that is typically associated with EID product development was mitigated by the fact that much of these investments were publicly funded due to the global nature of the disease. However, it is vital that companies continue investing resources and developing solutions for EIDs before another outbreak occurs – and not retroactively. This can be done in collaboration with global health partners and funders. For example, one way in which companies can proactively prepare, while mitigating the financial risks of investing in R&D for EIDs, is by collaborating with organisations such as the Coalition for Epidemic Preparedness Innovation (CEPI), which finances independent research projects to develop vaccines against EIDs.

There is one project in the pipeline, a medicine in discovery phase, that targets two different Flavivirus diseases: Chikungunya and Zika.

FIGURE 5 Number of projects targeting emerging infectious diseases (EIDs) has more than halved since the previous Index

The number of active R&D projects targeting EIDs, as identified by WHO and Impact Global Health (previously Policy Cures Research), has fallen from 80 to 33 since the 2022 Index. The main reason for this drop is a sharp decrease in companies developing products that target COVID-19. The pipeline for 12 out of 17 EIDs remains empty, meaning no companies in scope are engaging in R&D to counteract the risk of these 12 infectious diseases.

Disease flagged as an epidemic/pandemic risk	R&D 2018	R&D 2021	R&D 2022	R&D 2024	Active 2018	Active 2021	Active 2022	Active 2024
Arenaviral haemorrhagic fevers (incl. Lassa fever)	0	0	0	0	0	0	0	0
Chikungunya	3	4	5	1	3	4	3	1
Crimean-Congo haemorrhagic fever (CCHF)	0	0	0	0	0	0	0	0
Ebola virus disease (EVD)	7	5	4	1	5	4	1	1
Emergent non-polio enteroviruses (incl. EV71, D68)	1	1	0	0	1	1	0	0
Marburg viral disease (MVD)	1	1	0	0	1	1	0	0
Middle East respiratory syndrome coronavirus (MERS-CoV)	0	0	0	0	0	0	0	0
Nipah	0	0	0	1	0	0	0	1
Bunyaviral diseases (other than CCHF, RVF and SFTS)	0	0	0	0	0	0	0	0
Filoviral diseases (other than EVD and MVD)	0	0	0	0	0	0	0	0
Henipaviral diseases (other than Nipah)	0	0	0	0	0	0	0	0
COVID-19 and other coronaviral diseases (other than SARS and MERS-CoV)	0	63	68	30	0	17	17	9
Rift Valley fever (RVF)	0	0	0	0	0	0	0	0
Severe acute respiratory syndrome (SARS)	0	0	0	0	0	0	0	0
Severe fever with thrombocytopenia syndrome (SFTS)	0	0	0	0	0	0	0	0
Zika virus disease	3	4	7	1	3	4	4	1
Disease X*	0	0	0	0	0	0	0	0

Since the previous Index, only one new project targeting an EID (other than COVID-19) has been commenced by a company in scope. The project targets Nipah virus and is in the discovery phase.

The number of companies engaging in R&D for Coronaviral diseases has halved since the last Index.

* 'Disease X', added to this list in 2018, represents the knowledge that a serious epidemic or pandemic could be caused by a pathogen currently unknown to cause human disease. COVID-19 can be seen as a first example of Disease X.

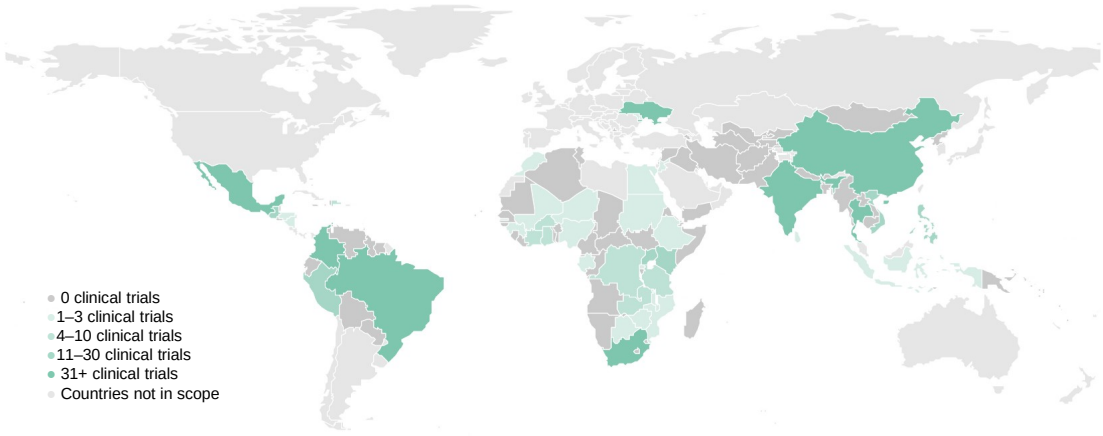
CLINICAL TRIALS

Where are companies carrying out clinical trials for their pipeline projects?

Clinical trials are undertaken to help evaluate the safety and effectiveness of treatments, so R&D projects can progress towards market approval. Moreover, clinical trials can also provide the opportunity for participants to access investigational health products. This access is particularly important for diseases where current treatment options are inadequate or lacking, meaning that enrolment in a trial could lead to improved health outcomes. Typically, companies will also conduct clinical trials in countries where they intend to market a product and provide post-trial access (also see p.47 later in this chapter). Assessing where companies are conducting clinical trials also serves as an indication of where new treatments will likely become available after a product is approved.

FIGURE 6 Companies predominantly conduct clinical trials in upper-middle-income countries

The 2024 Index finds that clinical trials for companies' pipeline projects are mostly undertaken in a limited set of countries, such as China, Brazil, Mexico, South Africa and Thailand. While these countries are all countries in scope of the Index, all five are classified as upper-middle-income countries, with few companies conducting clinical trials in low-income countries.



ONLY 43% OF CLINICAL TRIALS ANALYSED ARE CARRIED OUT IN THE 113 COUNTRIES IN SCOPE OF THE INDEX

When conducting clinical trials and accurately determining the varying health outcomes for different populations, it is important for companies to do this across a wider range of LMICs, and also consider the diversity of the candidates they include. For example, demographics such as sex, age and race can influence how a person responds to a new medicine or vaccine. This makes proportional representation of different populations in clinical research crucial for determining accurate dosages, understanding variations in efficacy due to differing factors (e.g. underlying nutritional profiles, comorbidities, etc.) and assessing the safety of health products across different groups.

Of the 685 trials analysed, the Index reveals that only 43% (297) are conducted in any of the 113 countries in scope, meaning most of the world's population does not have equal opportunity to enroll in trials for the latest innovations. The gap is even greater for the poorest countries, with only 3.5% (24/685) of trials carried out in any low-income country.

This global disparity in the clinical trial landscape means people in LMICs – where over 80% of the world's population resides – are not represented equally in clinical research. Recently, the lack of LMIC representation in oncology trials – which comprise half the clinical projects in the pipeline – was highlighted for exacerbating the gap in understanding the outcomes of cancer medicines in patients in LMICs, where a disproportionate global cancer burden lies.[4]

"Of the 685 clinical trials analysed, the Index reveals that only 43% (297) are conducted in any of the 113 countries in scope, meaning most of the world's population does not have equal opportunity to enroll in trials for the latest innovations."

Companies can engage in R&D capacity to ensure more diversity and inclusion in clinical trials

Several factors contribute to current disparities in clinical trials in LMICs, including lack of clinical trial capacity and health system infrastructure constraints. However, pharmaceutical companies can work alongside partners in LMICs to help build capacity and representation in these countries, with the Index identifying examples of such efforts from AstraZeneca, Johnson & Johnson and Novartis.

- Since 2019, AstraZeneca has been focusing on increasing the cancer clinical trial capacity in Vietnam through an R&D capacity building initiative. In this initiative, AstraZeneca Vietnam (AZ Vietnam) and the Cancer Research and Clinical Trials Centre (CRCTC), within the National Cancer Institute, partner to improve the development of oncology treatments across Vietnam.
- The Clinical Trials Community Africa Network (CTCAN). In this partnership, the Science for Africa Foundation partners with companies, including Johnson & Johnson, to build clinical trial capacity by combining data of research centres across Africa into an umbrella network, which is accessible to African and international trial sponsors.
- Novartis partners with the European & Developing Countries Clinical Trials Partnership (EDCTP) and TriNetX, LLC to support research capacity development in sub-Saharan Africa. The initiative's goals are to share data, facilitate industry-academic partnerships in clinical research and expand the clinical footprint across sub-Saharan Africa to promote health equity.

INCLUSION OF PREGNANT AND LACTATING PEOPLE IN CLINICAL TRIALS

Historically, pregnant and lactating people have been systematically excluded from clinical research due to ethical and legal concerns. This has resulted in a dearth of evidence, meaning the appropriate dosing regimens and safety profiles of medicines and vaccines in pregnant people is generally unknown. Consequently, the gap in data means using a medicine or vaccine during pregnancy is done at the patient's own risk.

A WHO framework for accelerating the inclusion of pregnant and breastfeeding people in HIV clinical trials contains specific recommendations and guidelines for the appropriate approach towards proportionate representation of pregnant people in clinical research.[5] The 2024 Index assessed instances in which companies do not have exclusion criteria for pregnant and lactating people as recommended by this framework.

Gilead and GSK demonstrate efforts to include pregnant and lactating people in certain HIV trials

The Index analysed 30 clinical trials for companies' pipeline projects that target HIV, malaria and TB, finding that only six (20%), all focused on HIV, did not systematically exclude pregnant and lactating people.

Four of the six trials are conducted by Gilead, the first company to intentionally include pregnant and lactating people in its Phase III HIV prevention trials. Another project, the Tshireletso study conducted by the Botswana Harvard Health Partnership, in collaboration with ViiV Healthcare (a company majority owned by GSK), evaluates the safety and acceptability of long-acting cabotegravir (CAB-LA), indicated for HIV prevention in postpartum breastfeeding women. The study is significant as new HIV infections disproportionately affect women, with the postpartum period posing the greatest risk for acquiring HIV.[6]

Prevention of new HIV infections among women of childbearing age is one of the primary strategies for eliminating new paediatric infections. Therefore, the decision by these two companies to include this population in clinical research represents a positive shift.

More companies should consider following suit and overall, consider adopting similar approaches for other diseases in accordance with WHO recommendations. The resulting evidence of such trials would enable informed decision-making about the appropriate use of medicines and vaccines during pregnancy and lactation.

"Gilead and GSK's decisions to include pregnant and lactating people in clinical research represents a positive shift in eliminating

ACCESS PLANNING

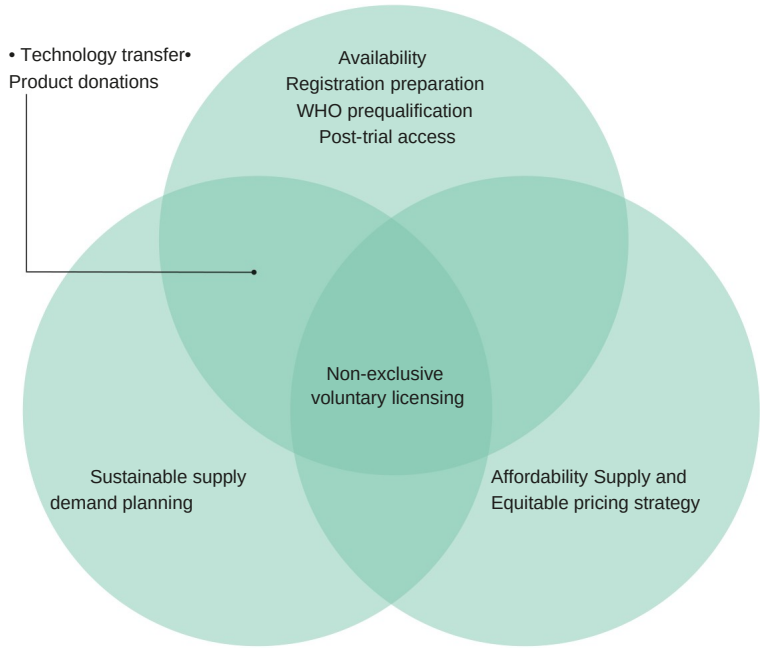
From pipelines to patients: Assessing companies' access planning during R&D

In tandem with developing products, companies must ensure that, should their pipeline projects prove successful and be introduced to the market, the resulting treatments will be accessible to those in need. By proactively developing access plans while a product is still in clinical development, companies can ensure measures are in place to make new products available in LMICs without delay (see Figure 7 below). To achieve the greatest impact, access plans should include many countries, with a particular focus on those with the greatest unmet healthcare needs.

The Index evaluates R&D projects in the pipeline to determine whether companies have access plans in place. For the 2024 iteration, the scope of assessment was expanded to include all R&D projects in the pipeline from Phase II, resulting in 409 projects assessed in 2024 (compared to 334 in the 2022 Index). Furthermore, the Index evaluates the quality and breadth of each access plan, to determine how effectively companies are planning for access and where they intend to make these products available.

FIGURE 7 A good access plan should address barriers to access during R&D

Access plans are essential to ensure that availability, affordability and supply are considered during the product development stage. Initiating plans from Phase II onwards means that companies have sufficient time to tailor plans to overcome barriers in LMICs, thereby reducing the time to market, should the product be approved.

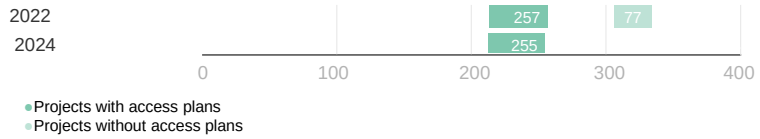


D ISPARIT Y I N TH E QUANTIT Y AN D QUALIT Y OF ACCESS PL ANS FOR NON - COMMUNICABLE DISEASES COMPARED TO COMMUNICABLE DISEASES

With the expanded scope of projects assessed, the 2024 Index finds that 62% (255/409) of projects have an access plan in place, representing a decline of 15 percentage points compared with the 2022 Index (see Figure 8).

In the 2022 Index, six companies had access plans in place for all their pipeline projects. However, in the 2024 Index, only four companies (Boehringer Ingelheim, Johnson & Johnson, Merck KGaA and Takeda) have access plans for all their pipeline projects.

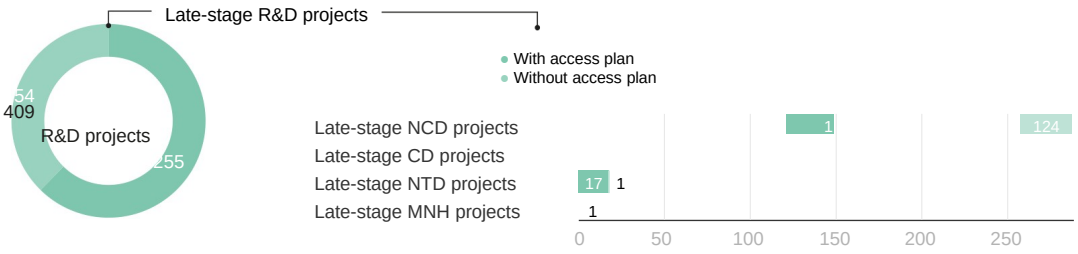
FIGURE 8 Fewer access plans in place compared with the previous Index



The primary reason for the decrease in access plan coverage is the expanded scope of projects in this iteration, which now includes all projects from Phase II onwards, resulting in more projects targeting NCDs falling within this scope. These projects generally have fewer access plans in place, compared to communicable diseases and neglected tropical diseases (NTDs), as set out in Figure 9.

FIGURE 9 Number of R&D projects with access plans per disease category

Overall, 62% of projects in the pipeline have an access plan. Late-stage projects for non-communicable diseases (NCDs) have proportionately fewer access plans in place (57%) when compared to other disease categories, such as communicable diseases (CDs) (71%), neglected tropical diseases (NTDs) (94%) and maternal and newborn health conditions (MNH) (100%).



In addition, access plans for NCDs tend to focus on registration in emerging markets, with only 46% (76/164 plans) including any of the additional considerations beyond purely commercial plans to facilitate access (see Figure 7 on p.47). By contrast, 85% (62/73) of plans for communicable diseases include additional provisions, such as equitable pricing plans, to help facilitate access beyond registration. The contrast in quantity and quality of access plans across disease categories may be partially explained by the fact that projects for NCDs are less likely to be developed in collaboration with, or funded by, access-oriented partners (1%), than those for communicable diseases (28%) and NTDs (73%). These partners integrate access planning in LMICs as a prerequisite during product development.

Since R&D for NCDs has not been at the forefront of global health funding, companies place less emphasis on developing access plans in LMICs for their in-house

developments for NCDs. This is despite the fact that 14 out of 20 companies have policies in place to systematically plan for access for all pipeline projects from Phase II onwards. Given the Index's finding that Boehringer Ingelheim, Johnson & Johnson, Merck KGaA and Takeda – all companies that have NCD projects in their pipelines – are the only companies with access plan coverage for all of their pipeline projects assessed, this would indicate that ten companies are not systematically implementing their access planning policies. It's also important to note that merely having an access plan in place does not ensure that it is comprehensive or extensive enough to guarantee widespread access. Novartis leads by implementing access plans with greater breadth and depth compared to peers across both NCDs and communicable diseases, but substantial improvement is still required industry-wide to ensure that companies plan for equitable access in LMICs.

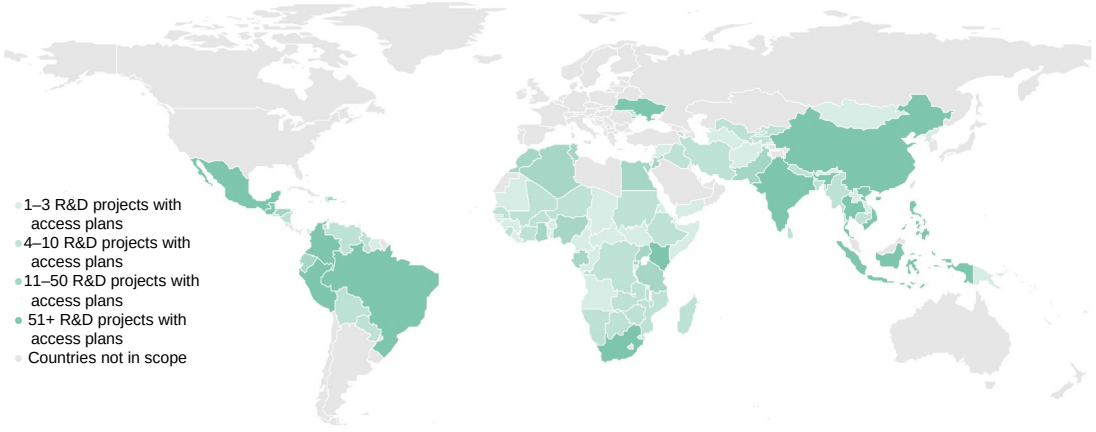
COMPANIES PREDOMINANTLY PLAN FOR ACCESS IN EMERGING MARKETS

In addition to assessing the quality of access plans, the Index also evaluates which countries companies include in their plans, finding that access plans predominantly focus on emerging markets such as Brazil, China and Mexico (see Figure 10). There is also significant overlap between where companies are planning to launch their products and where they are conducting clinical trials (see previous section in this chapter on p.44 for more details on companies' clinical trials). This finding is expected, as 15 of the companies in scope have policies in place where they commit to register their products where they have conducted clinical trials. However, it does mean that the uneven distribution of clinical trials exacerbates the access gap; patients in many countries are unable to participate in trials and will subsequently lack access to the medication once it is launched, as their country is not included in the companies' access plans.

On average, access plans include only six countries, which is only 5% of the total number of countries in scope. Furthermore, plans for NCDs include an average of only five countries, compared with eight countries for communicable diseases. Although the pharmaceutical industry is investing heavily in R&D for NCDs (82% of clinical trials), people in LMICs – where the burden of NCDs is high and increasing –may never see the benefits of these investments. Companies must take appropriate action by planning for access in LMICs to ensure these advancements are accessible to people worldwide.

FIGURE 10 Access plans predominantly focus on Brazil, China and Mexico

These plans, which are predominantly commercial launches in upper-middle-income countries, indicate that companies are focusing plans on markets with higher commercial potential, meaning much of the world's population living in poorer countries will not have access to these new innovations.



NOTABLE DEVELOPMENTS IN COMPANIES' PIPELINES IDENTIFIED IN THE 2024 INDEX

- Bayer, in partnership with DNDi, is repurposing emodepside – an antiparasitic drug originally used in animals – for the treatment of onchocerciasis. Ninety-nine percent of cases of this NTD, also known as river blindness, occur in 31 countries in sub-Saharan Africa.[7] A Phase II trial was conducted in Ghana and the Democratic Republic of the Congo, with results expected late 2024. Furthermore, Bayer, the Swiss Tropical and Public Health Institute (Swiss TPH) and its partners' Phase II trials in Tanzania, testing emodepside

- Since 2020, Novartis has had a licence agreement with DNDi for LXE408, a potential new oral treatment for visceral leishmaniasis. Visceral leishmaniasis, when left untreated, is fatal in over 95% of patients

and it is estimated that 700,000 to 1 million cases occur annually.[12] Novartis discovered the compound with the support of funding from Wellcome Trust and the EDCTP and, supported by results in earlier stages of development, initiated a Phase II study in India late 2022. A second study site in Ethiopia commenced operations early in 2024.

for the treatment of soil-transmitted helminths, have been successful.[8] Soil-transmitted helminths are one of the most prevalent infections globally, with approximately 1.5 billion infected people (24% of the world's population), as estimated by the WHO in 2023. Regions with a high burden of helminths are generally lower income and lack clean water and sanitation. In these regions, over 900 million children, 100 million adolescent girls and 130 million pregnant and lactating people are at risk of anaemia and malnutrition, raising the risk of developing various different diseases later in life. Because of this, the risk of maternal and infant mortality and low birth weight in neonates rises.[9] If Phase III trials prove successful,

X Novartis has 10 malaria projects in development, more than any other company in scope. Several of these focus on R&D to address the emerging threat of artemisinin-resistance of patients with gastrointestinal infections caused by whipworm (*Trichuris trichiura*), hookworm (*Necator americanus* or *Ancylostoma duodenale*) and possibly other soil-transmitted helminths can benefit from this treatment.

malaria in adults and children. For example, its project KAF156 (ganaplacide + lumefantrine), investigating one novel and one new antimalarial formulation, progressed from Phase II to Phase III during the period of analysis. The project is a result of a partnership between, among others, Wellcome Trust, Medicines for Malaria Venture (MVV), the Swiss TPH and the WANECAM2 (West African Network for Clinical Trials of Antimalarial Drugs) Consortium, which is funded by the EDCTP. The project is accompanied by a comprehensive plan for access in countries where malaria is endemic (also see Best Practice on p.113).

XEisai has numerous projects in development for four different NTDs: Chagas disease, mycetoma, leishmaniasis and filariasis. The projects are being conducted with multiple partners and are in various stages of development. In 2024, Eisai began a research collaboration with two German Universities to identify a new drug effective against onchocerciasis and lymphatic filariasis. Lymphatic filariasis still threatens the lives of almost 900 million people in 44 countries, with affected patients currently requiring preventative chemotherapy to stop the spread of

XPfizer's inclacumab and GBT021601 are two projects targeting sickle cell disease (SCD), with the latter also being investigated for paediatric patients aged six months onwards. Both NCD projects have robust access plans in place that address barriers to access in

LMICs and target several countries in scope where SCD is prevalent. With the right access plans, these projects can have a significant impact for the almost 8 million people living with SCD – most of which live in sub-Saharan Africa. Furthermore, in 2021, an estimated 515,000 children were born with SCD, an increase of 13.7% compared to 2000.[13]

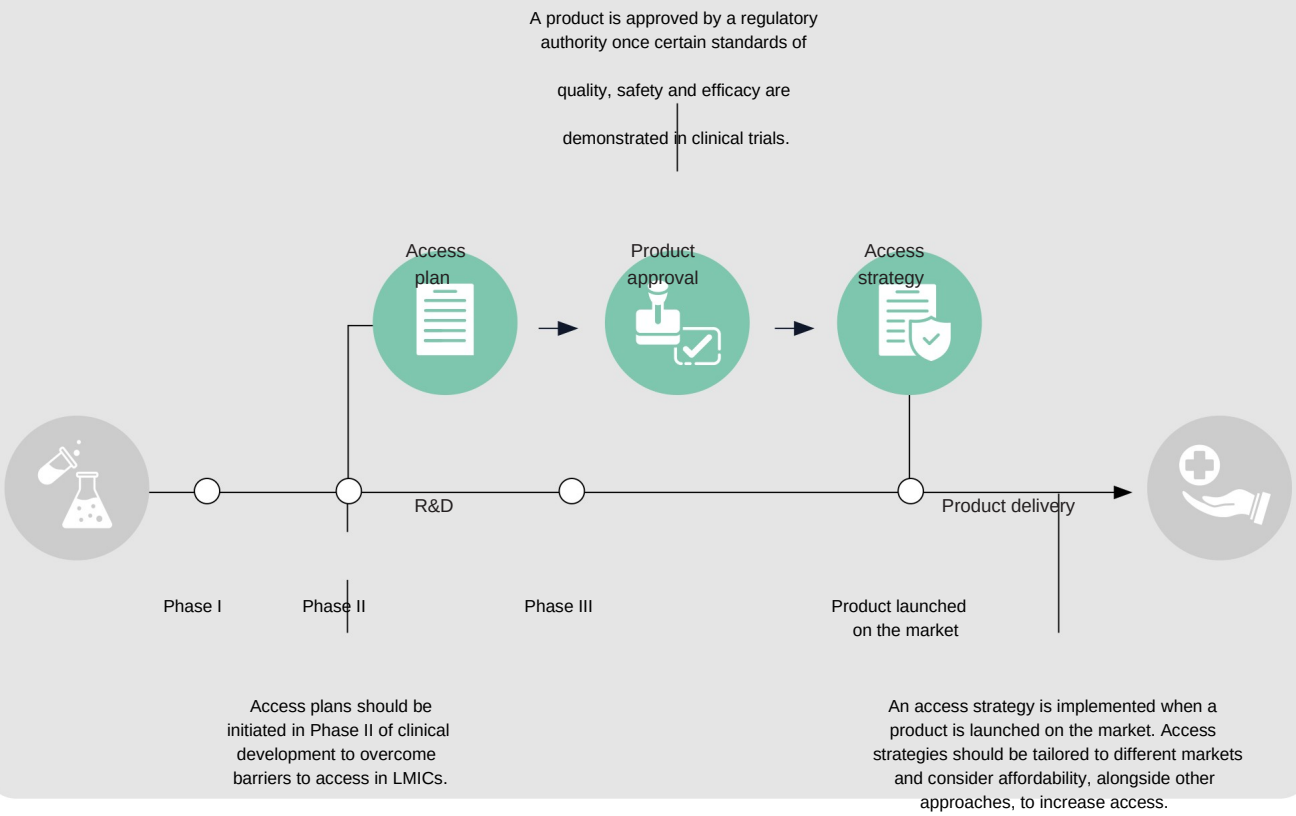
infection.[10]

In 2024, Gilead's Phase III PURPOSE 1 trial, which evaluates the twice-yearly investigational HIV prevention, lenacapavir, demonstrated 100% efficacy in preventing HIV infection in cisgender women (a group that shares a disproportionate number of new HIV infections). In October 2024, Gilead announced that it has signed a non-exclusive voluntary licensing agreement with six manufacturers to make and sell generic lenacapavir (subject to regulatory approval) in 120 LMICs.[11]

FROM R&D TO PRODUCT DELIVERY, WHAT HAPPENS NEXT?

To make a meaningful impact and reach patients, companies must act on their access plans and commitments. Once a product is approved, companies can move from planning to execution by implementing their access strategies in LMICs. Appropriate access planning can reduce the time it takes to successfully implement these strategies, meaning that products reach more patients in LMICs faster. Read more about how companies are implementing access strategies for products on the market in the Product Delivery sub-chapter on p.54.

FROM ACCESS PLAN TO ACCESS STRATEGY



NEXT STEPS

- Companies must invest in R&D to develop products that meet the needs of people living in LMICs. Product development is particularly important for diseases with high burdens in LMICs, especially where no treatment options are available.
  For disease areas that lack commercial incentives, companies can collaborate with access-oriented partners by contributing resources and expertise.
- Those that suffer from diseases and conditions in endemic countries should have equal access to participation in investigational trials, especially when alternative treatments are lacking or entirely unavailable. In addition, data collected from clinical research can provide insights into how treatments work in different populations and contexts, leading to more effective and tailored healthcare solutions.
  Furthermore, the correlation between the locations where companies conduct clinical trials and where they have access plans in place suggests that LMICs excluded from trials may experience delays in access post-approval or may never receive the product at all. Therefore, it is important that companies continue to work with local partners in LMICs to build trial capacity to reduce these disparities and close gaps in access.
- In addition to more equitable distribution of clinical trials, companies should ensure that a representative number of complex populations, such as pregnant and lactating people are included in clinical research (when appropriate). This would help to fill the data gap and allow patient populations that are routinely omitted from trials to make informed choices about their healthcare needs.
- Companies must plan for access in LMICs for all their pipeline projects. It is particularly important that companies apply the same principles of access planning used with access-oriented partners to their in-house R&D projects for NCDs. The disparity in the depth and breadth of access plans for communicable diseases and NCDs means that people in LMICs will lack access to the latest advancements in innovation, effectively widening the access gap.
- Access planning is necessary to ensure that companies take the needs of people in LMICs into account during the R&D stage. However, after product approval, it is crucial that companies fulfill their access planning commitments by implementing equitable access strategies in LMICs, either directly or in collaboration with licensing and manufacturing partners. For more on access strategies, and the outcomes of these strategies, please see the Product Delivery sub-chapter on p.54.

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PRODUCT

DELIVERY

CONTEXT

To ensure lifesaving products reach those who need them most, pharmaceutical companies must prioritise registration in regions with high demand. In addition, addressing local barriers to access and deploying effective access strategies can improve the supply and affordability of medicine, thereby promoting equitable healthcare access for all.

PRODUCT DELIVERY

What is the Foundation looking for?

In this chapter, the Index reports on how companies improve access to their products through various mechanisms, such as registration, pricing strategies, responsible intellectual property (IP) management, inclusive business models and product dona tions. It also assesses how companies design and measure out comes of their access strategies and modify their practices to boost access. Additionally, it explores how companies leverage their expertise and resources to overcome significant local bar riers to access, including gaps in healthcare infrastructure, supply chain inefficiencies and weak quality assurance systems.

How performance is measured

- Companies are assessed against 18 indicators across nine priority topics in the Product Delivery Technical Area. A sig nificant shift since the 2022 Index is a greater emphasis on evaluating the outcomes of companies' efforts to ensure their essential products reach patients in low- and middle-income countries (LMICs). Therefore, there have been updates and modifications within the Product Delivery Technical Area to reflect this.

For more details on the analytical framework of assessment for Product Delivery, please see p. 31-38 of the 2024 Access to Medicine Index Methodology, which you can view here.

MORE INFO ON COMPANY PERFORMANCE

- Best Practices *p.110*
- Company Report Cards *p.122*

PRODUCT DELIVERY	9 PRIORITY TOPICS	18 INDICATORS
	Equitable access strategies and outcomes	
	Intellectual property strategy	
	Quality and supply	
	Product donations	
	Health system strengthening	
	Inclusive business models	
	Licensing quality	
	Local manufacturing	
	Registration	

PORTFOLIO ANALYSIS

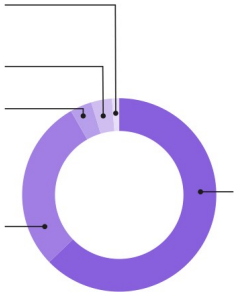
What products are included for analysis in the 2024 Index?

This section provides an overview of the products in companies' portfolios that are indicated for diseases within scope of the 2024 Access to Medicine Index and covered in the Product Delivery Technical Area. The product types and associated disease categories are summarised below.

A subset of companies' products is selected for analysis, which includes all innovative on-patent products targeting diseases in scope and off-patent products that meet specific inclusion criteria (see Appendix I on p.207).

664 products targeting a range of diseases and conditions

FIGURE 1 Disease categories of products in the companies' portfolios Most of the products in companies' portfolios in scope of the 2024 Index are indicated for non-communicable diseases (417), followed by communicable diseases (192).



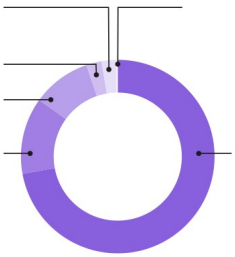
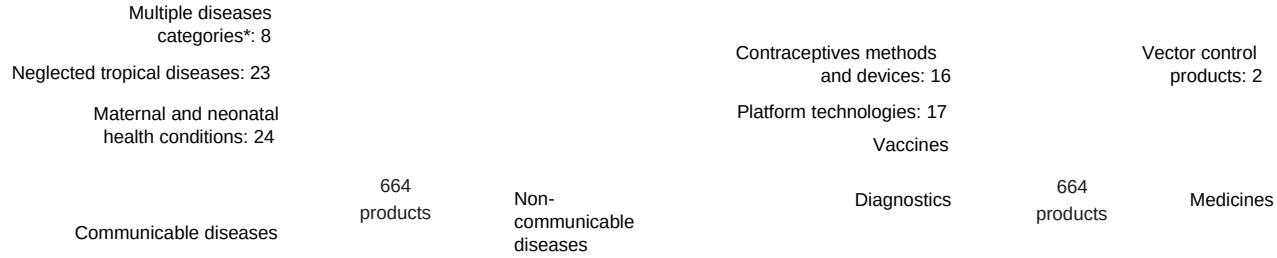


FIGURE 2 Product types in the companies' portfolios

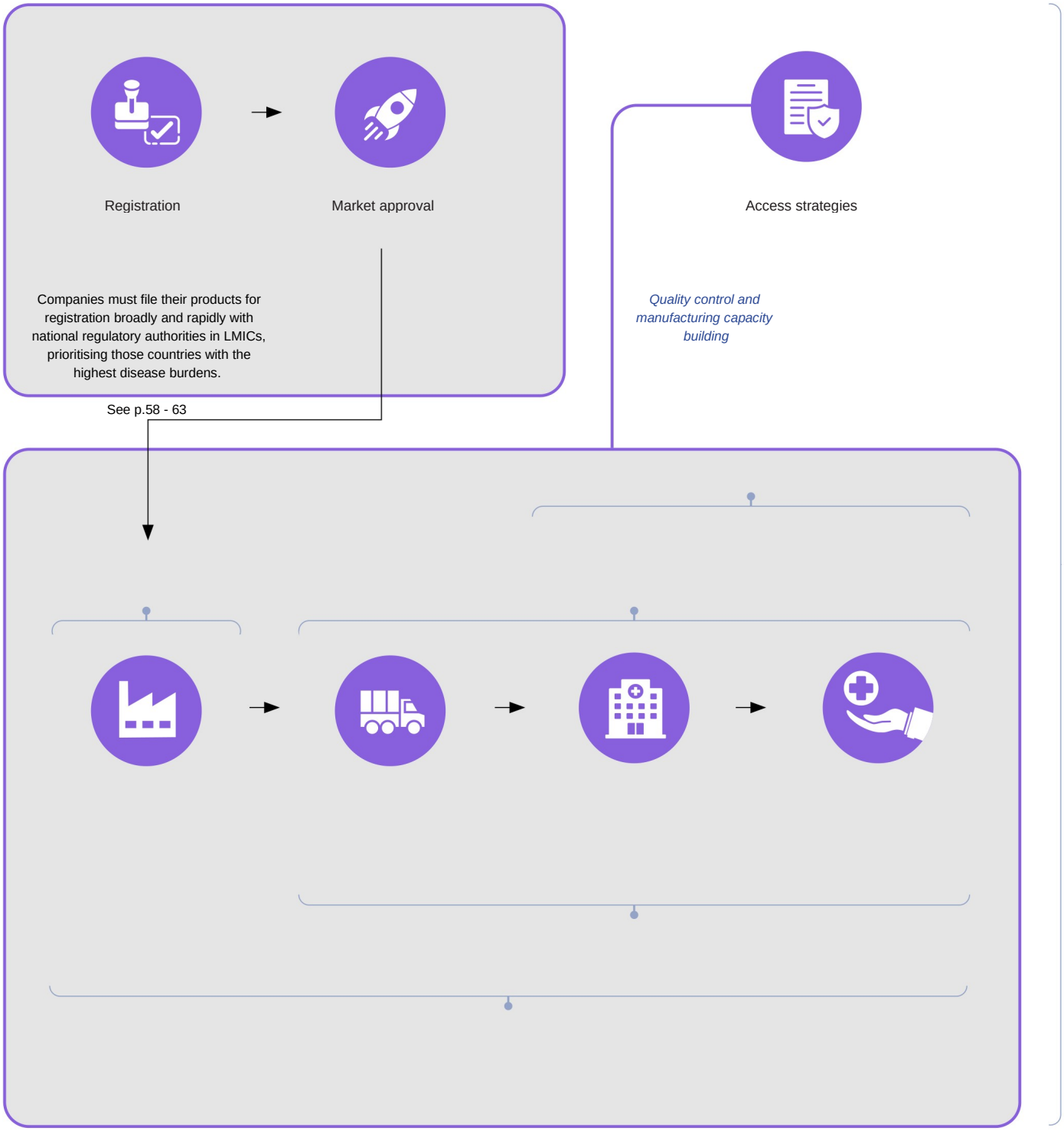
Of the 664 products in companies' portfolios, most are medicines (479), followed by diagnostics (85) and vaccines (65).



* Refers to products that are indicated for multiple diseases that fall into more than one of these disease categories. For example, broad spectrum antibiotics indicated for maternal and neonatal sepsis but also fall under the category of communicable diseases.

PRODUCT DELIVERY

This infographic sets out the main areas where pharmaceutical companies can intervene to expand access to their new and existing products. Areas assessed by the Index are specifically highlighted. It is important to note that some of these processes happen in parallel.



See p.58 - 63

Companies implement tailored strategies to ensure equitable access to their products in LMICs. These can include equitable pricing strat egies and/or additional strategies such as volun tary licensing, technology transfers and long-term donation programmes. For more information on these three topics, please see:

Long-term donations p.94 - 98
Licensing p.65 - 70
Access strategies p.71 - 84

Health system strengthening

Quality assurance – ensuring quality across the supply chain

Product is manufactured

Product moves throughout supply chain
Companies can help ensure continuous supply of their products

Product reaches hospital/ healthcare facility

Product reaches patient

Supply chain capacity building

See p.99 for assessment of companies' efforts to help strengthen supply chains in LMICs, including how they are working to support local manufacturing

Inclusive business models can cover multiple elements throughout product delivery. They aim to increase access to company products, specifically targeting neglected populations, using a comprehensive and long-term business approach. See page 85 for an overview of companies' approaches to operating inclusive business models.

PRODUCT DELIVERY – REGISTRATION

Companies are still not registering systematically across LMICs

Registration is the process by which companies attain official approval from a national regulatory authority (NRA) to market and sell their products within a country. A new pharmaceutical product must be registered and evaluated by an NRA before it can be put on the market. This 'marketing authorisation' procedure ensures that new products meet certain standards of quality, safety and efficacy, which is why registration is also a crucial component in safeguarding public health.

Although drug registration does not guarantee the availability of a product to all patients, it serves as a critical step for access to quality assured healthcare products. It is also typically a requirement for reimbursement, for example, through the public health system or private health insurance.

Registration is also particularly important for newer, innovative products, for which pharmaceutical companies are patent holders and have market exclusivity rights. This effectively means that as sole manufacturers of such a product – and in the absence of generic competition – innovative pharmaceutical companies determine which countries these products will be marketed in. As such, innovative pharmaceutical companies are the gatekeepers of access to their new products and hold a responsibility to register them as widely and quickly as possible to help ensure they are made available to the patients who need them across low- and middle-income countries (LMICs). Furthermore, these products can, for example, treat conditions or symptoms that existing ones cannot, making their availability essential to helping improve the lives of patients and reducing treatment disparities.

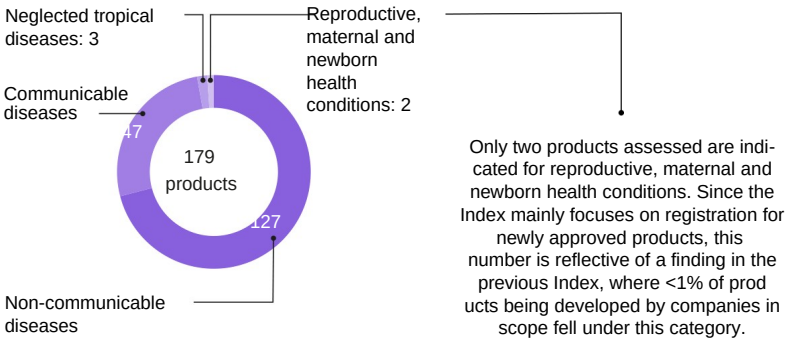
“Innovative pharmaceutical companies are the gatekeepers of access to their new products and hold a responsibility to register them as widely and

Assessing registration efforts for companies' most recently launched innovative products

To determine companies' registration efforts in LMICs, the Index assesses how widely companies have registered their most recently launched innovative products in countries within the scope of the Index. In addition, the Index also assesses the extent to which these products are registered in countries with the highest disease burdens. Aside from registering widely, it is especially important that companies consider which countries face the highest burden of disease so that they can prioritise registration for relevant products in these countries to address the most pressing, or sometimes unmet, health needs of people living here.

Based on this, 179 products were analysed collectively across the 20 companies, with the number of products selected proportionate to the size of the companies’ portfolios. As set out in Figure 1 on the next page (p.59), most of the assessed products (127/179) target non-communicable diseases (NCDs), followed by those targeting communicable diseases (47/179).

FIGURE 1 Products analysed per disease category
The breakdown of disease categories mirrors current research and development trends in the pharmaceutical industry, which are increasingly focused on non-communicable diseases (NCDs).

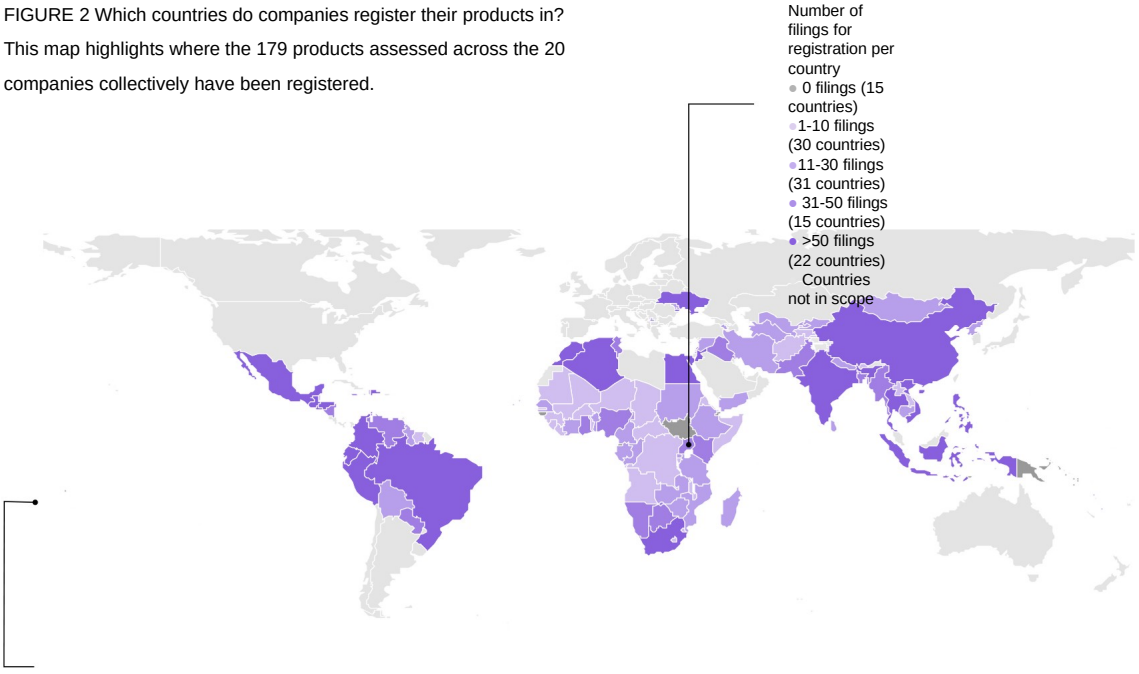


Companies demonstrate ability to register widely, however, registrations predominantly concentrated in upper middle-income countries

In many LMICs, NRAs are less resourced and often lack capacity and expertise to carry out regulatory functions. This can create a barrier for companies seeking market access, leading to delays in product registrations – ultimately inhibiting patients' timely access to quality-assured medical products. Nevertheless, there are several mechanisms currently available to companies and countries that support facilitated and accelerated registration of important medicines in LMICs, including those countries with NRAs with lower maturity. Refer to 'Companies can explore mechanisms to overcome registration challenges' on p.61. Despite some of the well-documented registration challenges present in some LMICs, the Index's analysis finds that, collectively, companies have registered products in the majority of countries in scope (98 out of 113).

While it is encouraging to see so many countries where registrations have taken place, the Index also finds that companies are still not registering systematically across all LMICs. In line with previous iterations of the Index, companies predominantly focus registration efforts in upper-middle-income countries (UMICs). The analysis also showed that low-income countries (LICs) have 11 product registrations on average, in comparison to 57 in UMICs. Considering that the number of LICs and

FIGURE 2 Which countries do companies register their products in?
This map highlights where the 179 products assessed across the 20 companies collectively have been registered.



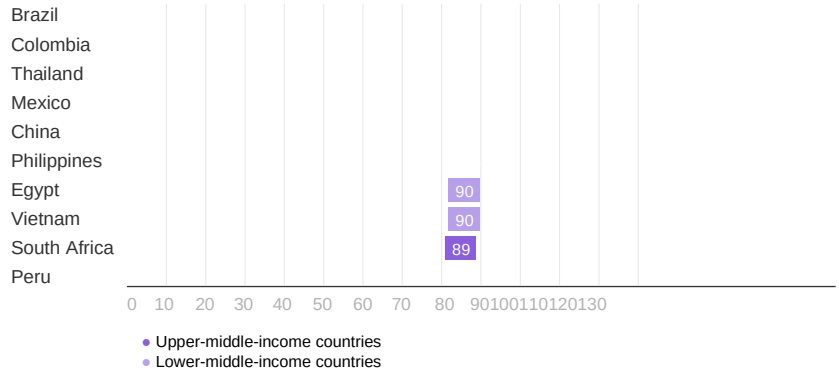
Among the 26 low-income countries, Uganda has received the most filings for registration (33), followed by Ethiopia (24), Rwanda (22) and Syrian Arab Republic (20). This remains largely unchanged from the 2022 Index.

The analysis showed that, collectively, companies have not registered any of their products assessed in 15 of the 113 countries in scope, mostly in the Pacific Islands and parts of Africa.

UMICs in scope is approximately the same, this illustrates that companies are five times more likely to register their products in a UMIC. Furthermore, seven of the ten countries with the greatest overall number of registrations are UMICs.

FIGURE 3 The 10 countries with the greatest number of product registrations

Seven of the 10 countries with the greatest overall number of registrations are UMICs. This is despite UMICs only representing 27% of countries in scope.



Bayer, Novartis and Roche outperform peers by registering their newly approved products widely in LMICs

When registering their new products, innovative pharmaceutical companies frequently prioritise high-income markets. As a result, people living in LMICs are often left waiting for access far longer than those living in high-income countries, or they miss out on new and innovative treatments entirely. Despite the challenges of registering in some LMICs, three companies – namely Bayer, Novartis and Roche – have registered their newer products* in comparatively more LMICs in scope on average than other companies, demonstrating that companies can register their new and innovative products rapidly and widely across LMICs. These three companies' registration efforts have also been highlighted as a Best Practice in the 2024 Index (see p.117).

- Bayer has two of the most widely registered new innovations. Bayer's access policy was highlighted as a Best Practice in the 2022 Index. The policy's aim is to develop quality access plans to make products available swiftly and widely in LMICs post-launch. In 2022, the access plan for vericiguat (Verquvo®), indicated for heart failure, included plans to register in 24 countries in scope. Findings from the 2024 Index show that Bayer has expanded and successfully implemented this plan, with Verquvo® now registered in 29 countries.
- Roche has four of the ten newer products* with the highest number of registrations. Roche's pertuzumab/trastuzumab (Phesgo®), indicated for breast cancer, has the highest number of registrations in countries in scope of any product approved within the last five years (see Table 1 on p.61). This demonstrates Roche's ability to register products widely and quickly in countries in scope.
- Roche and Novartis demonstrate good practice by registering their biological products widely. Biological products are more complex and variable,[1] and require different regulatory frameworks for development, manufacturing and clinical use.
  Therefore, approval by regulatory authorities is often more resource intensive and complex,[2] which can sometimes be a challenge in LMICs. For example, Roche has two innovative biologics in the ten newer products* with the highest number of registrations in countries in scope: pertuzumab, trastuzumab (Phesgo®) and polatuzumab vedotin-piiq (Polivy®) (see Table 1 on p.61).

* Products that received their first marketing authorisation within the last five years.

TABLE 1 Newer products* with the highest number of registrations in countries in scope.
This table lists products in scope approved within the past five years, that have the highest number of registrations in countries in scope. On average, Bayer, Novartis and Roche have registered their newer products in comparatively more countries in scope on average than other companies.

Company	Brand Name	International Nonproprietary Names (INN)	Indication	Year of first global regulatory approval	Number of countries in scope where the product is registered
Roche	Phesgo®	Pertuzumab, Trastuzumab	Breast cancer	2020	52
Johnson & Johnson	Johnson & Johnson COVID-19 vaccine	COVID-19 vaccine	Coronaviral diseases	2021	41
Novartis	Leqvio®	Inclisiran	Cardiovascular diseases	2020	41
Pfizer	Comirnaty®	COVID-19 mRNA vaccine	Coronaviral diseases	2021	39
Roche	Polivy®	Polatuzumab vedotin-piiq	Non-Hodgkin lymphoma (cancer)	2019	39
GSK	Tivicay PD®	Dolutegravir	HIV	2020	31
Roche	Rozlytrek®	Entrectinib	Lung cancer	2019	31
Bayer	Kerendia®	Finerenone	Kidney diseases	2021	30
Roche	VENTANA® HER2 Dual ISH	N/A	Breast cancer (diagnostic)	2020	30
Bayer	Verquvo®	Vericiguat	Cardiovascular diseases	2021	29

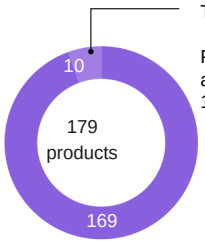
Roche extensively registers its oncology treatments and companion diagnostics, which are essential for diagnosing patients so they receive the correct treatment.

LMICs with the highest disease burdens left behind by companies' registration efforts

Despite a demonstrated ability to register in most countries in scope, almost half of products analysed (87/179) are not registered in any countries with the highest dis ease burdens.** Furthermore, registration performance varies significantly between companies, product type and the length of time since product approval.

Of the 20 companies, Roche demonstrated the widest number of registrations in countries facing significant disease burdens, on average registering its products in 30% of countries with the highest burden of disease,** compared to the overall aver age for all companies of 14%. Such low overall registration coverage of countries with high disease burdens means that products may not be available where people need them the most.

FIGURE 4 Only ten of 179 products are registered in 50% or more of countries with the highest disease burden**



Together, GSK (2), Pfizer (2) and Roche (2) account for six of these 10 products.

Companies can explore mechanisms to overcome registration challenges To overcome barriers to registration in LMICs, companies can engage in mechanisms that have been designed to streamline registration in these countries. These mechanisms and procedures aim to ensure the safety, efficacy and accelerated approval of medicines and vaccines on a global scale by promoting collaboration among regulatory authorities and in some cases are facilitated by the World Health Organization (WHO).
The Index identified three distinct categories of mechanisms to facilitate registration in LMICs that companies are engaging in:

- Collaborative regulatory pathways: Facilitated by an external regulatory authority or organisation outside the geographic area of use
- Regional joint assessment procedures (JAs): Collaborative assessments by regu latory authorities in certain geographic areas
- National reliance registration pathways: Process whereby an NRA in one country considers the assessment performed by another NRA

* Products that received their first marketing authorisation within the last five years.
** The ten countries in scope with the highest DALY rate per disease.

Mechanisms to facilitate registration

1. Collaborative regulatory pathways	2. Regional joint assessment	3. National reliance registration
• WHO Collaborative Registration Procedure for Pre-Qualified Products (WHO PQ CRP) • WHO Collaborative Registration Procedure for Stringent Regulatory Authority approved products (WHO SRA CRP) • EU-Medicines for all (EU-M4all) Swissmedic Marketing Authorisation for Global Health Products (MAGHP)	• African Regional Economic Communities (RECs) Joint Assessment Mechanisms, such as Zazibona, EAC-MRH and IGAD-JA • ASEAN NRAs Joint Assessment group (ASEAN JACG) • CARICOM Regional Assessment of Drug Registration and Regulatory Systems • Central American Mechanism for the Joint Evaluation of Medicines	• A mechanism where the National Regulatory Authority (NRA) of one country considers the assessment performed by another country's NRA. This is an individual national pathway where the NRA applies reliance or recognition to the assessment and registration con ducted by another NRA, based on its own requirements.

1 Collaborative regulatory pathways

Collaborative regulatory pathways are facilitated by an external authority/organisation (for example, WHO or a stringent regulatory authority) that support NRAs in LMICs and beyond by sharing the existing relevant product assessment reports. These pathways allow countries to leverage the expertise and resources of established regulatory bodies to accelerate the review and approval of products that have already been evaluated, avoiding duplication of regulatory work and resources required for the evaluation of the same product in other countries. The NRA maintains its national sovereignty on the final assessment outcome, remaining independent on the registration decision-making process.

2 Regional joint assessment procedures

Regional joint assessment procedures (JAs) involve regional groups of countries that come together to jointly assess and evaluate pharmaceutical products for registration. These procedures promote collaboration among neighbouring countries, with the purpose of allowing timely access to safe and effective medicines.

3 National reliance registration pathways

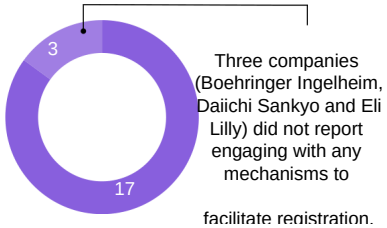
National reliance registration pathways provide a process whereby an NRA in one country considers the assessment performed by another NRA. This is an individual national pathway, whereby the NRA applies reliance or recognition to the assessment and registration conducted by another NRA, based on its own requirements. In this case, other institutions or authorities are not necessarily involved in the process.

These mechanisms can bring benefits to patients, companies and national governments through accelerating the regulatory process and potentially offering patients quicker access to quality assured, effective and safe medical products, while also reducing the burden on regulators. Engaging in these mechanisms can help to reduce approval times and improve efficiencies to register products in LMICs. For example, the EU-M4all procedure has led to 138 approvals worldwide in 90 non-EU countries based on 11 scientific opinions.[3] The WHO SRA CRP has led to more than 160 registrations in more than 50 countries.[4]

Are companies engaging in mechanisms to facilitate registration in LMICs? Seventeen of the 20 companies in scope provided evidence of engaging in mechanisms to facilitate registration in LMICs. Registration mechanisms facilitated by WHO (including WHO CRP SRA and WHO PQ CRP), were most reported, with 11 of 20 companies engaging with a WHO pathway. EU-M4all, joint assessments and national reliance registration pathways were the next most used mechanisms, with each of these pathways used by (a different set of) six companies.

Furthermore, half of the companies reported engaging in multiple mechanisms to facilitate registration in LMICs. No single mechanism was identified as the primary pathway, with companies engaging in various types of mechanisms depending on the region and/or product. It is a positive development that companies are widely utilising these various approaches, as it is important that regulatory strategies are tailored to overcome barriers to registration in LMICs.

FIGURE 5 17 of 20 companies engage in mechanisms to facilitate registration .



What are the benefits of engaging in mechanisms to facilitate registration? By using mechanisms to facilitate registration, companies can benefit from streamlined approval processes and reduced times for product registration, allowing them to broaden the number of countries in which their products are timely registered. Depending on the product and country of registration, companies can consider these pathways to navigate the challenges of registering in many LMICs.

Several companies reported reduced registration times in LMICs by engaging in mechanisms to facilitate registration. For example, Pfizer reported engaging with WHO SRA CRP to facilitate registration of several of its products in LMICs. Specifically, for its pneumococcal vaccine PREVNAR 20®(adult and paediatric), this mechanism is expected to expedite approval time in Thailand by six months compared to other available pathways. In addition, Novartis reported using regulatory reliance pathways to register products in several African countries, which resulted in significantly reduced time for regulatory approval.

Move towards regulatory harmonisation in Africa can provide opportunities for companies

In early 2024, 27 countries ratified the African Medicines Agency (AMA) treaty, with more African Union members expected to follow.[5] The establishment of the AMA aims to harmonise regulatory procedures in Africa, with the goal of improving access to safe, quality-assured medicines across the continent. This will provide an opportunity for companies to engage with an entity that will coordinate the evaluation of prioritised medical products in Africa.[6]

NEXT STEPS

Registration is a critical step to ensuring that health products meet the standards of quality, safety and efficacy as required by a regulatory authority.

Despite well-documented barriers to registering in LMICs, several companies in scope have demonstrated their ability to register their innovative products quickly in a broad range of LMICs.

- It is imperative that companies continue to include LMICs with high disease burdens in the regulatory strategy for their new products to facilitate the availability of their quality-assured products.
- Several mechanisms to facilitate and accelerate registration are available to companies and can serve as a pathway to overcome barriers to registration in LMICs, as evidenced by reduced approval times and increased number of countries where products are registered. However, the success and suitability of these pathways, is dependent on the product types and local contextual factors in the country where the product will be registered.
- Regardless of the route to regulatory approval, companies should register their new products widely in LMICs, particularly those with high disease burdens.
  However, as registration does not guarantee availability of products to all patients, it is crucial that companies implement access strategies in parallel with registering their products to maximise patient reach.

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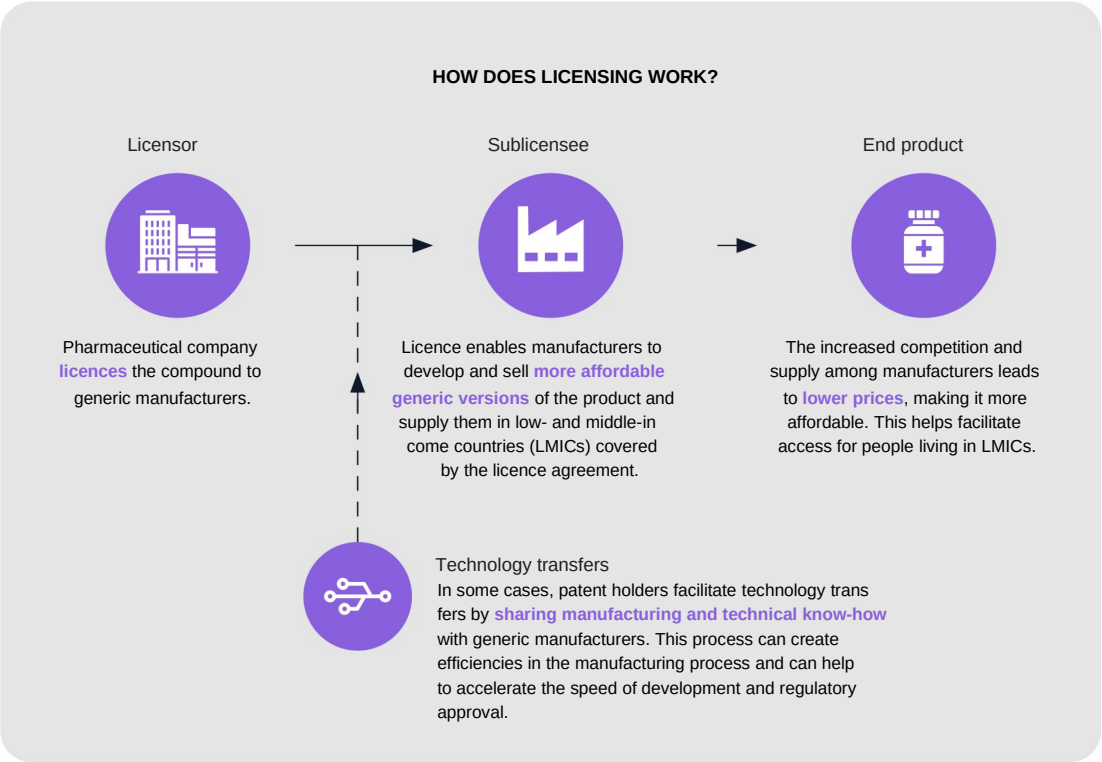
PRODUCT DELIVERY – LICENSING

Voluntary licensing as a mechanism to broaden access to patented medicines in LMICs

Voluntary licensing to generic manufacturers serves as a potential avenue for pharmaceutical companies to provide access in countries where they do not intend to commercialise their innovative products. Originator companies can improve access to their on-patent medicines by granting voluntary licences – i.e., permission to use intellectual property (IP) under specific conditions, sometimes accompanied with technology transfer – which allows generic medicine manufacturers to develop and sell more affordable generic versions of their patented products in low-and middle-income countries (LMICs).



In addition to licensing, companies can responsibly manage their IP by balancing the protection of their innovations with the need for public access to essential medical products by, for example, having overarching policies whereby they do not enforce or file for patents in certain LMICs. Although such commitments provide clarity about where patents are to be filed or enforced, it does not necessarily guarantee that quality-assured generics will enter the market in low-income countries and those with the highest burden of disease, especially if patents remain in force in

other lower-middle-income countries and upper-middle-income countries that have the capabilities to manufacture such generics.

Companies can also issue non-assert declarations, a statement where the innovator company commits to not enforce its patent rights for a specific product only, in a defined group of countries. Patent non-enforcement allows generic manufacturers to freely produce generic versions of patent-protected products, without the risk of infringing on the patent. However, unlike licensing, there is no contract in place with terms and conditions that are conducive to equitable access in LMICs. One such example of patent non-enforcement was identified by the Index during the current period of analysis:

XIn September 2023, Johnson & Johnson announced its intent to no longer enforce patents on bedaquiline (SIRTURO®), in 134 LMICs.

Bedaquiline is a critical component in the treatment regimen for multidrug-resistant tuberculosis (MDR-TB), with three out of every four MDR-TB patients undergoing treatment using a regimen that includes bedaquiline.[1]

The announcement from Johnson & Johnson covers all patents related to bedaquiline in 134 LMICs. Although the primary patent for the active ingredient, bedaquiline, expired prior to the announcement, secondary patents—i.e. those covering other aspects related to the product such as specific formulations and production methods[2]*—remained in existence in many countries. Secondary patents are often used to extend market exclusivity of a product, which effectively prevents generic companies from entering the markets.*[2] *The announcement followed proceedings in India regarding the validity of secondary patents for the drug*[3] *and allows generic manufacturers to manufacture and/or supply generic versions of bedaquiline in countries where secondary patents are still in existence.*

Urgent need for access to treatment for multidrug-resistant tuberculosis[5]

Multidrug-resistant tuberculosis (MDR-TB) is described as a public health crisis by the World Health Organization.

An estimated 400,000 people were diagnosed with MDR-TB in 2022.

Only 2 in 5 of those diagnosed had access to the right treatment.

Non-exclusive voluntary licences can widen impact

Licensing agreements differ from non-assert declarations in that they are formal agreements between the patent holder (innovative pharmaceutical company) and the licensee (generic manufacturer). In some cases, the patent holder may collect royalties from the sale of the generic medicines in LMICs. Furthermore, the licence may contain provisions for a technology transfer, where patent holders share know-how and expertise about a product and its manufacturing processes with generic manufacturers. This process can create efficiencies in the manufacturing process and can help to accelerate the speed of development, expediating access to critical products in LMICs. It is particularly useful for products that are more complex to manufacture, such as biologicals and injectables.

The licence is deemed a non-exclusive voluntary licence (NEVL), when it allows the licensor (patent holder) to provide the licence to more than one manufacturer, and hence the licensee (generic manufacturer) does not have exclusivity in the licence territory and field of use. The most impactful NEVLs are publicly available and agreed prior to, or shortly after, approval of the originator product. Furthermore, the licence should be free of terms that may restrict access and include a wide range of countries to maximise the reach of the licensed product to patients. In addition to building local manufacturing capacity, NEVLs are a proven mechanism to improve the availability and affordability of lifesaving medicines that would otherwise not be accessible to people living in LMICs.[4]

Industry stagnates on voluntary licensing agreements, with only two new NEVLs during the period of analysis

The 2024 Index finds that nine of the 20 companies in scope currently have NEVL agreements in place, namely, AbbVie, AstraZeneca, Bristol Myers Squibb, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc. (MSD), Novartis and Pfizer. Gilead has more NEVL agreements (11) than any other companies, followed by GSK (5). In total,

there are NEVL agreements for 27 compounds, most of which are indicated for HIV. Of the 27 licences, only two were issued during the current period of analysis, both of which were facilitated by the Medicines Patent Pool (MPP). Although both licences were announced outside the period of analysis for the 2022 Index, both were highlighted in the report due to their significance within the realm of voluntary licensing. These licences are included in the 2024 Index assessment and account for the only two new NEVLs issued from companies in scope during the period of analysis.

X*In July 2022, ViiV Healthcare (a company majority owned by GSK) granted a NEVL for cabotegravir long-acting (CAB-LA) for HIV pre-exposure prophylaxis (PrEP), marking the first NEVL for a long-acting injectable for HIV prevention. The licence was agreed seven months after FDA approval and covers 88 countries in scope, including all low-income countries, all least developed countries and all sub-Saharan African countries. It contains an important clause that allows supply "outside the scope of the patent rights," meaning that generic manufacturers may also supply the product in countries where CAB-LA is not patented, even if the country is not explicitly included in the licence. It has been estimated that at least 28 additional countries outside the licence territory will benefit from this clause.*[6]

X*In October 2022, Novartis issued a licence for nilotinib, indicated for chronic myeloid leukaemia. While the licence was agreed shortly before the expiration of the primary patent and covers only 43 countries in scope, it was the first licence of its kind for a non-communicable disease (NCD). Despite the expiration of the primary patents, the collaboration between generic companies and the MPP, a public health organisation, helped to ensure access is still accelerated.*

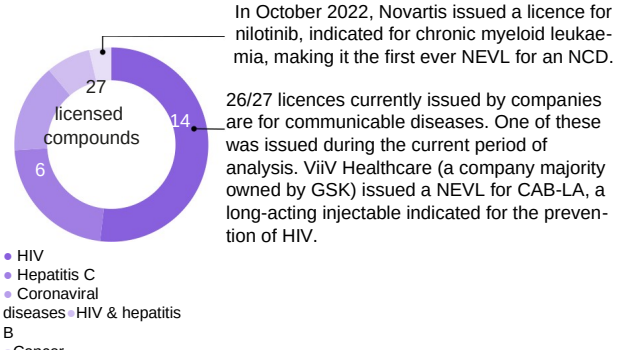
Since 2022, the CAB-LA licence has been issued to three sublicensees and the nilotinib licence has been issued to four sublicensees. CAB-LA is a more complex product, so the process of developing the product and obtaining approval for generics will take time. It is estimated that the first regulatory filings from generic manufacturers could be in late 2026, with potential registration estimated for 2027.[7]

Gilead announces NEVLs for generic lenacapavir

In October 2024, after the period of analysis concluded, Gilead announced non-exclusive voluntary licensing agreements (NEVLs) with six generic manufacturers to make and sell generic lenacapavir. The licence covers lenacapavir for HIV prevention (subject to required regulatory approvals), and for HIV treatment in heavily treatment-experienced adults with multidrug-resistant HIV. The licence covers 120 countries, including 96 countries in scope of the Index.

FIGURE 1 Licensing is mostly used for compounds targeting infectious diseases

HIV and hepatitis B and C voluntary licences account for 22 of 27 licences. However, treatment for these diseases is predominantly fixed-dose combinations of multiple licensed compounds. For example, Gilead's product Biktarvy®, indicated for HIV, is a combination of bictegravir, emtricitabine and tenofovir alafenamide, which all have separate licences.



MPP can help companies facilitate NEVLs

As demonstrated by the new voluntary licensing agreements issued by GSK's ViiV Healthcare and Novartis, the MPP can play a central role in helping companies facilitate NEVLs. The UN-backed public health organisation negotiates licence terms with patent holders and sub-licenses to generic manufacturers in the interest of increasing access to medicines and improving health outcomes in LMICs.[8] Licences agreed through the MPP are more transparent, include terms and conditions that may improve access, and offer additional benefits, such as facilitating the selection of the most suitable generic manufacturers. This provides significant advantages from a public health perspective, compared to licences that companies may negotiate directly with generic manufacturers.[8]

In 2024, the MPP published a Prioritisation Report of medicines for in-licensing, which includes:

- *A 'priority list', where voluntary licensing would lead to a substantial public health benefit. The list includes medicines for several disease areas, including infectious diseases (such as HIV and TB) and NCDs, such as oncology and diabetes. It also includes several biologic medicines and long-acting injectable formulations. The list is updated on a rolling basis and at the time of publication, it contained 13 specifically-named products, ten of which are patented by the companies ana lysed in the Index (see Table 1 below).*[9]
- *A 'watch list' of products, where licensing could provide significant health bene fits, but additional data and/or assessment is required before these products can be deemed a priority.*

TABLE 1 Medicines Patent Pool priority products made by companies analysed in the Index

The list below highlights the priority products listed by the Medicines Patent Pool (MPP) that are patented by the companies in scope. Licensing these medicines is a feasible option for companies and the result would be impactful for people living in LMICs.

Patent holder	MPP priority	Disease indication
AstraZeneca	osimertinib	Lung cancer
AstraZeneca/ Sanofi	nirsevimab	Respiratory Syncytial Virus (RSV)
Eli Lilly	abemaciclib	Breast cancer
Gilead*	lenacapavir	HIV
Johnson & Johnson	ibrutinib	Chronic Lymphocytic Leukaemia
MSD	pembrolizumab	Multiple cancer indications
Novartis	ribociclib	Breast cancer
Novo Nordisk	semaglutide	Diabetes
Roche	baloxavir marboxil	Pandemic and epidemic threats (influenza)
Roche	trastuzumab SQ	Breast cancer

* Gilead announced NEVL agreements for lenacapavir after the period of analysis concluded.

Voluntary licensing focuses primarily on communicable diseases, despite an urgent need for NCD treatments in LMICs

Given that the companies analysed by the Index are the patent holders of many priority products, as set out in Table 1 on the previous page, there is significant scope for them to engage in more licensing agreements to make an impact on expanding access to these products in LMICs. However, to date, companies' licensing agreements – whether issued to the MPP or otherwise – most commonly cover compounds targeting infectious diseases, with 26 of 27 licences in place for communicable diseases (also see Figure 1 on p.67). And while voluntary licensing has proven to be a successful mechanism for increasing access to affordable, lifesaving medicines to treat infectious diseases, such as HIV and hepatitis C, it continues to be severely underutilised in other therapeutic areas, specifically NCDs.

NCDs are the number one cause of death and disability worldwide, with three-quarters of these deaths occurring in LMICs.[10,11] Notably, many of the priority products listed by the MPP are indicated for NCDs, such as cancer and diabetes, for which companies in scope hold the patents. Applying the licensing model to these products has the potential to improve access to vital medicines, improve quality of life and save lives globally.

For this reason, the 2022 Index highlighted Novartis' NEVL for nilotinib, indicated for chronic myeloid leukaemia, as a pivotal development. The issuing of this licence marked the first NEVL for an NCD and was a promising sign for future expansion of access to innovative medicines in LMICs. Despite occurring towards the end of its patent life, it represented a turning point in the discussion around the feasibility of licensing for new therapeutic areas. Specifically, Novartis' licence signalled an opportunity for other companies to follow suit and engage in voluntary licensing for NCD products in their portfolios.

However, despite this cautious optimism in the face of growing burdens of NCDs in LMICs, there have been no additional NEVLs for NCD products issued since Novartis issued the licence for nilotinib in October 2022. In October 2024, after the period of analysis concluded, Gilead announced a licence for lenacapavir, indicated for HIV treatment and prevention (subject to regulatory approval), marking the first NEVL issued in almost two years. However, there has been no movement from other companies on licensing for priority products, signifying a missed opportunity to facilitate access to innovative medicines that address healthcare needs of people living in LMICs.

Licensing presents an opportunity for companies, while also benefitting the lives of people in LMICs

As the patent holders for lifesaving medicines, pharmaceutical companies hold the key to unlock the potential benefits of voluntary licensing in new therapeutic areas. Failure to provide access to their lifesaving innovations means that gaps in access will continue to widen, and by consequence, undermine patient health outcomes.

Licensing has the potential to advance global health equity while being economically viable for pharmaceutical companies. Not only can companies receive the payment of royalties for the licences they issue, but doing so can help them to achieve targets within their corporate social responsibility remit, such as patient reach. Moreover, if an innovator company does not intend to launch a product in LMICs, the licensing model poses minimal risks while achieving a broader societal benefit. As highlighted by a report from MPP, in addition to the broad societal benefit licensing can provide, it can also provide value for companies. Voluntary licensing can, for example, increase revenues for both innovator and generic companies by enabling them to tap into underserved markets in LMICs.[12] For companies seeking to build their sustainable business profiles, pursuing the licensing mechanism serves as a compelling case for improving access to their products and demonstrating a commitment to fulfilling their role in reducing global health disparities.[8]

The disproportionate burden of NCDs in LMICs

7.2 billion people affected globally[13]

5.7 billion of those affected live in LMICs[13]

NCDs are the number one cause of death and disability worldwide, with three-quarters of these deaths occurring in LMICs.[10]

NEXT STEPS

Licensing is a particularly important mechanism for companies to provide access in countries where they do not intend to commercialise their products. Failure to license priority products means that they will remain inaccessible to most of the world's population, thus perpetuating the cycle of inequitable access.

- As a first step, it is imperative that pharmaceutical companies prioritise licensing within their strategies, focusing on the essential products that are needed in LMICs.
- Companies can use MPP's priority list as a guide for identifying products for which licensing would have the biggest public health impact.
- Alternatively, companies can also choose to engage in licensing for products outside of the MPP framework. To have the most impact, these licences should be transparent and free from terms that unnecessarily restrict access, while including multiple countries with the highest unmet healthcare needs.
- Licences should be accompanied by a long-term commitment for licensee management, coordination and support functions to ensure the licence results in the generic medicines reaching those that require them the most.
- Given the significant need for NCD treatments in LMICs, companies can focus on working towards licensing these products in their portfolios and should consider collaborating with MPP to facilitate this.

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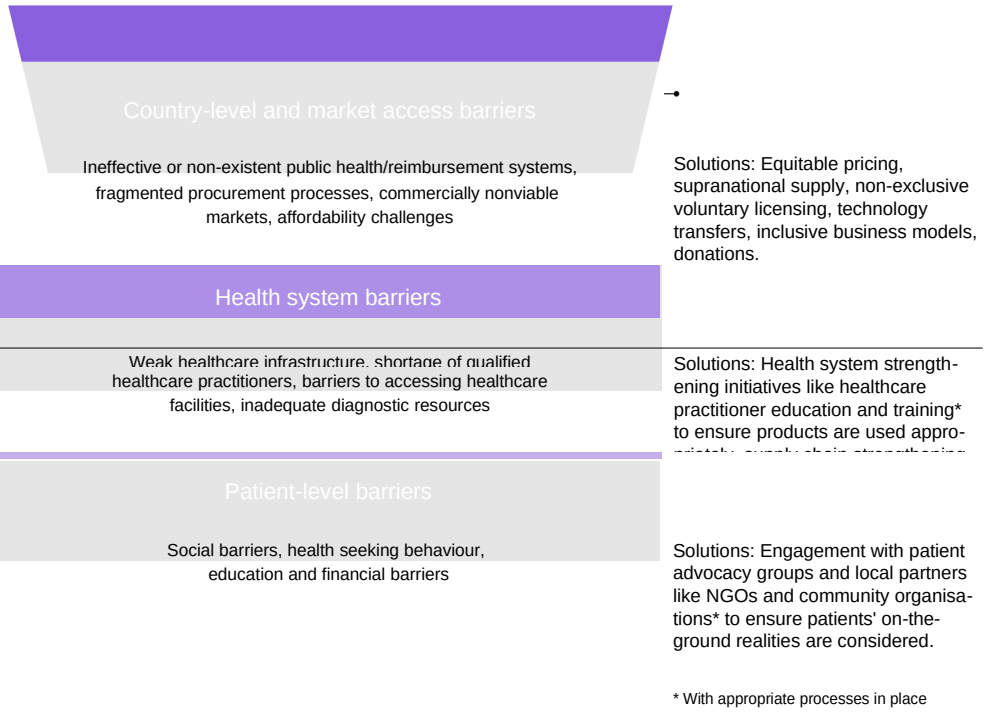
ACCESS STRATEGIES

Assessing companies' strategies for ensuring products reach patients in LMICs

Barriers to access in low- and middle-income countries (LMICs) are complex and vary across countries. To overcome these, pharmaceutical companies and a broad range of stakeholders, including policymakers, governments and global health organisations, can work collaboratively to develop tailored, sustainable solutions aimed at navigating some of the complexities faced in LMICs. However, as patent holders and manufacturers of innovative healthcare products, pharmaceutical companies play a key role in addressing gaps in access in LMICs through the 'access strategies' they can implement.

What is an access strategy?
An access strategy is the approach a company takes to ensure its marketed product reaches patients to improve treatment outcomes. The strategy should be tailored for each product to overcome the specific barriers within a country, and to ensure the product reaches the broadest number of eligible patients. An access strategy should include equitable pricing, which takes the 'payer's ability to pay' (for example, patients and procurers in LMICs) into account. It may also include alternative mechanisms to increase accessibility to products, such as voluntary licensing or donations (also see p.65 and p.94 of this sub-chapter). In LMICs, companies can complement their access strategies with additional approaches, such as health system strengthening to optimise the use of their products, improve the local healthcare ecosystem and build sustainable change for patients (also see p.99 of this sub-chapter).

FIGURE 1 Companies implement access strategies to overcome access barriers in LMICs
Barriers to access are complex and occur at every level, from systematic to personal barriers.
Since these barriers vary by product and country, tailored access strategies can provide solutions to address these barriers effectively at all levels, to ensure products meet patients.



to prevent conflict of interest.

How does the Index evaluate access strategies?

A nuanced approach for each product type is required to ensure patient access, taking the relevant barriers into consideration. For this reason, the Index assesses companies' access strategies and the impact of such strategies, distinguishing between:

1 SUPRANATIONAL ACCESS STRATEGIES

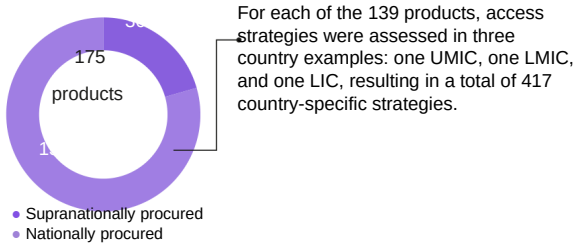
Products that are supplied through supranational procurement agencies, for example vaccines and anti-retroviral medicines for HIV.

2 NATIONAL ACCESS STRATEGIES

Products supplied bilaterally to a country in scope. National access strategies should be tailored to address access barriers in each country, including affordability. To evaluate how pharmaceutical companies are adapting their strategies to address challenges in countries with varying socioeconomic statuses, the Index assesses the quality and outcomes of strategies in three countries with different country income classifications: upper-middle-income countries (UMICs), lower-middle-income countries (LMICs) and low-income countries (LICs).*

Across the 20 companies, the Index analysed company access strategies for 175 products (36 supranationally and 139 nationally procured). Of these, 90 are listed on the World Health Organization (WHO) Model List of Essential Medicines (EML).

FIGURE 2 The Index assessed access strategies for a total of 175 products



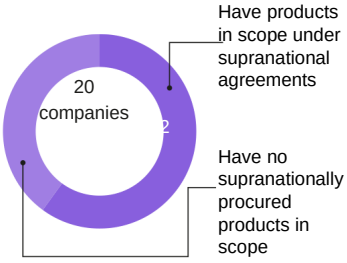
1 SUPRANATIONAL ACCESS STRATEGIES:

12 COMPANIES ENGAGE IN PROCUREMENT FOR SOME PRODUCTS

Supranational or pooled procurement mechanisms are agreements whereby an international organisation leverages its purchasing power by buying large volumes of health products for lower prices to supply in multiple countries. Such agreements are crucial for providing access to lifesaving healthcare products in LMICs, where health budgets and the buying power of individual countries are often constrained. Additionally, these agreements are mutually beneficial to all parties; they balance the interests of pharmaceutical companies by facilitating market access and generating revenue, while providing people in LMICs with access to more affordable lifesaving healthcare products. The 2024 Index identified 12 companies that engage in supranational agreements to supply a total of 36 products in scope (see Figures 3 and 4).

FIGURE 3 Which companies supply their products supranationally?

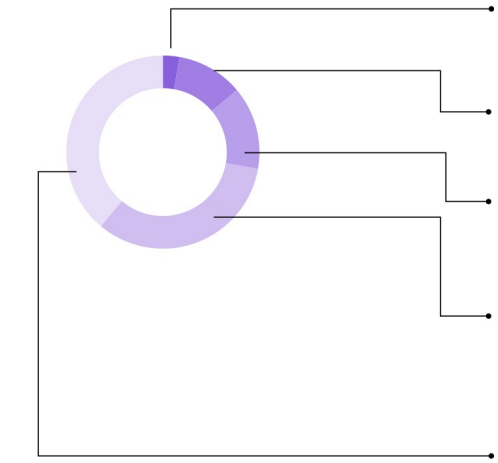
12 of the 20 companies in scope supply a total of 36 products through supranational mechanisms during the period of analysis, including AbbVie, AstraZeneca, Bayer, Boehringer Ingelheim, GSK, Johnson & Johnson, Merck & Co., Inc (MSD), Novartis, Pfizer, Roche and Sanofi.

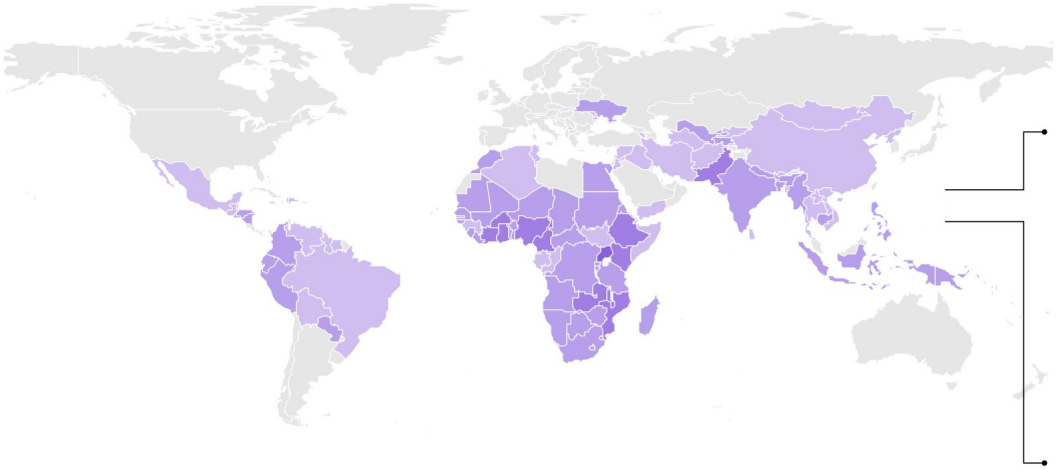


* The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income group classification. Likewise, the terms LIC and UMIC refer to low-income-countries and upper-middle-income countries.

FIGURE 4 Overview of the product types in scope that are procured supranationally

Supranational agreements mostly cover vaccines, medicines and diagnostics for communicable diseases that have been established as global health priorities, such as HIV (8), malaria (3) and tuberculosis (TB) (3), as well as reproductive health devices. No supranationally procured products** for non-communicable diseases (NCDs) were analysed.

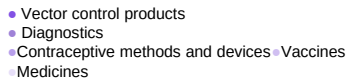




Boehringer Ingelheim supplies the veterinary rabies vaccine Rabisin® through the Pan Ameri can Health Organization (PAHO).

36
products

Roche supplies diagnostics for HIV (3) and HPV (1) to several procurers through its Global Access Programme.



Bayer (3) and Pfizer (2) supply contraceptive methods through different supranational

procurers, including the United Nations

Population Fund (UNFPA).

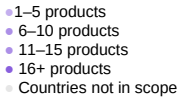
Six companies—AstraZeneca, GSK, Johnson & Johnson, MSD, Pfizer and Sanofi—supply vaccines for several indications through supra national procurers, including Gavi, the Vaccine Alliance.

Nine companies supply different medicines through supranational mechanisms, all of which target communicable diseases such as HIV, malaria and TB.

FIGURE 5 Countries within scope that receive products via supranational procurement channels All countries in scope – apart from the Marshall Islands – have received at least one product from companies assessed in the Index through supranational suppliers during the period of analysis. A large part of this coverage is due to Pfizer and AstraZeneca's COVID-19 vaccines. The countries receiving the highest number of products are in sub-Saharan Africa, with Uganda receiving the most (16), followed by Mozambique (14), Ethiopia (13), and Côte d'Ivoire (13).

Pfizer is a leading supplier in terms of the number of countries it serves through supranational agreements. Its long-acting contraceptive, Sayana Press®, is supplied in 90 countries, including all 26 LICs. This is followed by its COVID-19 vaccine, Comirnaty® (85 countries), and its 13-valent pneumococcal vaccine, Prevnar 13® (51 countries).

AstraZeneca's COVID-19 vaccine, Vaxzevria®***, is the second-most widely supplied product, reaching 88 countries through COVAX.



Companies in scope supply their products through several different procurers, including the United Nations Population Fund (UNFPA), the Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund) and Gavi, the Vaccine Alliance (Gavi). Of the products assessed, 44% (16/36) are supplied through Gavi, a global health public-private partnership that increases access to immunisation in LMICs.

** Three products target HPV (a communicable disease), and, in turn, prevent cervical cancer (an NCD).

*** In May 2024, AstraZeneca announced that Vaxzevria® would be withdrawn from the market.

Companies supplying products supranationally to address the needs of patients in LMICs

Listed below are some examples of how companies are addressing access needs for specific populations and diseases by supplying products through supranational procurement mechanisms.

HPV vaccines and diagnostics for cervical cancer

Companies: GSK, MSD, Roche

Human papillomavirus (HPV) is the primary cause of cervical cancer, with 90% of cases occurring in LMICs. Cervical cancer is highly preventable and curable, provided people have access to HPV vaccination and/or diagnostics. Although global coverage of vaccination has risen significantly to 27% in 2022, it is still far below the 90% target by 2030 set in the Global Strategy for cervical cancer elimination.[1] Global supply of HPV vaccines now meets demand, having previously been constrained.[2] X*MSD is on track to supply 115 million dosesof its quadrivalent vaccine (Gardasil®4) to Gavi from 2021 to 2025.*[3] *The product protects against four HPV serotypes and, since 2022, has been licensed and pre-qualified for storage out side a refrigerator for up to four days, making it easier to distribute to harder-to-reach populations.*[4]

X*GSK has a five-year contract with Gavi (from 2021 to 2025) to supply its biva lent HPV vaccine (Cervarix®), which protects against two serotypes of HPV. The company has expanded its supply to Gavi-supported countries, extending pro grammes to additional countries such as Bangladesh, Cambodia and Togo during the period of analysis.*

X*Roche supplies its HPV diagnostic Cobas® HPV Test (4800/5800/6800/8800) through its Global Access Programme (GAP), which offers a standardised price for specific resource-limited settings. Roche has supplied its diagnostic in 35 countries in scope through its GAP as well as an additional 14 LMICs in scope outside this programme, as reported in the Best Practice on p.119.*

Pneumococcal conjugate vaccines (PCV)

Companies: GSK, Pfizer

Pneumococcal disease, caused by the bacteria *Streptococcus pneumoniae (S. pneumoniae)*, is the leading cause of death by an infectious disease in children under five in LMICs. The bacteria also causes other infections, such as meningitis and sepsis, which can be deadly or lead to permanent disabilities.[5] Vaccination is one of the most effective interventions to prevent death and disability and has contributed to an estimated 57% decline in paediatric deaths from pneumococcal diseases since 2000.[6] However, there is wide variation in vaccination coverage in different regions, with immunisation at just 26% in the Western Pacific Region.[1] Two companies in scope have supplied PCV through supranational procurement:

X*GSK has committed to supplying 35 million doses of its 10-valent PCV (Synflorix®) every year from 2022 to 2028. Accounting for a recommended four-dose vaccination schedule, this equates to complete vaccination schedules for 8.75 million patients annually. In 2023, it exceeded this commitment and supplied 43 million doses in seven Gavi-eligible countries. Furthermore, it supplied its vaccine in an additional 25 countries in scope outside the Gavi agreement.*

X*Pfizer is the largest supplier of PCV; it supplies its 13-valent PCV (Prevnar 13®) through multiple procurement mechanisms including Gavi/UNICEF, through which it immunised 55 million children on a four-dose vaccination schedule from June 2022 to March 2024. During the period of analysis, it supplied Prevnar 13® in a total of 100 countries within scope, with 51 of these countries receiving the vaccine through supranational procurement mechanisms and 84† receiving the product through national access strategies.*

† 35 of these countries also received supply through supranational procurers.

Vaccine and treatments for malaria

Companies: GSK, Novartis, Sanofi

Significant gains have been made in combating malaria over the last few decades. However, in 2022, malaria cases were 249 million in 85 endemic countries, an increase of five million cases compared to the previous year. Globally, malaria claimed 608,000 lives in 2022.[7]

- *In 2022,* GSK *entered into an agreement with UNICEF, Gavi's procurement agent, to supply its malaria vaccine RTS,S/AS01 (Mosquirix®), indicated for children aged six weeks to 17 months. GSK has committed to supply 18 million doses between 2023 and 2025. Twelve African countries with the highest need have been pri oritised for the allocation of the vaccines, as the available supply falls short of the number of doses required.*[8] *During the period of analysis, GSK supplied more than two million doses as part of this agreement, supporting the immunisation programmes in Cameroon and Burkina Faso. More countries are expected to introduce the vaccine during 2024. GSK has also initiated a technology transfer to Bharat Biotech Limited India (BBIL), which will become the exclusive supplier by no later than 2029.*
- *Novartis and Sanofi both supply antimalarial products through supranational procurers, including the Global Fund to fight Aids, Tuberculosis and Malaria (The Global Fund). In parallel to their supranational supply efforts, both companies report reaching patients through their respective initiatives: the Novartis sub-Saharan Africa (SSA) business model and the Sanofi Global Health Unit (GHU). For example, in 2022 and 2023, Novartis supplied almost more than 900,000 packs of artemether/lumefantrine (Coartem®) in 13 countries through the Global Fund.Furthermore, it reached 15.6 million patients in 26 countries through the SSA business model in the same period. Sanofi reported reaching 9.8 million patients with its antimalarial artesunate/amodiaquine (ASAQ Winthrop®) through various supranational procurers and supplied the product in five addi tional countries through its GHU during the period of analysis.*

WHAT'S NEXT FOR SUPRANATIONALLY PROCURED PRODUCTS? As highlighted in the above findings, public-private collaborations between pharmaceutical companies and supranational procurement organisations have resulted in great strides being made in the fight against public health threats in LMICs. However, concerted efforts are still required by companies to ensure the supply of products meets the demand.

Pharmaceutical companies play a crucial role in helping to achieve ambitious global goals to control and/or eliminate diseases like HPV and malaria. Supranational procurement mechanisms offer a solution to enable supply of these products, particularly in low-resource settings where public health needs are high, but demand is fragmented. In addition to continuing to supply existing products through supranational procurers, companies can work together with procurers to ensure newer innovations reach those that need them most. For example:

- *Pfizer's maternal RSV vaccine (Abryvso®) and AstraZeneca/Sanofi's mono clonal antibody nirsevimab (Beyfortus®): Until recently, there were no effective products to prevent Respiratory Syncytial Virus (RSV), a lower respiratory tract infection that is a major cause of hospitalisation in infants, with more than 95% of RSV-related deaths occurring in LMICs.*[9] *Prevention can be achieved through the immunisation of infants or pregnant individuals. Pfizer's maternal RSV vac cine is now recommended during pregnancy, while AstraZeneca/Sanofi's mono clonal antibody nirsevimab, is advised for infants under eight months in national immunisation guidelines in several high-income countries.*[10] *Gavi is currently eval uating RSV immunisation for potential future investment but has not yet included it in its active portfolio.*

"In 2022, malaria cases were 249 million in 85 endemic countries, an increase of five million cases compared to the

- *Takeda's dengue vaccine (Qdenga®): In 2023, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) endorsed the use of Takeda's dengue vaccine in children aged six to 16 years in areas with high dengue transmission, and the vaccine was prequalified by WHO in 2024.*[11,12] *Gavi has also expanded its portfolio to include dengue fever in its Vaccine Investment Strategy (VIS) for 2026 to 2030, indicating future opportunities for expanded access through supranational procurement.*[13] *Although the vaccine has yet to be supplied through supranational mechanisms, Takeda has implemented a comprehensive access strategy to supply the vaccine in Brazil, which has been facing an unprecedented burden of dengue recently.*[14] *Additionally, in February 2024, it announced a strategic partnership with Biological E. Limited in India to increase production capacity to meet the expected demand and accelerate supply in endemic countries.*[15]

Most companies in scope of the Index are focusing their efforts on developing and marketing products for non-communicable diseases (NCDs). With the growing burden of NCDs in LMICs, pooled procurement mechanisms – which have traditionally been used to supply products for communicable diseases – can be considered as an avenue to expand access to NCD products. In doing so, companies can help address the pressing need for a system that enables countries, particularly those with limited resources, to procure affordable products for a wider range of diseases, while also ensuring the quality of their supplies.

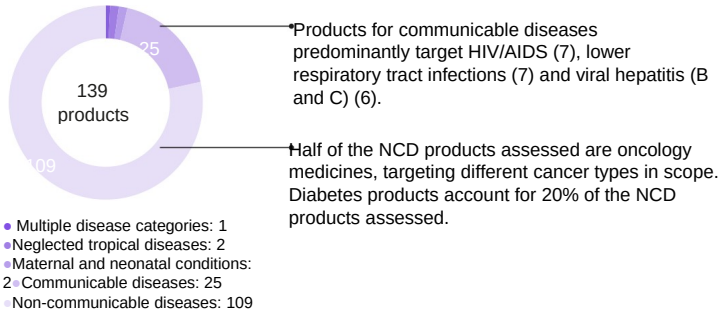
In addition to access strategies through supranational procurement mechanisms, companies can also supply products directly to countries through bilateral agreements with national procurers. Equitable 'national access strategies' are particularly important for countries that are not eligible for procurement from supranational organisations and for products that are not supplied through these mechanisms.

2 NATIONAL ACCESS STRATEGIES:

HOW ARE COMPANIES SUPPLYING PRODUCTS IN LMICs?

Companies typically supply their products directly to countries through national access strategies. The Index assessed national access strategies for 139 products across 20 companies in scope. Products were selected for assessment based on several criteria, including patent status (i.e., whether the company has market exclusivity), clinical relevance and WHO EML status. The evaluation covered country examples of access strategies in three income classifications: UMICs, LMICs, and LICs—as defined by the World Bank.‡

FIGURE 6 Products selected for assessment encompass all disease categories in scope
The Index assessed national access strategies for 139 products, across three country income classifications. While these products cover all disease categories within scope, there is a strong focus on NCDs. This aligns with company portfolios, where most products target NCDs, particularly cancer.



In which countries are companies supplying their products via national access strategies?

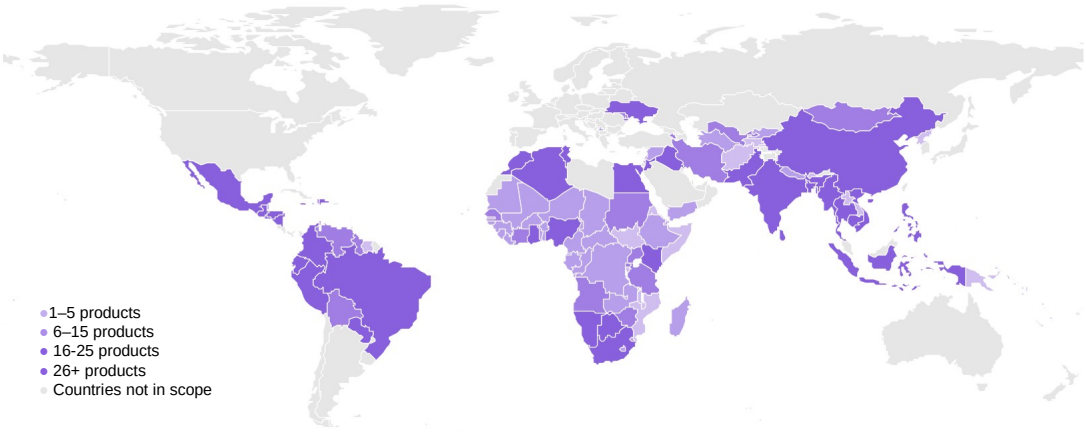
The barriers to supplying medicines in low-resource settings are well documented and, as expected, the products assessed are predominantly supplied in UMICs (see Figure 7 on the next page), countries which tend to have more developed procurement and reimbursement systems for healthcare products. However, despite some of the more challenging barriers often faced in LMICs and LICs, several companies outperform their peers in terms of the average number of countries (in scope of the Index) in which they supply their products.

- *GSK, Novo Nordisk, Roche and Sanofi supply their products in more countries on average compared with peers. Novo Nordisk supplies its products (5) in an average of 48 countries, with its human insulins, Actrapid® and Mixtard®, most widely supplied in 58 countries, while its analogue insulin, Tresiba®, is supplied in 30 countries. Roche supplies its products (9) in 41 countries in scope on average. Notably, it supplies both its monoclonal antibodies rituximab (MabThera®) and trastuzumab/hyaluronidase-oysk (Herceptin Hylecta™) in a total of 64 countries in scope. In this year's Index, Roche was selected for a Best Practice (see p.119) for registering its innovative products in a broad number of LMICs (average of 30 countries across six innovative products assessed). The finding that Roche both registers and supplies the widest number of LMICs of any company in scope indicates that it is managing to supply its products broadly despite barriers and fewer commercial incentives in many LMICs.*
- *Bayer, Bristol Myers Squibb, GSK, Merck, Novo Nordisk, Roche and Sanofi out-perform peers in terms of supplying their products in LICs. Aside from supply in LICs facilitated through voluntary licensing agreements, Merck and Sanofi have the highest coverage in LICs, with both supplying two of their products assessed in more than ten LICs. It is important to note that these products are in the later stages of their product life cycle, rather than newer medicines that have been recently launched on the market. Sanofi is the only company in scope that supplies all products analysed (9) in at least one LIC.*

‡ For more details on how the Index assesses companies' access strategies, including disease, country and product type scope, refer to the 2024 Access to Medicine Index Methodology.

FIGURE 7 Countries where companies supply their products via national access strategies

The map provides an overview of where companies are making their products available across 113 countries in scope.



What strategies are companies implementing to increase access to their products in different countries?

In addition to assessing where companies supply their products, the Index does a more in-depth analysis of companies' national access strategies, using proxy countries from three different country income classifications. To ensure equitable access to their products, and reduce health disparities, companies can go beyond commercial strategies and tackle the systematic barriers to access at different levels.

The Index evaluated the quality of access strategies using a range of parameters to determine if and how companies are addressing barriers to access at different levels within countries' health systems. As there is 'no one-size-fits-all' approach to access strategies, the Index finds that companies are implementing a range of measures to increase access to their products in different countries. The quality of approaches varies significantly between companies and even within companies for different products. However, several trends were identified in the approaches that companies use to provide access across different country income classifications.

Across the analysis of the 20 companies' access strategies in UMICs, LMICs and LICs, the 2024 Index identified eight primary approaches used by companies to provide access in different country income classifications (see Table 1 on the next page).

TABLE 1 Approaches utilised by companies to provide access in different markets

Several of these approaches can be deployed simultaneously. For example, a company may introduce a 'second brand' that is publicly reimbursed or supply medicines through both public and private channels within a country.

Primary approaches utilised by companies	Upper-middle-income countries	Lower-middle-income countries	Low-income countries
1. Public reimbursement	●	●	
2. Strategies to support out-of-pocket payments and increase affordability for patients	●	●	
3. Second brand strategies	●	●	●
4. Partnerships to reach vulnerable populations		●	●
5. Interventions to reduce supply chain mark-ups		●	●
6. Non-exclusive voluntary licensing		●	●
7. Inclusive business models			●
8. Donations			●

Some examples of how companies are implementing these approaches:

1. Public reimbursement Achieving public reimbursement is the primary market access strategy of companies in UMICs. This strategy is not always feasible across all countries in scope of the Index, as some – including certain LMICs and most LICs – lack established public reimbursement systems. It is also important to note that public reimbursement does not guarantee access for all patients, particularly if a product is only partially reimbursed, and patients are required to make large co-payments to cover the remaining costs.

X*Pfizer has achieved public reimbursement for almost all (8) products analysed in UMICs and is working towards inclusion in the public system for the remaining two. In contrast, for the same products in LMICs, it applies different strategies to support patients who must pay for healthcare out of pocket, which is common in most of these countries.*

2. Strategies to support out-of-pocket payments and increase affordability for patients

This iteration of the Index finds more widespread implementation of solutions to financially support patients' out-of-pocket expenses for healthcare,

including companies' utilisation of patient support/assistance programmes (PSPs/PAPs).

- *Bayer has implemented numerous PAPs in several UMICs and LMICs in scope for all (6) its products assessed. For example, in India – an LMIC with a high percentage of out-of-pocket payments – it has launched a PAP for darolutamide (Nubeqa®), indicated for prostate cancer, to improve affordability for patients.*
- *Novartis implements different solutions in Egypt, an LMIC with high levels of out-of-pocket expenditure. For its product nilotinib (Tasigna®), indicated for chronic myeloid leukemia, it has shared contribution and co-payment models to increase affordability and access. For its product inclisiran (Leqvio®), a cholesterol-lowering drug, it has a comprehensive strategy that includes a PSP with microfinancing solutions to support out-of-pocket payments.*
- *Takeda has implemented different PAPs for its product brentuximab vedotin (Adcetris®), indicated for lymphoma, in the Philippines (LMIC), while aiming for national reimbursement. The company offers an affordability-based PAP and a fixed-scheme PAP that provides co-payment support.*
  In addition, it has a PAP specifically for those patients living in isolated and disadvantaged areas.

3. Second brand strategies

Companies use alternate branding or packaging to the original brand that is marketed in high-income countries. This strategy is primarily used to introduce the 'second brand' into emerging markets, where the product is sold at a lower price than the original brand.

- *Bristol Myers Squibb uses the second brand strategy for its oncology drugs, ipilimumab (Yervoy®) and nivolumab (Opdivo®). In 2023, it launched a second brand of luspatercept (Reblozyl®), indicated for beta thalassemia, in India (LMIC), with plans to expand this strategy to additional countries, including Indonesia and Brazil, in 2025.*
- *Novartis has implemented the second brand strategy for several products and is expanding it further by launching additional second brands, such as inclisiran (Leqvio®), erenumab (Aimovig®), and ribociclib (Kisqali®), in more countries, including several LICs.*
- *Sanofi, as part of its Global Health Unit (GHU), has introduced 'Impact brands' for two of its products in several LMICs and LICs: enoxaparin (Clexane® / Lovenox®), an anticoagulant, and its analogue insulin glargine (Lantus®).*

4. Partnerships to reach vulnerable populations

Partnering with local organisations or NGOs is a strategy used by some com panies to reach lower-income and vulnerable groups within a population.

- *Boehringer Ingelheim, as part of its Access to Healthcare programme, is partnering with mPharma – a technology-driven healthcare company that aims to improve equitable access to affordable medicines. Through this partnership, the company supplies three of its products in sub-Saharan Africa. As part of this strategy, currently piloting in Kenya (LMIC), the products' prices are determined by considering an individual's ability to pay as assessed by a survey administered by mPharma.*

5. Interventions to reduce supply chain mark-ups

Mark-ups added by regional and local distributors along the supply chain can greatly inflate drug prices, and consequently restrict access for patients. Several companies have put measures in place to control mark-up along the supply chain, for example:

- *Novo Nordisk works with local partners to limit mark-ups and ensure affordability for its human insulin products in different LMICs.*
- *Pfizer is partnering with mPharma to reduce mark-ups in Ghana and Nigeria (LMICs) for five of its products assessed.*

6. Non-exclusive voluntary licensing

Non-exclusive voluntary licensing is used by companies to facilitate generic market access of their patented products. Licenses typically apply to communicable diseases, such as HIV and hepatitis, and cover mostly LMICs and LICs (with UMICs more likely to be omitted from such agreements).

- *Both Gilead and GSK have utilised this strategy for several of their products analysed, including Gilead's sofosbuvir/velpatasvir (Epclusa®) for hepatitis C and GSK's dolutegravir (Tivicay®) indicated for HIV. For more details, please see p.65 in this sub-chapter.*

7. Inclusive business models

Companies have been increasingly introducing business approaches that aim to provide sustainable and equitable access to their products in low-resource settings.

- *Examples include Pfizer's An Accord for a Healthier World, Sanofi's GHU and Bristol Myers Squibb's recently launched Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity (ASPIRE) strategy. See section on Inclusive Business models on p.85 of this sub-chapter for further analysis.*

8. Donations Donations provide an avenue to reach the most vulnerable populations in the lowest income groups, particularly in countries where there may not be a viable market to implement a sustainable access strategy.

- *For example, during the period of analysis, Bristol Myers Squibb (dasatinib, Sprycel®), Novartis (nilotinib, Tasigna®), Pfizer (crizotinib, Xalkori®and sunitinib, Sutent®) and Takeda (ponatinib, Iclusig®) all donated these respective oncology products through the Max Foundation, an organisation that provides lifesaving cancer medicines to patients in countries where the medicine would otherwise not be available.*

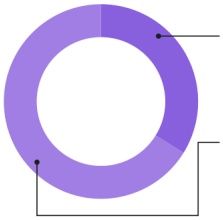
The most comprehensive strategies incorporate multiple mechanisms to reach patients across the income pyramid within a country. Typically, companies have more comprehensive strategies in UMICs. For example, supplying through private and public channels, as well as additional financing mechanisms to increase affordability for patients. In LICs, strategies focus more on donations, which do not provide long-term, sustainable solutions to access. However, some companies have introduced new inclusive business models to improve sustainable access in low-income settings. Providing diverse access pathways in all country income classifications could maximise the impact of these strategies.

HOW DO COMPANIES MEASURE THE IMPACT OF THEIR STRATEGIES AND TRACK THEIR PROGRESS?

To ensure the effectiveness of their access strategies, companies can establish systems to track progress against the goals they have committed to. These measures help identify gaps and enable companies to adjust their strategies to ensure they are truly reaching patients. Equitable access strategies should have clear and measurable goals that include objectives to reach as much of the total eligible§ patient population as possible. While previous iterations of the Index have assessed patient reach, the 2024 Index conducted a deeper dive into how companies track the outcomes of these strategies (see also the Governance of Access sub-chapter on p.28).

FIGURE 8 Strategies with shared eligible patient data

There is a gap between the number of strategies for which companies reported how they calculate the eligible population (47%) and for which they shared the actual number of eligible patients, suggesting companies are either unable to calculate the number or unwilling to share the data.



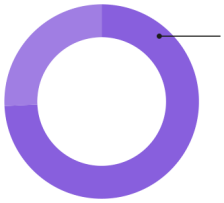


FIGURE 9 Strategies where outcomes are reported

Companies perform relatively well on reporting patients reach numbers of their strategies. However, the absence of clear data on the total eligible patient population hinders the ability to assess whether the number of patients reached truly represents equitable access.

Outcomes data varies across companies

Implementing approaches to track outcomes at the outset of a product's launch can help identify potential shortcomings in the access strategy early on and allow for adjustments to improve it. Conversely, it can highlight successes that can help facilitate the expansion of the strategy to more countries. Most companies use sales and volumes sold to derive patient reach figures based on consumption assumptions. Patient Support Programme (PSP) enrollment tracking is also a common approach reported by companies. However, the level of reporting varies significantly across companies and products. Two companies, AstraZeneca and Novartis, stand out for having established processes to track the progress and impact of their access strategies as reported in the Best Practice on p.120. The examples below highlight some other companies' efforts in tracking the impact of their strategies and increasing their reach.

- *Pfizer has consistently reported on the outcomes of its strategies for five products in LMICs. Different solutions to support patient affordability have been implemented, contributing to an increase in patients reached. While the company also shared how the strategy targets are set, including the eligible patient population, it did not share the corresponding numbers.*
- *Takeda implements different patient assistance programmes (PAPs) for its cancer product brentuximab vedotin (Adcetris®) in the Philippines (LMIC). For this strategy, Takeda reports having a process in place to define targets and track patient enrollment in the PAPs. Takeda also demonstrates efforts in monitoring the outcomes of its newly launched dengue vaccine (Qdenga®) in Brazil (UMIC). The company reports comprehensive approaches for determining eligible and target populations and utilises different metrics to monitor patient reach.*

§ Eligibility refers to patients diagnosed or identified by a healthcare professional as suitable recipients of the product, based on the licensed indication(s).

Companies need to increase focus on reaching vulnerable populations with their access strategies

Tracking the impact of their access strategies is an important yet demanding exercise for companies, especially in LMICs. The Index has noted some efforts in this area, with most strategies analysed reporting on outcomes at some level. However, the lack of defined data on the total eligible patient population makes it difficult to assess whether the absolute number of patients reached reflects equitable access. Companies should strive to reach as many eligible patients as possible through their strategies, prioritising countries with a high burden of disease, for key products or when no alternative treatments are available.Furthermore, current efforts are primarily commercial initiatives, and whilst companies must endeavour to have sustainable access strategies, fewer examples specifically target vulnerable populations.

Moving forward, companies can further develop their methodologies and improve their transparency to more comprehensively track the impact of their strategies. This will help ensure more sustainable access to products and extend reach, particularly to patients in LICs.

Companies' efforts in tracking patient adherence

Patient adherence is critical to ensure the health benefits of treatments are optimised, particularly for chronic conditions. Monitoring patient adherence is an important metric for determining whether products effectively reach patients in need for the whole treatment duration. However, only a few companies have shown efforts in tracking treatment duration and patient adherence, as seen with GSK and Merck KGaA through their patient support/access programmes implemented in some LMICs.

NEXT STEPS

- More companies can increase their reach to those living in LICs by extending strategies such as second brands, previously implemented in UMICs and LMICs, or by launching inclusive business models (IBMs) specifically dedicated to under served populations (see section on IBMs on p.85 of this sub-chapter.)
- Companies can implement multiple and parallel approaches within their product- and country-specific strategies to comprehensively address access barriers and expand reach across the income pyramid. For example, they can pursue public reimbursement while also implementing solutions to financially support patients not covered by the public system or facing high co-payments. At the same time, companies can launch second brands to offer more affordable options and collab orate with local partners to tailor strategies to local needs.
- Companies can improve tracking and reporting the outcomes of their strategies, starting from the data on eligible patient populations. Identifying gaps will help prioritise actions, such as which products to make available and where to focus efforts. Collaboration with governments, local partners and data providers can help identify local barriers to access. With this information, companies can implement more tailored solutions within their access strategies.

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PRODUCT DELIVERY – INCLUSIVE BUSINESS MODELS

Exploring business models that have been developed to include the needs of people in LMICs

Commercial business models that are designed for higher-income markets are not well-suited for implementation in low- and middle-income countries (LMICs). Pharmaceutical markets in these countries, especially lower-income countries, may be smaller or less mature, and countries may have limited infrastructure, constrained supply chains or insufficient training for healthcare professionals, for example. While pharmaceutical companies are implementing access strategies that aim to overcome some of these challenges, the Access to Medicine Index has consistently found that far fewer strategies are developed for low-income countries than for upper-middle-income and lower-middle-income countries. This means that many patients – especially the most vulnerable – remain consistently overlooked.

Traditionally, companies have relied on philanthropic approaches, such as donating medicines, in situations where access barriers may be particularly challenging. While these approaches can be appropriate for certain circumstances, on their own they do not offer long-term solutions for addressing access barriers. Companies can support sustainable access by taking a more inclusive approach that incorporates the needs of people living in LMICs into their business models.

By developing 'inclusive business models' (IBMs), companies can provide more sustainable access to their products for vulnerable patients, including those in low-income countries. These models can be tailored to specific markets, thereby improving affordability and health outcomes. At the same time, they can enable companies to expand to additional markets and generate innovative strategies that can be applied elsewhere — enhancing their reputations as they fulfil their role in providing equitable access.

What the Index looks for in inclusive business models

1) A comprehensive approach to addressing underserved or unserved populations' access needs

The model is designed to improve access to the company's products by addressing multiple access barriers of individuals that are underserved or unserved (further referred to as neglected) by existing business models. This includes individuals living in low-income countries[1] and least developed countries[2].

The company, either independently or through partnerships, addresses barriers related to, for example:

- Regulatory/policy processes: Engages with local or national governments and/or regional/continental bodies to navigate regulations that impact access.
- Affordability: Develops pricing strategies or financing options that make the product affordable to the target populations.
- Supply chain capacity: Builds or strengthens supply chains to ensure reliable distribution and improve accessibility, affordability and quality.
- Health system capacity: Enhances the ability of local health systems to support screening, diagnosis, treatment and disease management.
- Patient awareness and empowerment: Promotes awareness and empowerment of patients to prevent disease or seek out treatment when needed.

2) Long-term aims for a

sustainable source of revenue

Through the model, the company aims to generate a sustainable source of revenue in the long term, while addressing access issues in countries where it operates. The business model distinguishes itself from access-to-medicine strategies or short-term, philanthropic and/or donation-based projects.

3) Long-term plans for scalability

The company shows evidence of long-term plans for scalability of the model, including product scope, country scope and patient reach. Especially when making these commitments public, companies demonstrate their intention to allocate resources to expand patient access and improve outcomes on a larger scale.

SNAPSHOT OF COMPANY APPROACHES TO IMPROVING PRODUCT ACCESS FOR NEGLECTED POPULATIONS

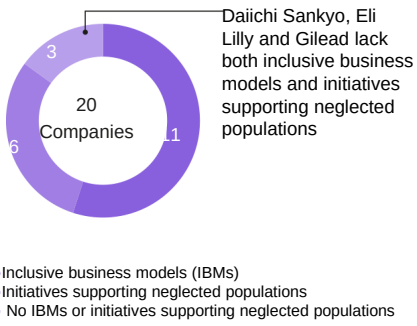
The 2024 Index finds that six of the 20 companies in scope engage in initiatives that aim to address access needs of neglected populations but lack IBMs: Astellas, Bayer, GSK, Johnson & Johnson, Merck KGaA (Merck) and Merck and Co. Inc., (MSD). These companies engage in targeted initiatives, such as patient assistance programmes, investments in social entrepreneurships, or access-to-medicine strategies for specific products in their portfolio. While these initiatives can effectively improve access to medicine for underserved populations, they typically address only a limited range of access barriers and lack sufficient evidence of scalability and long-term commercial viability. Three companies do not demonstrate evidence of operating either IBMs or initiatives that aim to address access needs of neglected populations.

There are 11 companies with IBMs: six of them engage in models that are less com prehensive in addressing the access needs of neglected populations, lack evidence of long-term plans for generating a sustainable source of revenue or lack evidence of long-term plans for scalability. These companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Eisai, Roche and Takeda. Although these models may be more limited in terms of their access approach for neglected populations or their long-term aims, companies operating these models demonstrate efforts to incorporate some of these elements into a model to improve access to their products.

Five companies – Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi – have IBMs that distinguish themselves by operating models with comprehensive approaches to addressing neglected populations' access needs, including in multiple low-income countries and least developed countries. These companies' models all have long-term aims to generate a sustainable source of revenue and plan to scale by including additional countries and products.

Due to these models' large product and geographic scope and long-term aims, they have the potential to sustainably impact the lives of more patients in broader geographies. The five companies take varying approaches across their models, with some operating separate business units focused on LMICs, some launching non-profit units and others developing business-integrated approaches. Some are based on existing access programmes or initiatives that companies have previously established. These companies' IBMs have also been highlighted as a Best Practice in the 2024 Index as set out on p.115.

FIGURE 1 Just over half of companies engage in inclusive business models



A CLOSER LOOK AT THE BROAD PRODUCT AND GEOGRAPHIC SCOPE COMMITMENTS OF INCLUSIVE BUSINESS MODELS

The remainder of this chapter focuses on the five IBMs launched by Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi since 2019, listed chronologically below:

- Novartis launched its Sub-Saharan Africa (SSA) Business Unit in 2019, which is headquartered in Nairobi, Kenya. The business unit covers 44 countries in scope of the Index, offering 12* products addressing diseases in scope. Through the unit, Novartis uses approaches, such as tiered pricing, second brands, investment in social business and health system strengthening to address access barriers. Since completing its spin-off of Sandoz in 2023, Novartis has focused the unit on the company's innovative medicines portfolio, including products for cardio vascular diseases and neurology, as well as specialty medicines and programmes covering, among others, cancer, malaria and sickle cell disease.
- Novo Nordisk's iCARE, which uses a business-integrated approach, was launched in 2021 and covers 46 countries in scope of the Index in middle Africa**, offering nine reduced-cost diabetes products. The model addresses four pillars: capacity (i.e., increasing treatment capacity through healthcare practitioner training), affordability (i.e., developing affordability plans for insulins), reach (i.e., implementing supply chain initiatives to the last mile), empowerment (i.e., patient education and support programmes).
- Sanofi's Global Health Unit (GHU) was also launched in 2021 and operates as a social business unit, covering 40 LMICs offering 29** products addressing diseases in scope. Through the GHU, Sanofi implements product access strategies (e.g., its second brand: Impact®), builds health system capacity and invests in entrepreneurs addressing health system barriers. The small profit margins generated by product sales within the unit are reinvested in programmes across countries where the GHU operates.
- The Pfizer Accord for a Healthier World (the Accord) was launched in 2022, offering 45 lower-income countries in scope all the on- and off-patent products that the company has global rights to – both current and future products

2019 Novartis' Sub-Saharan Africa Business Unit

2021 Novo Nordisk's iCARE
Sanofi's Global Health Unit

2022 Pfizer's Accord for a Healthier World

2024 Bristol Myers Squibb's ASPIRE

 * There are additional products included in the model, but these products are not in scope of the 2024 Index analysis. ** 'Middle Africa' includes all countries in sub-Saharan Africa as defined by the World Bank, excluding South Africa. iCARE also operates in Djibouti which is not part of sub-Saharan Africa by the same definition.

(including 144* products addressing diseases in scope of the Index) on a not-for-profit basis. Through bilateral agreements, Pfizer collaborates with governments to assess health system needs to supply its medicines and vaccines and also to co-create solutions that can help strengthen supply chain and logistics, develop healthcare workforce capabilities and enable more efficient regulatory pathways, as permitted by local regulation. The Pfizer Accord team is integrated within Pfizer's Emerging Markets commercial business unit and has dedicated resources in medical, supply chain, commercial, regulatory, market access and government relations.

XThe latest company to launch an IBM during the period of analysis is Bristol Myers Squibb, which launched its Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity (ASPIRE) model in 2024. The model operates in 85 countries in scope, offering nine** products addressing diseases in scope.

The company has launched tailored product access strategies (e.g., second brands), managed access programmes and health system strengthening efforts to improve access to its products. To operationalise the model and integrate it within Bristol Myers Squibb's corporate strategy, the company has formed a cross-functional LMIC governance committee.

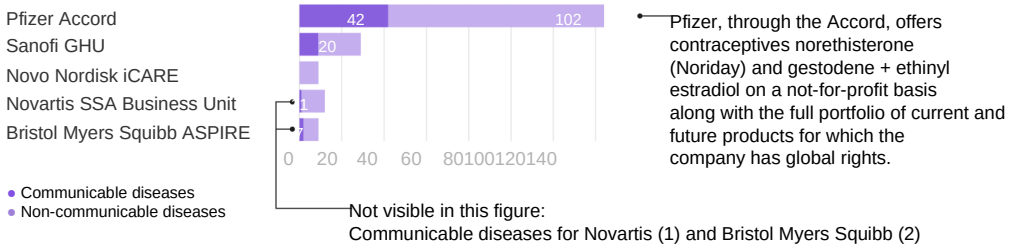
In May 2024, Bayer announced the launch of its Global Health Unit. The company reports that the unit will focus its efforts on countries where Bayer has limited or no presence and includes strategies such as patient affordability programs, innovative access models, capacity-building platforms, and digital education. The full strategy, product and geographic scope have yet to be disclosed, therefore it was not assessed as part of the 2024 Index cycle.

INCLUSIVE BUSINESS MODELS' PRODUCTS ARE MOSTLY FOR NON-COMMUNICABLE DISEASES

As illustrated in Figure 2, the majority (73%) of products included in IBMs are for non-communicable diseases (NCD) such as cancer, diabetes and cardiovascular diseases. Among these NCD products, there are examples of both older treatments as well as newer on-patent medicines that typically are not covered by access strategies in lower-income countries. Products indicated for communicable diseases make up a smaller proportion (27%) of total products covered by these models.

FIGURE 2 Products covered by inclusive business models

This figure shows the number of communicable and non-communicable diseases in scope of the Index for each inclusive business model.



* There are additional products included in the model, but these products are not in scope of the 2024 Index analysis.

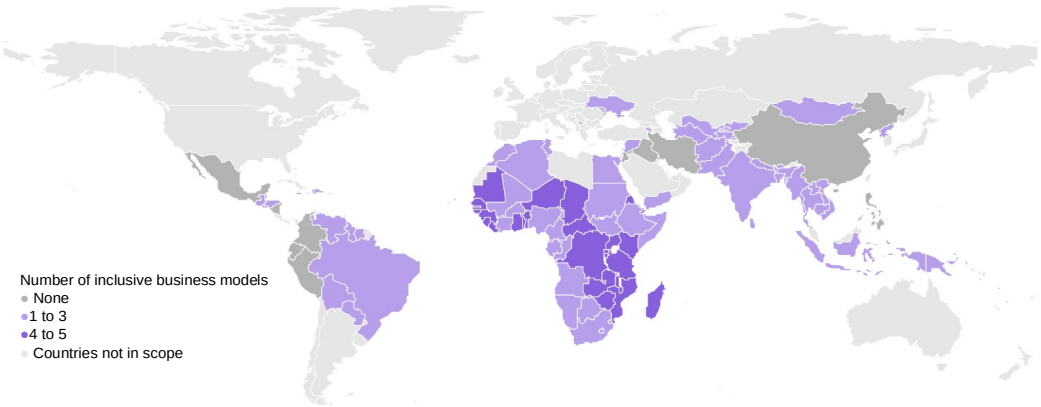
Bristol Myers Squibb, Novartis and Sanofi have all launched second brands for select products in their portfolios as part of their respective IBMs. Second brands are launched by pharmaceutical companies as an additional brand of an existing product, under a different brand name and meant for a specific part of the patient population. Companies use different terminologies to refer to a second brand strategy (e.g. emerging market brand, impact brand). They can be used to address the needs of low-income and neglected segments of a population, as they typically have a lower list price and are tailored in other ways (e.g., packaging) to meet patient needs.

PROGRESS AND OUTCOMES OF INCLUSIVE BUSINESS MODELS

Companies have made commitments to operate their IBMs in countries across all six regions defined by the World Bank: Latin America & Caribbean, Europe and Central Asia, sub-Saharan Africa, South Asia, Middle East and North Africa, and East Asia and Pacific. However, the focus is mostly on sub-Saharan Africa, which makes up between 40-98% of each model's planned geographic scope. This region is home to 15% of the global population and bears 20% of the global disease burden.[3] Therefore, these models have the potential to address a significant unmet need for access to care. None of the companies have committed to operate their models in the following 11 countries: China, Colombia, Ecuador, Iran, Iraq, Jordan, Kosovo, Mexico, Nicaragua, Peru and the Philippines.

FIGURE 3 Countries where companies have committed to operate their inclusive business models

Across the five inclusive business models, companies commit to making their products available in 102 countries. At least one model covers each of the 48 low-income countries and/or least developed countries in its commitments.



STATUS AND TRANSPARENCY OF COUNTRY-LEVEL PROGRESS

Even when faced with the inevitable challenges to rolling out a large-scale IBM in LMICs, transparency on progress is crucial. When companies transparently report on the countries where their models are active, it can drive accountability and implementation. Disclosing details about the level of implementation across these countries (e.g., whether products have been made available, what kinds of capacity building efforts are ongoing) can also accelerate implementation by attracting local partnerships that can drive sustainability and integration into the local health system.

While all five companies have made large geographic commitments through their IBMs, they have varying levels of transparency around the current progress and implementation:

- At the time of submission, Bristol Myers Squibb reported that its ASPIRE model was currently active in 19 countries, also supporting over 80 LMICs through its Direct Import and Direct-to-Institution managed access pathways. The company reports that the ASPIRE model is in various stages of implementation in each country. Bristol Myers Squibb publicly shares an example of a country, Thailand, where it has launched an emerging market brand for its beta thalassemia treatment.
- Novartis reports that products from its second brand strategy, one of the elements that make up the SSA Business Unit, have been made available in most countries in scope of the Index, for example in Ghana, Kenya and Nigeria. Novartis' SSA Business Unit also conducts health system strengthening initiatives (e.g., community health programmes, health worker training), with four examples reported to the Index in Côte d'Ivoire, Kenya, Tanzania and Uganda.
- During the period of analysis, Novo Nordisk had active partnership agreements with sub-national or national governments in 17 countries in scope (e.g., Ghana, Kenya, Mali, Nigeria, Senegal and Uganda). For seven of these 17 countries, affordability plans have already been initiated since the start of the partnerships. Through the Accord for a Healthier World, Pfizer has signed agreements with ten countries, including, for example, Ethiopia, Ghana, Malawi, Rwanda and Senegal, to enable access to Pfizer medicines and vaccines on a not-for-profit basis. Eight agreements were signed during the period of analysis, two were signed after the period of analysis. In September 2022, Rwanda was the first country to receive a shipment of Accord medicines and vaccines for infectious and inflammatory diseases, as well as certain cancers.
- Sanofi reports that as of 2023, its Global Health Unit has reached patients in 31 countries with NCD care, 23 countries for tuberculosis care and 19 countries for malaria care.* The exact countries have not been disclosed, however, Sanofi publicly reported that it delivered its first products through the Impact® brand – analogue insulin, insulin glargine Impact SoloStar® and anticoagulant enoxaparin sodium Impact® – to Djibouti in late 2023. Sanofi also reported that Tanzania was scheduled to be the second country to receive insulin glargine Impact SoloStar.®

* After the period of analysis, in October 2024, Sanofi reported that over 40 LMICs had been supplied with NCD treatments, ten through the Impact® brand.

NUMBER OF PATIENTS REACHED

It is important that companies critically monitor the number of patients their models reach, so that they can identify persistent gaps, allocate resources to meet unmet needs and amplify successful strategies more effectively. Sanofi stands out from the other four companies for its regular public patient reach reporting, which is also disaggregated by disease categories (i.e., tuberculosis, malaria and NCDs).

Although not examined in this chapter, it is important to note that patient reach commitments across these models do not necessarily cover a large part of the patient population in LMICs. For example, while Sanofi and Novo Nordisk both report on patients reached, their patient reach commitments collectively cover only about 1% of the total population living with diabetes (both type 1 and type 2) in LMICs in scope.[3] Furthermore, due to the public-facing nature of these IBMs and their potential impact, there is an incentive for companies to publicly share details about their measurement approaches for patient reach. Transparency about the underlying metrics used to calculate patient reach varies across the five models (also see the 'Spotlight on Patient Reach' on p.35).

XBristol Myers Squibb

- *Commitment:* ASPIRE contributes to Bristol Myers Squibb's overall public company commitment to reach more than 200,000 patients in LMICs by 2033 with its innovative treatments.
- *Patient reach:* As of 2023, Bristol Myers Squibb reports having reached 104,000 patients worldwide (in LMICs) through its endeavours.[4] However, it is not clear whether this represents access to company products or other non-product-related initiatives like capacity building.

XNovartis

- *Commitment:* Novartis made a public commitment through its sustainability-linked bond, not specific to the SSA Business Unit, to increase the number of patients reached with strategic innovative medicines in LMICs by at least 200% by 2025 (compared with 2019 baseline).
- *Patient reach:* According to the company, Novartis reached its overall company goal of 1.6 million patients in 2023.[5] The company does not report publicly on the number of patients reached through the business unit specifically.

XNovo Nordisk

- *Commitment:* Novo Nordisk, through iCARE, has publicly committed to reach over two million vulnerable people living with diabetes in middle Africa by 2030.
- *Patient reach:* Novo Nordisk reports having reached 433,000 people living with diabetes by 2023 through iCARE,[6] but it is not clear whether this solely represents access to diabetes products, or includes patients reached through other initiatives, such as patient empowerment and education. Although the model was launched in 2021, patient reach has only been publicly disclosed in 2023.

XSanofi

- *Commitment:* Through the GHU, Sanofi has publicly committed to provide care for two million people living with NCDs by 2030.
- *Patient reach:* Sanofi reports that in 2023, it reached 261,977* patients living with NCDs with treatments through the GHU.[7] The company further disaggregates its patient reach data by disease (i.e., malaria, tuberculosis and NCDs).
  Sanofi has reported patient reach annually since the model was launched in 2021.

XPfizer

- *Commitment:* Through An Accord for a Healthier World, Pfizer has publicly committed to provide equitable healthcare to 1.2 billion people. While the company has stated a broader, company-wide goal to change one billion lives a year by 2027 as part of its "Purpose Blueprint 2.0",it has not set a specific deadline for achieving the Accord's goal.
- *Patient reach:* No patient reach outcomes publicly reported.

* After the period of analysis, in October 2024, Sanofi reported that 586,024 patients had been reached with NCD treatments.

Three companies also publicly report non-product-related outcomes of their models. As of March 2024, Sanofi reports that the GHU had piloted 44 active healthcare system strengthening partnerships in 21 countries*.[8] Novo Nordisk reports having trained 3,523 healthcare professionals by 2023 through iCARE.[6] Bristol Myers Squibb reports that it has trained or supported approximately 215,000 healthcare providers.[4] Novartis reports numbers across multiple programmes and initiatives and Pfizer does not disclose any information publicly, making it challenging to gauge the outcomes of their models specifically.

ADDRESSING MULTIPLE ACCESS BARRIERS IS KEY FOR ENSURING SUSTAINABLE ACCESS TO MEDICINES

IBMs, by definition, are comprehensive, addressing multiple access barriers such as affordability, supply chain constraints, and limited health system capacity. Companies can tailor their models to address specific needs in countries they operate in. Through partnerships with stakeholders such as non-governmental organisations and social entrepreneurships, companies can help ensure that products are properly administered, supply and quality is upheld, and healthcare facilities and caregivers are equipped to provide needed care. Importantly, some of these initiatives (e.g., patient awareness, healthcare professional training) should be designed in a way that mitigates conflicts of interest and does not inappropriately promote company products. Below are two examples of how companies are addressing access barriers in addition to affordability issues:

“Companies can tailor their models to address specific needs in countries they operate

- *Sanofi's health system strengthening initiatives and Impact Fund*

  Sanofi reports several examples of initiatives that the GHU operates which aim to strengthen supply chains, conducting medical trainings and provide services to patients. As an example, the GHU is working with Touch Foundation in Tanzania to improve supply chain management for NCD medicines and use patient tracking at each facility to help improve treatment adherence. Through the GHU, Sanofi has also committed EUR 25 million to its Impact Investment Fund that provides financing and technical assistance to entrepreneurs that work on delivering technology driven healthcare solutions in underserved regions. During the period of analysis, investments have been made into SwipeRx, Viebeg Technologies, mPharma and Dawa Mkononi.

- *Novo Nordisk's iCARE – Capacity building, supply chain strengthening, patient empowerment*

  Through iCARE, Novo Nordisk reports that it works with multiple partners to provide education for healthcare professionals, increase awareness about diabetes, promote early diagnosis and treatment and increase the number of diabetes and endocrinology specialists in Africa. In 2022, as part of the 'reach' track of iCARE, Novo Nordisk partnered with an online pharmacy and telehealth service, MYDAWA, to address accessibility and affordability of insulin in Kenya. Novo Nordisk is utilising the MYDAWA online platform to provide people living with diabetes the option of fulfilling their prescriptions for insulin.

PARTNERSHIPS FOR IMPLEMENTING IBMs

Given that IBMs aim to address multiple access barriers, companies can work with a variety of stakeholders to help with the rollout of initiatives. These stakeholders are involved in several components of the business model, including regulatory processes and policymaking, healthcare delivery, patient support, procurement and supply chain operations.

Local partnerships are especially important for ensuring that these models are tailored to and align with unique country needs and priorities. The next page sets out examples of partners that the five companies are working with across multiple sectors.

* After the period of analysis, in October 2024, Sanofi reported that the GHU had activated 74 health system strengthening initiatives with 52 partners in 39 countries. To address access issues for NCDs, the GHU engaged with 128 health facilities, trained 12,453 healthcare practitioners and community health workers, and reached 763, 817 beneficiaries.

TABLE 1 Examples of implementing partners involved in inclusive business models

Partner type	Examples
Governments	• Ministries of Health - Nigeria and Ghana
NGOs/faith-based organisations	• Christian Health Association for Kenya (CHAK)• Kenya Conference of Catholic Bishops (KCCB)• Christian Health Association of Zambia (CHAZ)• Population Services International • Action4Diabetes • Touch Foundation Tanzania
International organisations	• UNICEF • The Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund) • The World Bank
Academia and research institutions	• East Central & Southern Africa College of Physicians (ECSACOP) • University of South Wales (USW) • University of Geneva
Distributors	• Mission for Essential Drugs and Supplies (MEDS) Kenya• Salama pharmaceuticals Tanzania • Gokals Laborex Ghana • National Medical Supplies Fund Sudan • Ethiopian Pharmaceutical Supply Agency • Joint Medical Store (JMS) Uganda • La Nouvelle PSP Côte D'Ivoire
Patient, medical and scientific associations	• Tanzania Diabetes Association • Diabetes Association of Botswana
Private sector	• MYDAWA Kenya • Reach52 • The World Continuing Education Alliance Ltd• mPharma • SwipeRx

NEXT STEPS

As more companies engage in IBMs with large product and geographic scopes, it is important that they drive progress and implementation to effectively address the comprehensive range of access challenges they have been designed to overcome. Moving forward, companies can take additional steps to enhance their efforts and companies that are not yet engaging in comprehensive models can look to current examples for guidance.

- Companies can take steps to go beyond philanthropy, embedding access to products, especially in low-income countries and least developed countries, as part of a comprehensive long-term business model with plans for scalability.
  - For companies without IBMs, this means finding areas where their unique product portfolios can address significant access gaps for neglected populations and tailoring models to address unmet needs.
  - For companies with existing IBMs, this means continuing to expand models in a way that is informed by local needs and countries' priorities.
- Companies developing IBMs can design their models to address a comprehensive range of access barriers to support sustainability of the model and address multiple needs. This can include, for example, barriers such as pricing, regulatory challenges, health system capacity, and reach of supply chains. This strategy should be developed in partnership with local stakeholders to promote sustainability.
- As companies roll out their IBMs, they should be transparent about the level of implementation in countries (e.g., where products are being made available, what parts of the strategy are being rolled out in which countries). Not only does this promote accountability, it also supports partnerships with other key stakeholders (e.g., local governments) who are working on existing initiatives to promote access to care.
- Companies can transparently and frequently report on patient reach outcomes. Doing so can help foster accountability and identify critical gaps. Metrics for patient reach should be publicly available, to help understand the impact of the IBMs.

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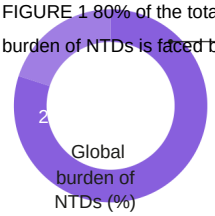
LONG-TERM DONATIONS

How are companies working to provide access to treatments for neglected tropical diseases?

Through long-term donation programmes, pharmaceutical companies can provide access to medicine for people living in low- and middle-income countries (LMICs) who are unable to – or have limited resources – to pay for treatment. This access avenue is especially relevant for the management of neglected tropical diseases (NTDs), which pose a disproportionately high burden in LMICs. Of the 113 LMICs in scope of the Index*, 80% of the global disease burden of NTDs is concentrated in 15 of these countries, contributing to an estimated 14.5 million disability-adjusted life years (see Figure 1). [1,2]

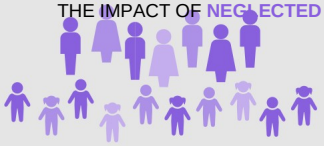
NTDs are a diverse set of 21** diseases and disease groups. They are typically related to inadequate sanitation systems, poor access to clean water and are trans mitted via infectious vectors such as mosquitoes, flies and snails, as well as domestic animals and livestock. The risk posed by NTDs for people living in the hardest-to-reach and impoverished communities is particularly great, with the resulting physical and socioeconomic consequences especially pronounced in these communities. For example, in eastern Sudan, where visceral leishmaniasis is endemic, untreated cases are fatal in over 95% of instances. The cost of treatment can be catastrophic, with out-of-pocket expenditure accounting for as much as 40% of a household's annual income.[3] (See infographic below.)

FIGURE 1 80% of the total global disease burden of NTDs is faced by just 15 LMICs



15 LMICs: Bangladesh, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, India, Indonesia, Madagascar, Mexico, Mozambique, Myanmar, Nigeria, Pakistan, Philippines, Uganda and Tanzania.

THE IMPACT OF **NEGLECTED TROPICAL DISEASES** IN LMICs [4,5]



Results in deaths of over **170,000 people** every year.

More than **1.65 billion people, including one billion children**, in LMICs are at risk of being maimed, debilitated or disfigured due to NTDs.

In **children**, infection results in malnutrition, cognitive impair ment, stunted growth and hin- ders their ability to attend school.

Drains the equivalent of **USD 33 billion** from under- served communities every year in direct treatment expenses, lost productivity and decreased socioec onomic and educational opportunities.

* All 15 LMICs are in scope of the Index (country-wise proportion of people needing inter vention against NTDs: Bangladesh- 3.33%, Côte d'Ivoire- 1.24%, Democratic Republic of the Congo- 3.39%, Ethiopia- 4.19%, India- 40.56%, Indonesia- 4.81%, Madagascar- 1.42%, Mexico- 1.23%, Mozambique- 1.49%, Myanmar- 1.47%, Nigeria- 8.58%, Pakistan- 1.71%, Philippines- 3.07%, Uganda- 1.65% and Tanzania- 2.15%)[1]

** Since noma was only recognised as an NTD by the World Health Organization (WHO) at the end of 2023, it was not included in the disease scope of the 2024 Access to Medicine Index, which covers 20 NTDs (refer to page 18 of the 2024 Access to Medicine Index Methodology.)

Companies' commitments to the control, elimination and eradication of NTDs

Recognising that NTDs cause such a devastating impact on patients, as well as placing a significant burden in LMICs, the World Health Organization (WHO) has made several efforts to accelerate progress to alleviate the burden of NTDs since 2012.* In that year, the London Declaration on NTDs was signed, and a roadmap for the control or elimination of NTDs by 2020 was launched. A group of diverse partners, comprising pharmaceutical companies, bilateral and multilateral donors, trusts and foundations, non-governmental organisations, academic institutions and governments, endorsed this Declaration and formed a partnership, 'Uniting to Combat NTDs'.

Pharmaceutical companies, in particular, made long-term commitments and donated a range of medicines for ten NTDs that were identified as needing urgent action. In 2020, with the creation of a second roadmap, WHO set targets to be achieved by 2030 for the control, elimination or eradication of 20 NTDs, which later became 21 NTDs after the inclusion of noma in 2023.

WHO targets set for the control, elimination or eradication of NTDs by 2030

Control	Elimination	Eradication
• Buruli ulcer	• Chagas disease	• Dracunculiasis
• Dengue and chikungunya	• Human African trypanosomiasis	• Yaws
• Echinococcosis	• Leishmaniasis**(visceral)	
• Food-borne trematodiases	• Leprosy	
• Leishmaniasis**(cutaneous)	• Lymphatic filariasis	
• Mycetoma, chromoblastomycosis and other deep mycoses	• Onchocerciasis	
	• Rabies	
• Noma	• Schistosomiasis	
• Scabies and other ectoparasites	• Soil-transmitted helminthiases	
• Snakebite envenoming	• Trachoma	
• Taeniasis/cysticercosis		

Another important milestone in combatting NTDs was the June 2022 Kigali Summit on Malaria and NTDs, where several partners, including pharmaceutical companies, renewed their commitments to combat NTDs.[6] Currently, more than 50% (11/20) of companies in scope of the Index endorse the Kigali Declaration on NTDs:

- AbbVie
- Bayer
- Eisai
- Gilead
- GSK
- Johnson & Johnson
- Merck KGaA (Merck)
- Merck & Co., Inc. (MSD)
- Novartis
- Pfizer
- Sanofi

Through this, companies commit to aligning with the WHO 2030 NTD roadmap by engaging in long-term donation programmes; supporting research and development for new treatments and their delivery to patients; working with partners to co-create sustainable solutions for health system strengthening; and supporting countries to take ownership of their NTD programmes.[6]

* Although WHO accelerated efforts to address the burden of NTDs in 2012, it started initiatives targeting specific NTDs much earlier. For instance, its Onchocerciasis Control Programme was launched as early as 1974.

** Although Leishmaniasis is listed as a single disease in the 'Diseases in scope of the 2024 Access to Medicine Index' (see p.211), for the purposes of this list, it is separated into different forms as WHO has established distinct targets for each form of Leishmaniasis.

Significant progress in achieving these 2030 targets have been made, with a 26% reduction in the number of global interventions required against NTDs between 2010 and 2022; by 2023, 50 countries had eliminated at least one NTD. However, the COVID-19 pandemic caused severe disruptions in these efforts, with progress in achieving eradication and elimination targets stagnating somewhat as a result.[1]

What do companies' NTD programmes look like?

The 2024 Index identified that the long-term donation programmes of the 11 companies target 13 of the 21 NTDs recognised by WHO (see Figures 2 and 3).[1]

FIGURE 2 Companies with donation programmes for NTDs

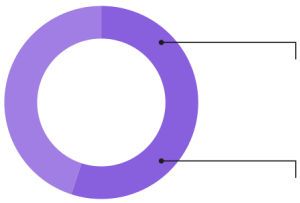


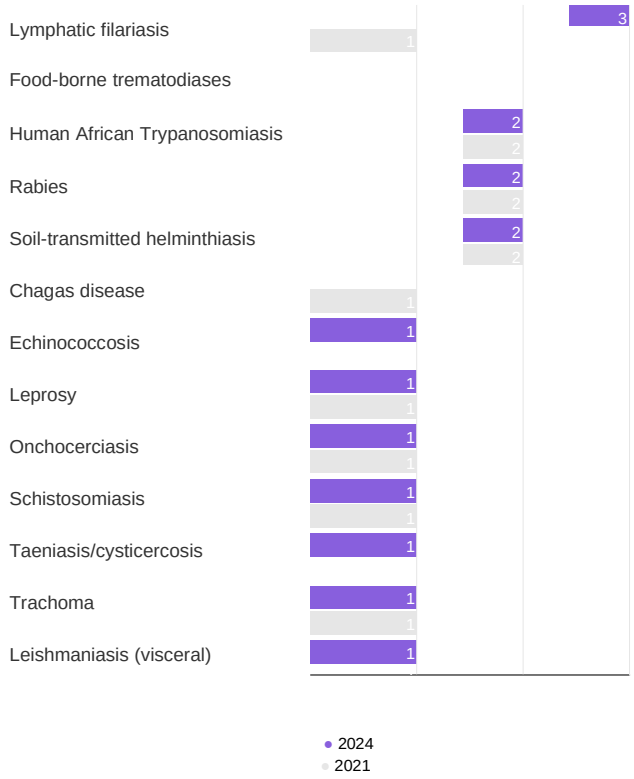
FIGURE 3 Collectively, companies' 19 NTD long-term donation programmes cover 13 of the 21 NTDs recognised by WHO

Since assessing companies' long-term donation programmes targeting NTDs in the 2021 Index, companies

FIGURE 4 Improved commitment with five additional NTD donation programmes by companies in scope since 2021

have demonstrated increased commitments. Overall, in the 2024 Index assessment, five additional donation programmes have been identified – bringing the total number of long-term donation programmes targeting NTDs to 19, compared with 14 in 2021 (see Figure 4).

The geographical scope of the programmes ranges from one to 80 countries where the products are donated, with some of the company programmes being initiated as far back as 1987. These programmes are initiated through a memorandum of understanding (MoU) between a company and partners, whereby the company makes a public commitment to contribute to a structured donation programme targeting one or more NTDs.



Companies with widened and additional commitments

Product donations from companies are managed by WHO, except for two that are managed by the International Trachoma Initiative and the Mectizan® donation programme. Five companies – Eisai, GSK, Merck, MSD and Sanofi – committed to donate their medicines until the elimination, eradication or control goals for the long-term programmes they currently support are fully achieved.

Recently, Boehringer Ingelheim, Gilead and Merck expanded their commitments to include additional countries in scope of the Index, and three companies – GSK, Johnson & Johnson and Pfizer – extended donation commitments for an additional five years through to 2030. See Table 1 below for a detailed breakdown of companies' NTD programmes and commitments.

TABLE 1 A breakdown of companies' NTD programmes

Company	NTD	Product	Countries*	Period of MoU**	Status of companies' commitments to elimination, eradication or control of NTDs
Bayer	Chagas disease	Nifurtimox (Lampit®)	5	2007-2025	Publicly commits to continue manufacturing and donating essential medicines for Human African trypanosomiasis, Chagas disease and taeniasis to support the achievement of WHO NTD 2030 goals
	Human African trypanosomiasis	Nifurtimox (Lampit®)	15	2009–2026	
		Suramin (Germanin®)		2002–2026	
	Taeniasis/ cysticercosis	Niclosamide (Yomesan®) and praziquantel (Biltricide®)	1	2020–2024	
	Food-borne trematodiases	Praziquantel (Biltricide®)	1	2020–2024	Bayer agreed unofficially to continue donations for 2024-2025
Boehringer Ingelheim	Rabies	Rabies vaccine (Rabisin®)	9	2019-2030	Aims to provide more than 500 million vaccine doses and educate 15 million children on rabies through its Information and Education Campaign for the period 2023 to 2038
Eisai	Lymphatic filariasis	Diethylcarbamazine citrate	25-26	Since 2012	Remains committed until elimination
Gilead	Leishmaniasis (visceral)	Amphotericin B liposome (AmBisome®)	11	2012–2016	Some developments in commitments beyond 2025
				2016–2021	
				2022–2025	
GSK	Echinococcosis	Albendazole (Zentel®)	2	2022–2025	Launched a new programme and will donate 5 million tablets annually until 2025
	Lymphatic filariasis		29	Since 1997	Remains committed until elimination
	Soil-transmitted helminthiases		38	2012–2025	Some developments in commitments beyond 2025
Johnson & Johnson	Soil-transmitted helminthiases	Mebendazole (Vermox® Chewable)	55	Since 2012; current MoU is until 2025	In 2024 extended its commitment for an additional 5 years from 2026 through 2030, ensuring up to 200 million doses annually for children and women of reproductive age in endemic countries
Merck	Schistosomiasis	Praziquantel (Cesol®)	45	Since 2007	Some developments in commitments beyond 2025
MSD	Rabies	Rabies vaccine (Nobivac®)	3	Initiated in 1997	Remains committed to help ensure there are zero human deaths from dog-mediated rabies by 2030
	Lymphatic filariasis	Ivermectin (Mectizan®)	27	Since 1997	Remains committed until elimination
	Onchocerciasis			Since 1987	
Novartis	Food-borne trematodiases	Triclabendazole (Egaten®)	21	2016–2025	No recent developments in commitments beyond 2025
	Leprosy	Clofazimine (Lamprene®), dapsone (Dapsone®) and rifampicin (Rimactane®)	Approximately 80	2000–2025	No recent developments in commitments beyond 2025
Pfizer	Trachoma	Azithromycin (Zithromax®)	20	1998–2025	Some developments in commitments beyond 2025
Sanofi	Human African trypanosomiasis	Pentamidine (Pentacarinat®), eflornithine (Ornidyl®) and melarsoprol (Arsobal®)	21	2001–2026	Commits an unlimited quantity for treatment
		Fexinidazole (Fexinidazole Winthrop®)		2019-2026	

Bayer committed to support donations and proposed extension after 2025.

Boehringer Ingelheim expanded donation to three additional countries in 2024: India, Indonesia and Vietnam, all countries in scope.

Gilead expanded donation to two additional countries in 2023: Eritrea and Yemen, both in scope.

GSK extended donation, pledging up to 100 million doses annually from 2026 to 2030.

Merck expanded donation to two additional countries in scope and remains committed for an unlimited period.

Pfizer extended donation for an additional five years through 2030.

* Number of countries with active or ongoing donations that are within the scope of the Index.

** As of December 2023

NEXT STEPS

In order to achieve the targets set by WHO for the elimination, eradication and control of NTDs:

- XCompanies can commit to engaging in donation programmes for NTDs for an unlimited period.
- XCompanies can expand ongoing programmes to include additional high-risk groups, endemic countries and additional NTDs.
- XCompanies can consider making commitments towards NTD long-term donation programmes for upcoming products in the pipeline.
- XMore companies can publicly endorse the Kigali Declaration, to demonstrate their commitment to the control, elimination and eradication of NTDs.
- XCompanies can increase investment in research and development for developing new technologies for treating NTDs. (For more details see Research and Development sub-chapter on p.37).
- XCompanies can work with global stakeholders or partners beyond WHO to explore avenues for sustainable funding for procurement, supply and last-mile delivery.

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SUPPLY, QUALITY & MANUFACTURING

Pharma's essential role in ensuring a steady supply of medicines in LMICs

Pharmaceutical companies play a critical role in ensuring that medicines reach patients safely, effectively and in a timely manner. Their role extends beyond just manufacturing, particularly in low- and middle-income countries (LMICs) where supply chains can be complex and fragmented (see supply chain graphic on p.100).[1] To ensure a steady supply of medicines in these settings, pharmaceutical companies can collaborate with and support various stakeholders, including governments, national regulatory authorities, healthcare facilities, central medical stores, non-governmental organisations and the private sector, all of whom play critical roles in managing the various processes surrounding the supply of medicines. These processes include regulation (i.e., market authorisation, licensing and post-market surveillance), building health system capacity (i.e., infrastructure, workforce), supply chain management (i.e., procurement, proper storage and distribution networks), affordability and pricing strategies as well as patient awareness and empowerment.

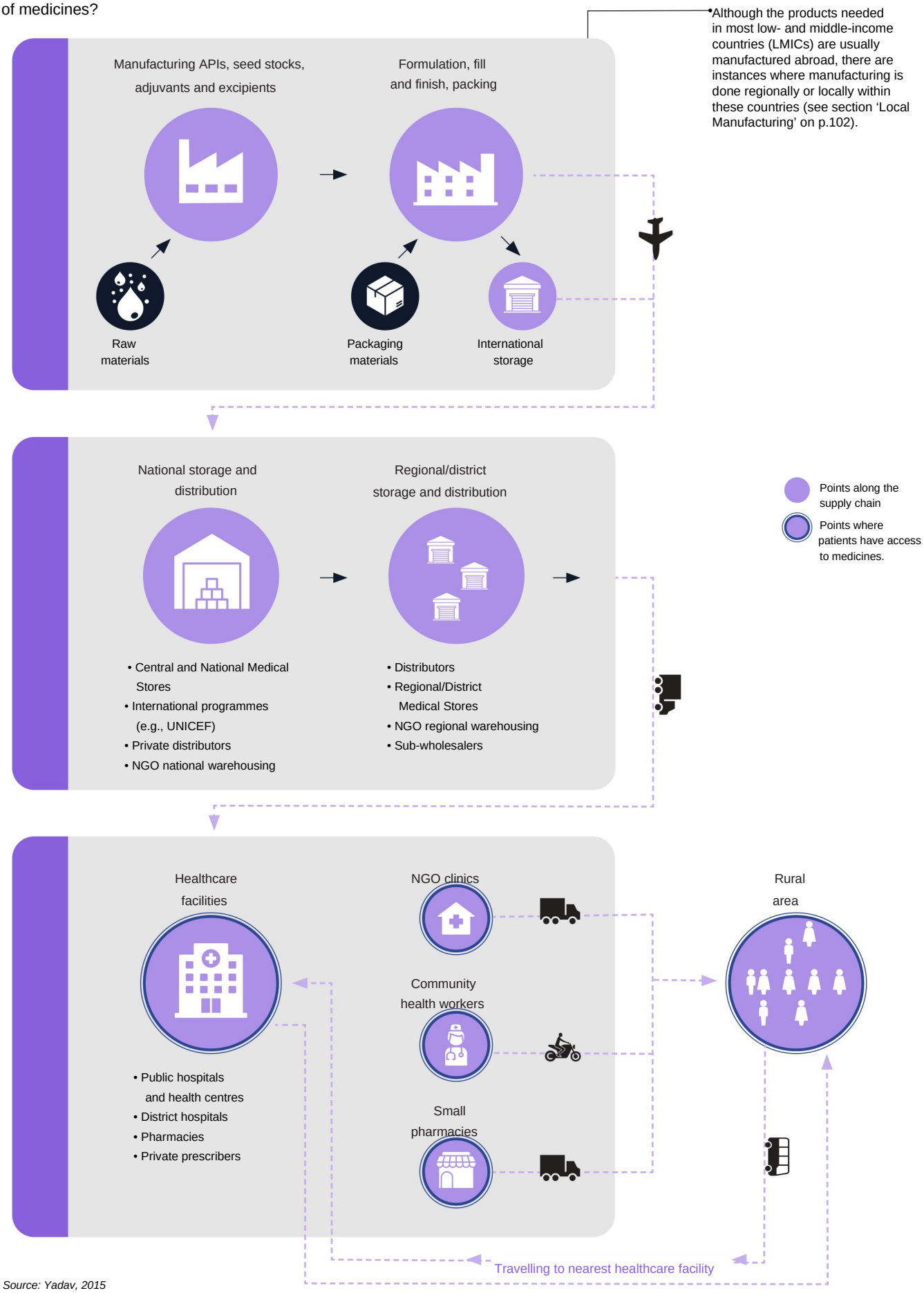
Much of the recent discussion on ensuring continuous supply of medicines in LMICs has included localisation of supply chains and development of domestic manufacturing capabilities. In fact, local manufacturing as a strategy to expand access to quality-assured products has gained significant traction, especially in Africa. In 2005, the African Union Development Agency (AUDA-NEPAD) initiated the Pharmaceutical Manufacturing Plan for Africa, which was further generated into a Business Plan by the African Union in 2012.[2] Since then, donors, international organisations, regional bodies and individual countries have all demonstrated significant efforts to advance local manufacturing. These stakeholders are making financing available, developing strategies for ensuring predictable demand and are working towards developing a strong regulatory framework for local manufacturing. That said, pharmaceutical companies are contributing to local manufacturing efforts with varying degrees of engagement (see section ‘Local manufacturing’ on p.102).

PHARMACEUTICAL COMPANIES PLAY A LARGE ROLE IN QUALITY ASSURANCE

In addition to timely supply, stakeholders across the supply chain are responsible for ensuring quality assurance to protect patient’s lives, uphold healthcare credibility and ensure that resources are not wasted. The World Health Organization (WHO) defines pharmaceutical quality assurance (QA) as the sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe, effective and acceptable.

As suppliers of essential health products, pharmaceuti cal companies hold responsibility for both the upstream and downstream aspects of QA. Upstream, this includes upholding quality standards of suppliers of raw materials, active ingredients and excipients. Downstream, this includes ensuring internal and third-party manufacturing processes adhere to Good Manufacturing Practices, ensuring that distributors adhere to Good Storage and Distribution Practices, conducting post-market surveillance and managing product recalls and implementing corrective actions as needed.

What are companies doing along the supply chain to ensure continuous supply of medicines?



Source: Yadav, 2015

2.

Preparing buffer stocks to address importation challenges

Buffer stocks are a reserve or surplus quantity of essential materials, components, or finished products that a company maintains as a safeguard against potential disruptions in the supply chain. AstraZeneca reports that as a result of the military build up on the Russia/Ukraine border in late 2021, the company built up a 60-day buffer stock for the Ukrainian market and created additional storage at sites in a distribution centre in Hungary. These stocks were used at the beginning of the war when importing medicines into Ukraine was not possible. The company reports that it has maintained this level of buffer stock throughout the war, resulting in no stock outs impacting patients.

1. 2.

Setting up and training partners in a multinational storage and distribution network

Merck's Go-To-Marketmodel was launched in 2023 and aims to reduce stockouts and improve distribution to 21 African countries in scope, such as Ethiopia, Guinea, Madagascar and Senegal. Merck is partnering with a local third party, that has two distribution centres in Botswana and Kenya, and will be responsible for distribution and storage. Merck is conducting a knowledge transfer of Good Distribution Practices, demand forecasting and inventory management. The company holds monthly meetings with the partner to align and plan for geographic expansion, portfolio expansion, knowledge transfer and product knowledge. As a next step, Merck reports that local manufacturing capacity will be assessed.

HEALTHCARE DELIVERY

Improving pharmacy stock management and setting up additional dispensing sites

Through a 2023 partnership between its Global Health Unit, Touch Foundation and the Ministry of Health in Tanzania, **Sanofi** is working on an initiative aiming to improve supply of and adherence to cardiovascular and diabetes medicines in the country. Partners are designing training packages to help pharmacies improve stock management and ordering. They are also working with the NCD Alliance to develop a framework on additional dispensing sites such as small private pharmacies to be involved in dispensing medicine to communities. Sanofi reports that within two years the initiative will reach 28 facilities and train 84 staff members nationwide. Sanofi reports that the initiative has led to a 20% increase in availability of hypertension and diabetes medicines across eight facilities.

1. MANUFACTURING

HEALTHCARE DELIVERY

Using track-and-trace to gauge needs and reduce circulation of counterfeit products

In September 2022, as part of 'An Accord for a Healthier World', **Pfizer** collaborated with the Ministry of Health in Rwanda to develop a traceability system to track Pfizer products from manufacturing site to the patient. The aim is to reduce the circulation of counterfeit medicines and help governments understand and plan for community needs. As of March 2024, Pfizer has tracked seven products in Rwanda and is planning to expand to more countries with the goal to expand to all 45 Accord-eligible countries.

HEALTHCARE DELIVERY

Partnering to deliver to rural communities using temperature-controlled drones

Pfizer has worked with Zipline since 2021 to deliver temperature controlled COVID-19 vaccines, including from other manufacturers, to rural Ghana. As of February 2024, 3.5 million COVID-19 mRNA vaccine doses from various manufacturers were delivered. In late 2023, Zipline signed a new partnership agreement with the Pfizer Foundation whereby the Pfizer Foundation will provide USD one million in funding over the next two years to create vaccination dosing sites in conflict-affected parts of Nigeria, which are home to millions of children who have not received any routine vaccinations. Since July 2023, **Boehringer Ingelheim** has also partnered with Zipline to deliver rabies vaccines in two counties in Kenya.

LOCAL MANUFACTURING CAN HELP FACILITATE SUSTAINABLE ACCESS

Particularly in the aftermath of the COVID-19 pandemic, donors and governments have been sharply focused on the role of local manufacturing as a way to mitigate supply risks for essential health products. The supply chain disruptions during this global health crisis, coupled with sudden shifts in demand and overreliance of imports, left many countries with limited or no access to essential healthcare products.

WHAT IS LOCAL MANUFACTURING?

The Access to Medicine Index aligns its definition of local manufacturing with the definition proposed by Unitaid and others.[3]

Who

Local manufacturing covers both companies manufacturing products in their own facilities in LMICs, as well as transferring technology to third parties (e.g., generic manufacturers and contract manufacturers) to manufacture essential health products such as medicines, vaccines and diagnostics.

Where

Locally manufactured products, as defined by the Index, include products that are supplied domestically, but also regionally and continentally.

What

The Index's definition of local manufacturing covers all steps of the manufac turing process including active ingredients, seed stocks, adjuvants, excipients and finished products.

While progress is being made, bolstering local manufacturing remains a multifaceted challenge that requires action and resources from various stakeholders. This includes investments to set up and expand manufacturing facilities and technology; ensuring adequate demand for locally produced medicines; strengthening health systems and supply chains; developing comprehensive policies to promote local production; and sufficient financial and regulatory capacity to uphold quality and support regional access.

Recent developments in local manufacturing

Since 2020, there have been several developments in local manufacturing, particularly in Africa. The page that follows sets out a timeline of some of the key developments, followed by the Index analysis of what pharmaceutical companies are doing to contribute to local manufacturing.

Recent developments in local manufacturing

2020
- The World Health Organization (WHO) granted regulatory authorities in Ghana and Vietnam with Maturity Level 3 (ML3)[4] signifying that they are stable, well-functioning, integrated and capable of effective oversight and quality assurance.

2021
- Treaty that established the African Medicines Agency (AMA) came into force to facilitate regulatory harmonisation across the African Union (AU).
- Under the Africa Centres for Disease Control and Prevention (Africa CDC), the AU launched the Partnership for African Vaccine Manufacturing to enable the African vaccine manufacturing industry to produce 60% of vaccine doses required on the continent by 2040.[5]
- The mRNA vaccine technology transfer hub was initiated by WHO, the Medicines Patent Pool (MPP) and the Act-Accelerator/ COVAX, with Afrigen in South Africa established as its headquar ters. The aim of the hub is to build capacity in LMICs to manufac ture mRNA vaccines through a centre of excellence and training.

2022
- WHO granted regulatory authorities in China, Egypt, Nigeria and South Africa with ML3[4] signifying that they are stable, well-functioning, integrated and capable of effective oversight and quality assurance.

2023
- The Africa CDC announced a pooled procurement mechanism, as man dated by the AU, to create predictable demand for medicine, enabling local manufacturers to make long-term plans.[6]
- The government of Canada and the Pan American Health Organization (PAHO) announced an initiative to strengthen vaccine manufacturing capacity in Latin America and the Caribbean.
- The Bill and Melinda Gates Foundation (BMGF)[7] announced new invest- ments in initiatives aiming to bolster mRNA vaccine manufacturing and access in LMICs.
- Board of Gavi, the Vaccine Alliance, approved the African Vaccine Manufacturing Accelerator,[8] an innovative financing instrument, aiming to support manufacturing of Gavi-supported vaccines in Africa.
- Between late 2023 and mid-2024, countries, including Kenya,[9] Nigeria,[10] Ethiopia,[11] Indonesia[12] and Vietnam[13] launched initiatives and targets aiming to develop domestic manufacturing capabilities.

2024
- Unitaid[3] made financial resources available to invest in local and regional manufacturing efforts in Africa for postpartum haemorrhage, malaria and HIV products.
- WHO granted Zimbabwe's national regulatory authority with ML3, signifying that it is stable, well-functioning, integrated and capable of effective oversight and quality assurance.
- In June, Cote d'Ivoire deposited its instrument of ratification for the treaty establishing the AMA, making it the 29th country of 55 AU member states to do so.
- AUDA-NEPAD, through a stakeholder consultation on continental priori ties, identified 24 priority products for local manufacturing in Africa.

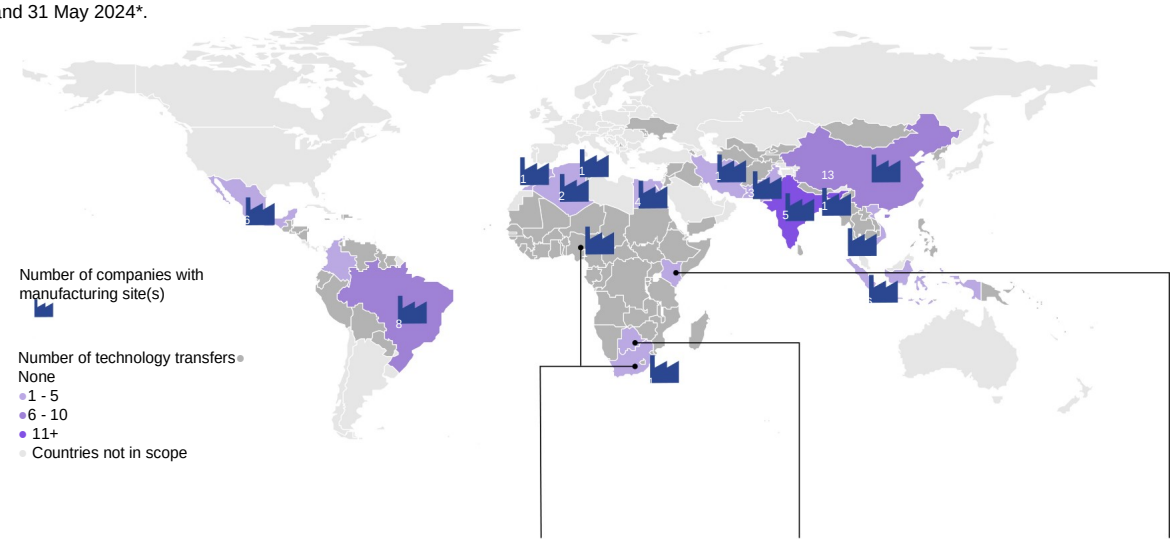
How pharmaceutical companies are contributing to local manufacturing

Pharmaceutical companies' vast resources, knowledge, expertise and capacity are invaluable in helping to expand manufacturing capacity in LMICs. Overall, companies are providing financial resources, infrastructure and know-how to expand manufacturing capacity; however, these efforts continue to be concentrated in specific countries and limited in scale. A consistent finding over the last three Index cycles (1 June 2016 to 31 May 2024) is that technology transfer initiatives of companies in scope in LMICs continue to focus on India (11 of 47 technology transfers), Brazil (9 of 47 technology transfers) and China (7 of 47 technology transfers). China (13 of 20 companies) and Brazil (8 of 20 companies) are where most companies have their own manufacturing sites for products addressing diseases in scope, followed by Indonesia (6 of 20 companies), Mexico (6 of 20 companies) and India (5 of 20 companies). No technology transfers were reported in the European and Central Asian countries within the scope of the Index. These countries may rely on imports and/or partner with generic manufacturers for technology transfer.

Relative to the higher disease burden compared to other regions, companies in scope have the fewest manufacturing efforts in sub-Saharan Africa – including technology transfers and company manufacturing sites (see Figure 1). Even though sub-Saharan Africa bears 20%[14] of the global disease burden by disability-adjusted life years (DALYs), countries in this region rely on imports for 70-90% of pharmaceutical products.[15] Of the companies in scope of the Index, six – Boehringer Ingelheim, Gilead, Merck, Novo Nordisk, Pfizer and Sanofi – have technology transfer initiatives in the region. These initiatives are mostly focused in South Africa (5 of 47 initiatives).

FIGURE 1 Companies' manufacturing efforts overlook sub-Saharan Africa

This map shows, for companies in scope of the Index, manufacturing sites and technology transfer initiatives that were active between 1 June 2022 and 31 May 2024*.



Bayer has manufacturing sites in Nigeria and South Africa for over-the-counter products.

Boehringer Ingelheim has part nered with the Botswana Vaccine Institute (BVI) to distribute its veterinary rabies vaccine (Rabisin®) in sub-Saharan Africa.

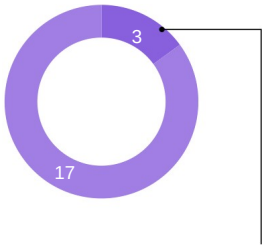
Merck is partnering with Universal Corporation Ltd. in Kenya in a tech-nology transfer for formulation and packaging of its schistosomiasis treatment, arpraziquantel for supply to endemic countries in Africa.

* This figure includes five technology transfers addressing diseases such as polio and multiple sclerosis, which are not in scope of the Index. It also includes three technology transfer initiatives that are ongoing during the period of analysis but not analysed as part of an individual company's performance due to limits to the number of initiatives that can be included for analysis.

Transferring technology promotes availability as well as local ownership and knowledge

When a pharmaceutical company transfers knowledge, tools and/or technology necessary for producing a specific product (e.g., medicine, vaccine) to local manu facturers in LMICs, it provides an opportunity for upskilling and qualifying additional manufacturing sites, preparing them for cooperation in regional and international supply chains and scaling up access to products. It also helps to ensure that the capacity built is locally owned, sustainable and can be applied to other products beyond those in a single company's portfolio. Further, when companies prioritise technology transfer in countries with a high disease burden, they can help ensure that patients have faster and more reliable access to lifesaving medications.

FIGURE 2 Three companies do not engage in technology transfer initiatives in LMICs in scope



AbbVie, Astellas and Bristol Myers Squibb do not show evidence of engaging in technology transfer initiatives.

Technology transfer can support long-term partnerships

Technology transfer partnerships with a single company can serve as a catalyst for future collaborations, expanding into broader and more impactful industry relationships. By building expertise in the manufacturing of specific product types (e.g., biologics, vaccines, small molecules), companies can open the door to new partnerships, particularly for similar or related product types. For example, Bio Farma, an Indonesian manufacturer, initially partnered with Sanofi to manufacture its polio vaccine and more recently in 2024 formed a partnership with MSD for its HPV vaccine.

Overall, as set out in Table 1 on p.106, the Index finds that the most common partners across technology transfer initiatives are Brazil's Bio-Manguinhos/Fiocruz - Fundação Oswaldo Cruz (6 initiatives, 5 companies), India's Aurobindo (3 initiatives, 2 companies), Viatris through its operation in India (3 initiatives, 2 companies) and South Africa's Biovac (3 initiatives, 2 companies). Five companies, namely, Indonesia's Bio Farma, Algeria's BioPharm SPA, Egypt's EVA Pharma, India's Macleods Pharmaceuticals and Cipla, are each involved in two technology transfer initiatives with two companies. The remaining partners are engaged in one technology transfer each with a company in scope.

Companies in scope transfer technology for small molecules (28) in more initiatives than for vaccines (12) and other biologics (12), particularly in the Middle East and North Africa (81%). In Latin America, companies in scope transfer technology almost evenly between small molecules (40%), vaccines (30%) and other biologics (30%). Sub-Saharan Africa hosts a relatively large number of vaccine technology transfers (57%) compared to small molecules (29%) and other biologics (14%) but has fewer total initiatives. None of the companies engaged in technology transfers for diagnostics.

TABLE 1 Global partnerships for technology transfer

This table displays examples of manufacturers that companies in scope of the Index were actively partnering with through technology transfer between 1 June 2022 and 31 May 2024. The partners marked in bold are involved in more than one technology transfer. The table also displays the number of technology transfers for biologics, vaccines and small molecules per region. The product type is unknown for one technology transfer displayed in this table.

Region	Number of manufacturing support initiatives *(by product type)*			Partners (examples)
	V	B	S	
South Asia	2	4	7	• Aurobindo India (S) • Viatris, through its operation in India (S) • Cipla India (S) • Macleods India (S) • Bharat Biotech India (V)
Middle East and North Africa	0	2	9	• BioPharm SPA Algeria (S) • EVA Pharma Egypt (S) (B) • Minapharm Egypt (S) • Somedial Algeria (S)
East Asia and Pacific	3	2	6	• Bio Farma Indonesia (V) • POLYVAC, the Center for Research and Production of Vaccines and Biologicals Vietnam (V) • Gosun Ltd. – China (B)
Latin America	3	3	4	• Bio-Manguinhos/Fiocruz - Fundação Oswaldo Cruz Brazil (V) (S) (B)• Pharmetique Colombia (S)
Sub-Saharan Africa	4	1	2	• Biovac South Africa (V) • Botswana Vaccine Institute (V) • Aspen South Africa (B) • Universal Corporate Limited Kenya (S)
Europe and Central Asia	0	0	0	N/A

Product type(s) supported by ongoing technology transfer initiatives with companies in scope
(V) – Vaccine
(B) – Other biologic
(S) – Small molecule

Technology transfer can improve availability of medicines where disease burden is high

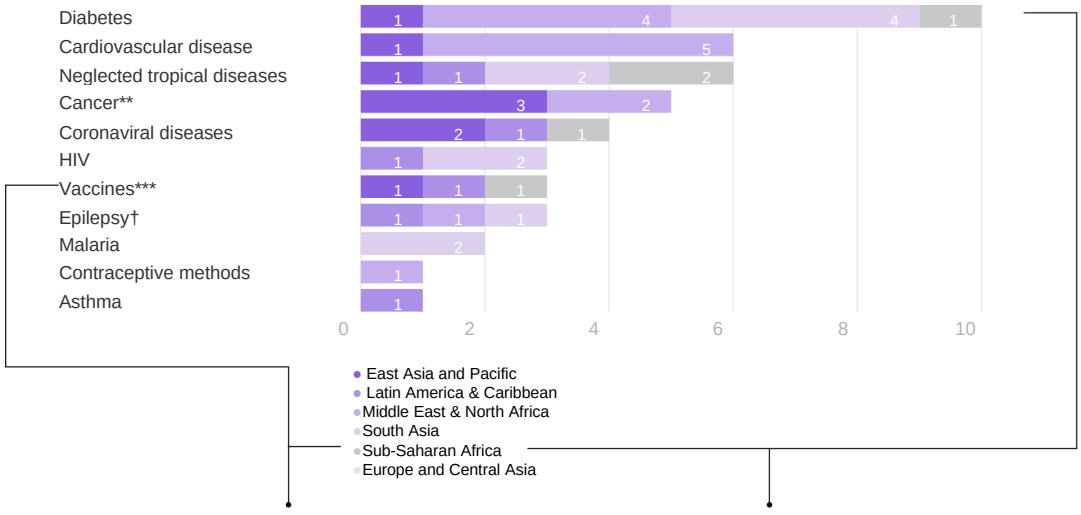
The most common disease addressed in the technology transfers in the 2024 Index are diabetes, cardiovascular diseases and neglected tropical diseases. For these diseases, two companies in scope, Takeda and Merck, are transferring technology to local manufacturers for domestic supply in countries ranked among the top ten with the highest DALY rates.[14]

X*Takeda is partnering with India's Biological E. Limited for its dengue vaccine QDENGA® (TAK-003) for supply in India and other endemic countries.*

X*In 2021, Merck signed a contract manufacturing agreement with Universal Corporation Ltd. in Kenya to manufacture a pediatric schistosomiasis treatment arpraziquantel, aiming to supply in endemic countries in Africa once the product is registered.*

Technology transfers for cancer are limited to countries in North Africa, East Asia and the Pacific, including Algeria, China, Egypt and Indonesia. Active technology transfer initiatives for vaccines and treatments for coronavirus are ongoing in Brazil, China and South Africa.

FIGURE 3 Large number of technology transfers focused on diabetes
This figure shows the number of technology transfer initiatives per disease per region. The data comprises technology transfer initiatives of companies in scope of the Index that were active between 31 May 2022 and 24 June 2024.*



Sanofi has an ongoing partner-
ship with Biovac in South Africa
to fill-and-finish/package its

paediatric combination
vaccine (Hexaxim®) to supply to the national immunisation
programme.

Novo Nordisk is transferring technology to South African manufacturer Aspen to fill and finish human insulin vials. The collaboration aims to supply over one million patients on the African continent in 2024.

* Three technology transfer initiatives include two products, so they are counted twice. Seven initiatives were not included because they have an undetermined disease scope or address a disease that is not in scope of the Index. Gilead's technology transfer agreements through its voluntary licensing programme for HIV and Hepatitis C are not included because it is unclear what agreements are ongoing during the period of analysis in which countries.

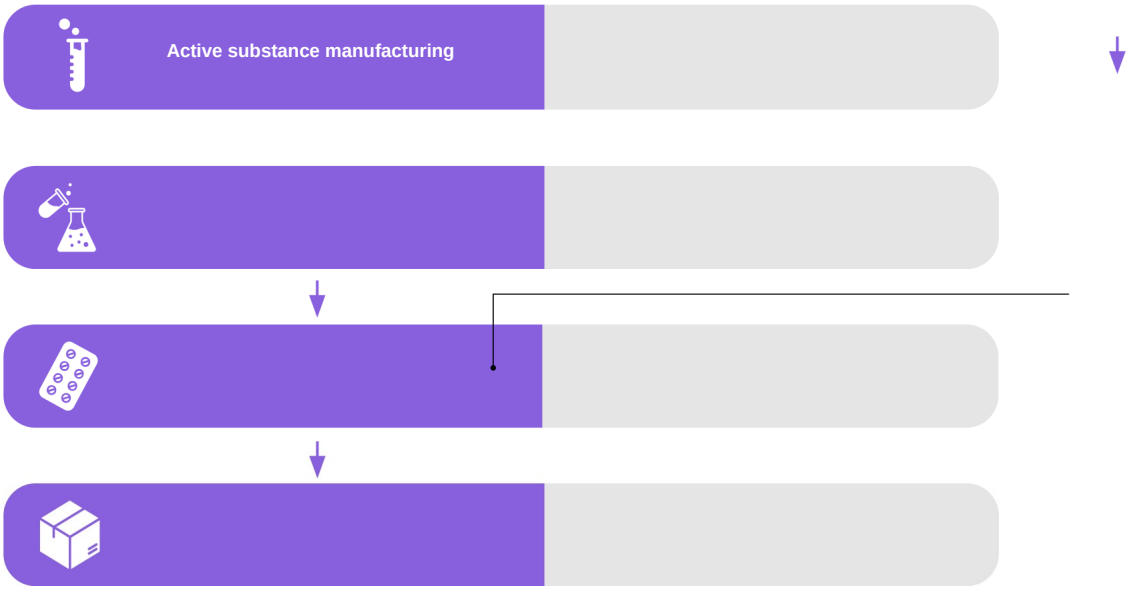
** Includes human papillomavirus vaccine to prevent cervical cancer.

*** Non-coronaviral vaccines, including those for measles, meningitis, diptheria, tetanus, rotaviral gastroentitis, lower respiratory diseases, pertussis and hepatitis B.

† One of the products is also indicated for bipolar effective disorder.

Transferring technology for ‘end-to-end’ manufacturing can reduce supply risks
Technology transfer partnerships can take various forms, with skills and technology transferred allowing third-party manufacturers to perform different steps of the manufacturing process (see Figure 4). Supporting local manufacturers to perform additional steps of the manufacturing process (i.e., API manufacturing, formulation) can mitigate risks caused by having limited suppliers and ultimately lead to enhanced availability of medicine regionally.

FIGURE 4 Steps of the manufacturing process



Synthesising and purifying active substances

Active substances combined with excipients to create a stable dosage form

Formulation transferred into (e.g., vials, syringes, blister packs, sachets) and labelled

‘Fill and finish’ is a term typically used to describe vaccine and injectable manufacturing. On the other hand, primary packaging relates to product types like tablets and sachets.

Outer packaging is applied and labelled, grouping primary packaging together (e.g., cartons, boxes)

The 2024 Index finds that nine of 47 technology transfer initiatives (19%) cover API manufacturing, with all taking place in either Brazil, China or India. Gilead reports that it conducts full technology transfer, including API manufacturing, for its hepatitis C and HIV products in Egypt, Pakistan and South Africa. However, it is unclear for which countries and products the transfers are ongoing during the period of analysis. API synthesis is often complex and requires significant infrastructure, technology and know-how, meaning that qualifying new API manufacturers in additional countries can be costly. However, relying on a limited set of countries poses supply threats if there are disruptions or demand fluctuations.

Only two companies engage in more comprehensive technology transfers in sub-Saharan Africa

None of the nine technology transfers that support API manufacturing take place in sub-Saharan Africa. For later stages of manufacturing like formulation, fill and finish and packaging, only two examples are ongoing in sub-Saharan Africa that support the formulation process for two products. The first is Merck's partnership with Universal Corporation Ltd. (discussed previously on p.105). Although it does not address a disease in scope, the second is a technology transfer agreement, signed in 2024 by Sanofi, with South Africa's Biovac to manufacture and supply Sanofi's polio vaccine in Africa through UNICEF. The remaining technology transfer initiatives in sub-Saharan Africa are fill and finish operations in Botswana and South Africa for products like human insulin and vaccines. The gap in full manufacturing technology transfers in the region underlines a potential supply risk, and an area where additional investment is needed.

NEXT STEPS

Companies assessed by the Index vary in their approach to ensuring supply of products in LMICs. Most companies engage in technology transfer, but their initiatives are concentrated in a fixed list of countries, that also often host company manufacturing sites. Companies' technology transfer initiatives are concentrated on small molecules which are relatively simpler to produce. Decisions on regions for technology transfer are rarely informed by disease burden, except for two companies.

As momentum builds for strengthening supply chains in Africa, company efforts in this area lag, especially in sub-Saharan Africa. As the impact of the country commitments, funding and policy changes unfold, pharmaceutical companies can help drive progress by:

- Investing resources in private sector manufacturing partners to ensure access to sustainable financing and help build resilient supply chains.
- Increasing investments and collaboration with stakeholders along the supply chain in LMICs. This includes capacity-building efforts, such as training in storage and distribution, partnerships (e.g., universities) for workforce development and building infrastructure (e.g., cold chain, warehousing).
- Integrating technology transfer partnerships into company strategies for product access in LMICs, alongside activities in areas, such as expanding registration and pricing strategies. This includes supporting API manufacturing, as well as fill and finish and packaging operations.
- Actively participating in harmonisation initiatives with local and regional regulatory authorities that aim to increase availability of medicines.
- Work in partnerships for product manufacturing, including public-private partnerships and consortia to pool funding and resources and accelerate product availability.

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CHAPTER 3

BEST PRACTICES

GOVERNANCE OF ACCESS

RESEARCH & DEVELOPMENT

PRODUCT DELIVERY

Best Practices in the 2024 Index

The 2024 Access to Medicine Index has identified eight ‘Best Practices’ across the three Technical Areas. There is one in Governance of Access, one in Research & Development, and six in Product Delivery. Some of these focus on a single company, while others draw on examples from several companies.

The aim of a Best Practice

The diffusion of Best Practices is one of the Access to Medicine Index’s mechanisms for supporting the pharmaceutical industry in achieving greater access to medicine. Best Practices are shared to accelerate adoption of similar practices by other companies, and to help raise the overall level of standard practice. Furthermore, recognising those companies trialling or scaling up innovative, unique policies or initiatives is an important way of acknowledging companies that stand out from peers and are willing to risk new approaches to expand access to their products in low- and middle-income countries (LMICs).

What defines a Best Practice in the Index?

Best Practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best Practices are not new practices – they have already been conceived of, applied and proven to meet at least some of the following criteria:

- Sustainability
- Replicability
- Alignment with external standards/stakeholder expectations
- Proven effectiveness

In different Technical Areas within the Index (for example, in Research & Development vs. in Governance of Access), the way in which a Best Practice is identified may be different. Best Practice need not be unique among companies; it might be an example of a ‘gold standard’ of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations.

Best Practices should be considered as an exemplar of positive practices in the corresponding Technical Area in comparison to those of the other companies that submitted data within the current period of analysis. These Best Practices are identified based on evidence of progress submitted in the data collection period and verified with public information and through consultation with experts, where appropriate.

How Best Practices were selected for the 2024 Index

To determine which of the company’s practices would be highlighted as Best Practice, the Foundation’s Index Research Team evaluated all aspects of company practices, compiling those that met the criteria used for the purpose of scoring with additional standards for each Technical Area, where necessary. Company practices that met these outlined criteria were reviewed and finalised by the Foundation’s senior management with additional input from experts in the corresponding field, when required.

GOVERNANCE OF ACCESS – RESPONSIBLE BUSINESS PRACTICES

GSK voluntarily discloses information about transfers of value to healthcare professionals

GSK

Location: Algeria, Dominican Republic, Ecuador, El Salvador, Egypt, Guatemala, Honduras, Jamaica, Morocco, Thailand and Vietnam

Focus: Promoting high ethical standards for engaging with healthcare professionals (HCPs) in low- and middle-income countries (LMICs) by publicly disclosing information on transfers of value

Action: Demonstrating responsible business practice by voluntarily disclosing information on transfers of value to HCPs in LMICs, despite the absence of any legal obligation or regulatory requirement

Aim: To uphold high ethical standards engaging with HCPs in LMICs by publicly disclosing information on transfers of value, promoting transparency and fostering accountability

When companies publicly declare their transfers of value to HCPs, they demonstrate transparency, increasing account

Best Practice

GSK demonstrates best practice by being the only company to proactively and voluntarily disclose information related to transfers of value in countries in scope of the 2024 Index.

Notably, it discloses voluntarily for LMICs where there is no legal mandate or requirement in place*. While other companies in scope disclose their transfers of value to HCPs, they do so only when mandated by local law or regulation.

GSK goes beyond the minimum obligation of compliance, upholding a high ethical standard in its interactions with HCPs in LMICs. In this, the company shows a strong commitment to responsible business practices.

On its website, GSK discloses the transfers of value it makes to HCPs in countries where it operates, including 11 LMICs in scope that do not mandate such disclosures: Algeria, Dominican Republic, Ecuador, Egypt, El Salvador, Guatemala, Honduras, Jamaica, Morocco, Thailand and Vietnam. The company also details its cumulative payments and includes averages paid per HCP where such information is legally permitted.

ability in their interactions with HCPs and building trust in healthcare systems. Transfers of value can be financial or non-financial and relate to fees for services (for instance, speaking at conferences or symposia), sponsorship agreements, travel expenses, grants and research funding, among other activities.

Public disclosure of transfers of value diminishes the likelihood that pharmaceutical companies improperly or unduly influence

Conclusion

HCPs to prescribe certain medications and, in turn, affect whether patients obtain the medicines they need. This also helps lessen the risk of any additional costs for treatment (overspending on unnecessary or inappropriate prescriptions,

The Index encourages all companies to make proactive, voluntary disclosures of transfers of value to HCPs, and not just when required to do so. To promote transparency and accountability while demonstrating the highest level of commitment to responsible business practice, companies should disclose transfers of value to HCPs that relate to all countries in which they operate, regardless of legal obligations or regulatory mandates.

for example) on an already strained healthcare budget, which is often the case in LMICs.

In Europe and the US, pharmaceutical companies are required to disclose such transfers of value. Under the respective legislations, the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code and the Sunshine Act, companies must publish annual disclosure reports that detail payments and transfers of value made to HCPs. In LMICs, where healthcare systems may not be as robust and disclosure is not always mandated, there is a greater risk that HCPs will be vulnerable to inappropriate transfers of value from companies through their sales agents or marketing representatives.

For a more detailed analysis of companies' responsible business practices, see p.32 in the Governance of Access sub-chapter.

*Includes and is not limited to adherence to codes for e.g., the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice and European Federation of Pharmaceutical Industries and Associations (EFPIA).

RESEARCH & DEVELOPMENT – ACCESS PLANNING

Novartis targets R&D gaps for antimalarials with access plans for its late-stage projects that are superior in quality and breadth

NOVARTIS

Location: Eighteen countries, including Burkina Faso, Democratic Republic of the Congo, Côte d'Ivoire, Ghana, Gabon, India, Kenya, Malawi, Mali, Mozambique, Niger, Nigeria, Rwanda, Tanzania, Thailand, Uganda, Vietnam and Zambia

Focus: Projects addressing research and development (R&D) gaps for malaria

Action: Product development with novel mechanisms, accompanied by robust access plans

Aim: To develop products to address R&D gaps for malaria, and planning to ensure these products reach people living in low- and middle-income countries (LMICs) soon after market approval where the burden of disease continues to exist

Malaria is among the world's most severe public health problems. Nearly half the global population (mostly living in lower-income countries, especially people in sub-Saharan Africa) is at risk of infection. Globally, in 2022, there were an estimated 249 million malaria cases, and 608,000 deaths caused by the disease.[1]

While huge strides have been made in developing anti-malarial drugs, all combination therapies for uncomplicated

Therapy (ACT) in 1999. It currently has six projects in late-stage clinical development and three stand out for their relevance, importance and quality of access plans.

The first, ganaplacide + lumefantrine (KAF156), tests a novel non-artemisinin combination treatment for uncomplicated malaria. Following successful outcomes from Phase II trials, it progressed to Phase III during the period of analysis.

The second is the development of a new IV formulation of cipargamin (KAE609) to treat severe malaria, for which the primary treatment is already prone to resistance. Both candidates are being tested in adults as well as children, who are often neglected in access planning. Novartis' third project addresses a significant gap in treating young infants with malaria, for whom no evidence-based therapy exists.

Its Phase II/III CALINA study tested a new formulation of artemether-lumefantrine (Coartem®) for neonates and infants weighing less than 5 kilograms, and Novartis has since submitted positive data for regulatory review.

For the three above-named late-stage candidates, Novartis has developed access plans that address countries where malaria is endemic. The plans include countries in sub-Saharan Africa and Asia with the highest burdens of malaria, consider socioeconomic and contextual barriers to access (looking to work with potential procurers, for example) and focus on building capacity to help researchers in LMICs carry out their own R&D.

malaria recommended by the World Health Organization (WHO) contain the drug artemisinin.[2] This critical drug is susceptible to emergent resistance, with resistant parasites causing over 10% of cases in some parts of Africa.[3] As such, R&D to develop next-generation antimalarials is urgently

Novartis' robust access plans are underscored by its collaboration with partners working to combat malaria, including its participation in consortia, such as WANECAM2 (West African Network for Clinical Trials of Antimalarial Drugs) and PAMAfrica, as well as its ongoing work with partners, such as needed.

To make the biggest impact on malaria and combat drug resistance, companies must plan for access to products in

Medicines for Malaria Venture, among others.

countries with the greatest burden of disease. Planning early, when drugs are still in clinical development, will ensure they can be made available quickly once approved.

Conclusion

While there are treatments for malaria available, the scale of cases and spread of resistance to current treatments calls for further action. It is essential for originator companies to develop alternative treatments, and importantly, develop com

Best Practice

Ten companies in scope of the Index have a total of 35 malaria R&D projects in the pipeline. Novartis demonstrates best practice, with more projects in development (10) than any other company that addresses current R&D gaps for malaria, including novel treatments and one trial in a new population

prehensive plans to ensure access after products are approved.

Whether for products for malaria or other diseases, all companies should consider how to engage with partners to identify R&D gaps and aim to address unmet healthcare needs of the world's most vulnerable populations, especially in LMICs.

(paediatric). Moreover, its access plans – particularly for late-stage projects – are superior in quality and breadth to those of its peers.

Novartis has a long history in malarial product development, launching the first fixed-dose artemisinin-based Combination

For a more detailed analysis of companies' access planning covering late-stage R&D projects, please refer to p.47 of the Research & Development sub-chapter.

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PRODUCT DELIVERY – INTELLECTUAL PROPERTY

MSD shares high-value intellectual property assets to accelerate drug development for tuberculosis

MERCK & CO (MSD)

Location: Global

Focus: Developing novel antibacterial compounds to treat tuberculosis (TB), including drug-resistant strains

Action: Granting the Bill & Melinda Gates Medical Research Institute (Gates MRI) an exclusive global licence to conduct non-clinical and clinical studies on two antibacterial candidates, to evaluate efficacy for inclusion in new affordable combination TB treatment regimens

Aim: To develop shorter, more effective regimens to simplify treatment and improve outcomes

Developing new drugs can often be challenging, time-consuming and uncertain. However, companies hold a wide array of intellectual property (IP) assets, which are valuable for product development, from unpublished clinical trial data to libraries of target-specific compounds.

When companies share these high-value assets for advancing drug development transparently with access--oriented organisations, it can reduce duplication of efforts and accelerate research and development of potential treatments that, if proven successful, can target diseases with high

Best Practice

TB is preventable and curable but remains one of the leading infectious causes of death globally. In 2022, it affected 10 million people and caused 1.3 million deaths worldwide. More than 80% of cases and deaths are in LMICs, mostly concentrated in 30 countries that face a disproportionately high burden of TB.[1] Organisations, including the World Health Organization (WHO) and Impact Global Health (formerly Policy Cures Research), have identified critical research gaps in product development for TB, such as the need for new treatments, more effective vaccines, and improved diagnostics.[2,3]

Late in 2022, MSD announced an exclusive global licensing agreement with the Gates MRI for two preclinical candidates (MK-7762 and MK-3854). These were discovered by MSD scientists as part of the TB Drug Accelerator, a collaborative effort to create innovative therapeutic options.

Under the agreement, MSD will provide IP and Gates MRI will conduct non-clinical and clinical studies to evaluate candidates' efficacy for new combination treatment regimens. With the burden of TB rising rapidly, and multidrug-resistant TB a major health challenge, leveraging expertise and resources could help MSD and Gates MRI tackle these issues and develop shorter, more effective and affordable regimens.

Furthermore, such partnerships can improve access to these medicines in low-and middle-income countries (LMICs) once the drugs are approved, serving to improve global health outcomes in the long term.

Additionally, MSD publicly discloses information about its IP-sharing agreement on its website, supporting collective efforts in drug development.

In 2008, GSK already demonstrated that IP sharing could create a substantial impact when it partnered with Medicines for Malaria Venture (MVV) to develop tafenoquine as an anti-relapse medicine for Plasmodium vivax malaria.

Conclusion

This collaboration led to increased availability of effective treatments in areas that faced a high burden of malaria.

By sharing high-value IP assets that target TB, one of the world’s primary infectious killers, MSD aligns with global health priorities and stakeholder expectations and the company is helping to maximise the potential to develop affordable treatment regimens for TB, including drug-resistant strains.

More recently, as identified in this iteration of the Index, GSK has newly engaged in 17 IP-sharing agreements with public research institutions and drug discovery, which include assets of high value during the period of analysis. However, GSK shares information under a non-disclosure agreement.

MSD demonstrates best practice in the 2024 Index by sharing its high-value IP assets, two antibacterial candidates targeting TB, with an access-oriented organisation and - maintaining transparency about the process.

1. World Health Organization. Tuberculosis. Published November 7, 2023. Accessed

Companies can emulate MSD's transparent approach of sharing high-value IP assets for potential drug candidates that could address product gaps for specific diseases. By collaborating with access-oriented organisations in this way, pharmaceutical companies can help speed up drug development, which could in turn result in new, innovative, much-needed treatments making it to market in LMICs.

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PRODUCT DELIVERY – INCLUSIVE BUSINESS MODELS

Comprehensive inclusive business models to provide more sustainable access in LMICs

BRISTOL MYERS SQUIBB, NOVARTIS, NOVO NORDISK, PFIZER, SANOFI

Location: Global

Focus: Inclusive business models

Action: Launching comprehensive inclusive business models covering broad geographic and product scopes

Aim: To sustainably improve access to a portfolio of products for people living in low- and middle-income (LMICs)

Commercial business models that are designed for higher-income markets are not well-suited for implementation in LMICs. Insufficient infrastructure, lack of equipment, or insufficient healthcare worker training can present challenges for pharmaceutical companies in these countries. As

model covers 85 LMICs, including 32 LICs and/or least developed countries, with nine mostly on-patent products addressing diseases in scope (beta thalassemia, cancer and viral infections). The company has launched tailored product access strategies (e.g., second brands), managed access programmes and health system strengthening efforts to improve access to its products. ASPIRE contributes to Bristol Myers Squibb's aim to reach over 200,000 people by 2033.

Novartis established its Sub-Saharan Africa Business Unit in 2019. The unit covers 44 countries in scope of the Index, including 30 LICs and/or least developed countries, and includes 12 products* in scope of the Index (for diabetes, cardiovascular diseases, cancer, malaria, neurology and sickle cell disease). Through the Unit, Novartis uses approaches, such as tiered pricing, second brands, investment in social business and health system strengthening to address access barriers.

an alternative, companies have attempted to address access issues through philanthropic approaches, which can be appropriate for certain circumstances, but may not offer long-term solutions to access barriers, especially on their own.

In order to achieve reliable access to medicines in countries where their products are needed, companies can invest in establishing more sustainable approaches that are tailored to specific markets. By design, inclusive business models aim to be more financially sustainable for companies than philanthropic or donation-based approaches, while also providing more long-term and comprehensive solutions that can ensure the most vulnerable populations, especially those living in low-income and least developed countries, can receive the healthcare products they need.

Novo Nordisk's iCARE, launched in 2021, is part of the company's core business. It provides nine reduced-cost diabetes products in 46 countries in scope of the Index in middle Africa, including 33 LICs and/or least developed countries. Affordability is addressed through partnerships with governments, religious and supply organisations. The model also addresses health system capacity and patient empowerment through trainings, tele-counselling and community health events. Supply chain barriers are addressed through partnerships with e-pharmacies. iCARE aims to reach over two million people with diabetes by 2030.

Pfizer's Accord for a Healthier World (the Accord) was launched in 2022, offering 45 countries (including 40 LICs and/or least developed countries) all the company's current and future on- and off-patent products** that it has global

Best Practice

Working closely with local implementing partners, five companies – Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi – demonstrate Best Practice with their inclusive business models. These models address a comprehensive range of access barriers and have long-term plans for generating a sustainable source of revenue.

Notably, these models are also wide-reaching – committing to offer multiple products in a wide range of countries, including many low-income countries (LICs) and least developed countries. Other companies may have inclusive business models with a more limited scope or engage in targeted initiatives such as patient assistance programmes, -investments in social entrepreneurships or access-to-medicine

rights to on a not-for-profit basis. Through Accord bilateral agreements, Pfizer collaborates with governments to assess health system needs in order to: supply its medicines and vaccines; co-create solutions that can help strengthen supply chain and logistics; develop healthcare workforce capabilities; and enable more efficient regulatory pathways, as permitted by local regulation. The Accord is also collaborating with governments, global health organisations and others to identify opportunities to improve the quality of healthcare across the entire patient journey in key therapeutic areas (e.g. breast cancer and antimicrobial resistance). Pfizer aims to provide healthcare to 1.2 billion people through the Accord, although the company does not specify a timeline for accomplishing this.

strategies for specific products in their portfolios.

Bristol Myers Squibb's 2024 Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity (ASPIRE)

Sanofi’s Global Health Unit (GHU), launched in 2021, is a non-profit unit that reinvests its margins back into the

115 *In October 2023, Novartis completed the spin-off of Sandoz, delegating a large part of its generics portfolio in order to focus on innovative medicines.
**This includes 144 products addressing diseases in scope of the Index.

model to fund its operations. It provides 40 LMICs (including 35 LICs and least developed countries) with 29 products in scope of the Index indicated for non-communicable diseases (NCDs), such as diabetes, cancer and cardiovascular disease as well as malaria and the neglected tropical disease and leishmaniasis. Through the GHU, Sanofi implements product access strategies (e.g., its second brand: Impact©), builds health system capacity and invests in local start-ups. Sanofi aims to provide care for 2 million people living with NCDs by 2030 through its GHU.

Conclusion

These companies demonstrate Best Practice by operat ing comprehensive inclusive business models with long-term plans for scalability. To foster partnerships and drive accountability and implementation, outcomes and progress must be reported transparently – something that is not done consistently at present. Companies without inclu sive business models can identify areas where their unique product portfolios can address significant access gaps for underserved or unserved populations and tailor long-term inclusive business models to address unmet needs.

For a more detailed analysis of companies' inclusive business models, please refer to p.85 of the Product Delivery sub-chapter.

PRODUCT DELIVERY – REGISTRATION

Widespread and swift registration of newer products is a critical step towards improved access

BAYER, NOVARTIS AND ROCHE

Focus: Newly approved products in company portfolios

Action: Registering products widely and rapidly in low- and middle-income countries (LMICs)

Aim: To ensure and expand availability of quality-assured health products in LMICs

New and innovative products typically aim to improve on existing therapies, making it crucial to ensure they are available to every patient who needs them – regardless of where they live. As the patent holders of such products, the companies analysed in the Index can determine where they are made available. To this end, registration serves as a - critical step to ensuring the availability of these quality-assured healthcare products for patients.

While high-income markets are commercially lucrative and

average. Inclisiran (Leqvio®), indicated for patients with high cholesterol, is now registered in 41 countries, compared to only five in the previous Index – an increase of 36 countries, including three low-income countries. Like Roche (see below), Novartis demonstrates good practice by widely registering its biologicals, which are more complex and variable, and which require different regulatory frameworks.[2] Roche registered its newer products in 30 countries on average, the most of any company assessed in the 2024 Index. Notably, its product pertuzumab/trastuzumab (Phesgo®), indicated for HER2-positive breast cancer, is registered in more countries in scope (52) than any other product approved within the last five years. Furthermore, Phesgo®has been registered in 28 additional countries (including four low-income countries) since the previous Index, making it one of the largest increases for any product assessed.

have established stringent regulatory authorities, registration may be more challenging in LMICs. However, with LMICs being home to nearly 80% of the world's population,[1] registering their newly approved products swiftly and widely in these countries can help companies ensure equitable access to their much-needed medicines. This is especially vital in LMICs where burdens of disease are high.

Conclusion

Registering in LMICs can be challenging. Although much more work is needed to improve registration efforts across the 113 LMICs in scope of the Index, Bayer, Novartis and Roche have successfully registered newer products more widely and quickly than other companies assessed. Their regulatory strategies have been effective, showing it is possible to expedite registration in LMICs, even with more complex biologic

Best Practice

Three companies – Bayer, Novartis and Roche – lead in registering their newer products widely in LMICs in comparison to their peers. The Index categorises newer products as those that

products. By submitting product dossiers for evaluation,

have received marketing authorisation within the last five years. Overall, these three companies outperform others - analysed in the Index by:

companies can also help to build capacity and expertise in regulatory authorities in lower-income countries.

It must be noted that while registration is a critical step to enabling the availability of quality-assured products, companies must also implement access strategies in tandem to ensure equitable access to their products once they reach the market.

- Registering their products in the most LMICs in scope on average, and;
- Accounting for the largest increase in the number of LMICs scope where their products are registered, in comparison the previous Index (2022).

Given some of the challenges of registering in LMICs, in there are several mechanisms available to countries to and companies that support facilitated and accelerated regulatory authorities have lower maturity. For more on this and a detailed analysis of companies' registration efforts in LMICs, see p.58 in the Product Delivery sub-chapter.

registration in LMICs, including in countries where Bayer, which registered its newer products in 21 countries on average, leads in increasing registration of these products on average. It registers finerenone (Kerendia®), indicated for chronic kidney disease with albuminuria associated with type 2 diabetes, in 30 countries – an increase of 25 since the previous Index. Finerenone (Kerendia®) is one of the products with the largest increase in registrations in low-income countries for all companies assessed by the Index since 2022.

Novartis registered its newer products in 23 countries on

1. World Bank Group. Low & middle income. Population, total. Published 2023. Accessed August 27, 2024. https://data.worldbank.org/income-level/low-and-middle-income

2. International Federation of Pharmaceutical Manufacturers & Associations. Regulation of Biologics. Published online 2023. doi:10.1016/S1470

PRODUCT DELIVERY – LOCAL MANUFACTURING; QUALITY AND SUPPLY

End-to-end technology transfer initiatives for vaccines to improve availability

MERCK & CO, INC (MSD), TAKEDA

Location: India, Indonesia

Focus: Vaccines, technology transfer

Action: Actively transferring technology to third-party manufacturers for end-to-end vaccine manufacturing

Aim: To enable local manufacturers in low- and middle-income countries (LMICs) to more independently produce quality vaccines, improving availability for patients

programmes for children aged 6 to 16 years in India, a country ranked among the top 10 with the highest disability-adjusted life years (DALY) rate for dengue.[2] Qdenga® will also be made available in other countries where dengue is endemic, potentially supplied through organisations such as Gavi, the Vaccine Alliance and the Pan American Health Organization. Takeda and Bio-E have partnered to make up to 50 million doses per year, supporting Takeda's efforts to deliver 100 million doses per year by 2030.

Conclusion

Vaccines are a powerful tool for preventing illness, reducing the need for medical treatment and protecting lives. Many countries rely heavily on imports of vaccines from abroad; in fact, Africa imports 99% of its vaccines.[1] Technology transfer (see definition on p.xx) can be an effective way to boost domestic manufacturing in LMICs and reduce supply risks that ultimately impact the lives of patients.

Vaccine manufacturing involves multiple steps: synthesis

Where technology transfers can help ensure continuous supply of key vaccines and support countries' immunisation efforts, companies may consider partnering with local manufacturers to fully manufacture vaccines for local and regional supply. MSD and Takeda show what is possible for vaccine technology transfer in South Asia, but there are yet greater manufacturing gaps in sub-Saharan Africa that must also be addressed.

of active ingredients, formulation of a stable solution, filling syringes or vials and packaging products in labelled containers. By transferring skills and know-how for end-to-end manufacturing (see Appendix VI), companies can reduce reliance on imported vaccine substances from abroad and

End-to-end technology transfers do not, by themselves, ensure patients' access to products. That said, in addition to efforts, such as pricing strategies and health system strengthening, these initiatives can increase availability of lifesaving vaccines.

upskill new vaccine manufacturers that can be key partners in the vaccine supply network for LMICs in the future.

Practice

2024 Index identified that, MSD and Takeda are the only companies with active technology transfer initiatives for vaccines in LMICs that cover end-to-end manufacturing. Given the complexity of processes, stricter regulatory require ments and higher costs involved, vaccine manufacturing often requires the investment of more time and resources than for small molecule production or other biologicals. For this reason, these two companies' efforts stand out.

MSD is transferring technology to Indonesia's Bio Farma to make its quadrivalent HPV vaccine (NusaGard), with the aim for Bio Farma to assume end-to-end production in future, including the manufacture of active substances. Bio Farma has made an initial 3.1 million doses for Indonesia's HPV immunisation programme. Distributed across 38 provinces, this vaccine will be given to pre-teen girls supporting the government's aim to eliminate cervical cancer in the country by 2030.

Takeda is transferring technology to India's Biological E. Ltd (Bio-E) in India, enabling it to make all components for the vaccine Qdenga® (TAK-003), which protects against dengue. The manufactured vaccines will support dengue immunisation

For more on technology transfers and companies' Best efforts in this regard, see p.99 in the Product Delivery The sub-chapter.

1. UN Children's Fund. Africa CDC and UNICEF Expand Partnership to Strengthen Health Systems and Immunization of Children in Africa. Published online 2024. https://www.unicef.org/press-releases/africa-cdc-and-unicef-expand-partnership-strengthen-health-systems-and-immunization

2. Institute For Health Metrics and Evaluation. Global Burden of Disease (GBD) Results. Published online 2021. https://www.healthdata.org/data-tools-practices/interactive-visuals/gbd-results.

PRODUCT DELIVERY – ACCESS STRATEGIES

Roche supports early diagnosis of cervical cancer in LMICs by supplying its WHO-prequalified HPV test to nearly 50 countries in scope of the Index

ROCHE

Location: Global

Focus: HPV-related cervical cancer

Action: Supplying its WHO-prequalified HPV test through its Global Access Program at a standardised price across 89 low- and middle-income countries (LMICs)* and also supplying it directly to countries outside this mechanism

Aim: To expand access via different pathways to cervical cancer screening tools in LMICs where the burden of disease is high

Human papillomavirus (HPV) is the primary cause of cervical cancer. Each year, more than 600,000 women are diagnosed with cervical cancer globally, with the disease causing more than 340,000 deaths.[1] By 2030, annual cases of cervical cancer are set to rise to 700,000 globally, with 400,000 deaths.[2] Despite the fact that cervical cancer is preventable and curable if detected early, it remains among the main causes of cancer-related death in women, especially in LMICs.[2] Of those who die from the disease, almost 90% live in LMICs, where the disease incidence is almost double the

with GAP partners including the Clinton Health Access Initiative (CHAI); the President's Emergency Plans for AIDS Relief (PEPFAR); the United States Agency for International Development (USAID); Unitaid; and the Global Fund to Fight AIDS, Tuberculosis and Malaria Global Fund (Global Fund).

Through the GAP, Roche supplied 35 countries in scope of the Index during the period of analysis, including eight low-income countries (LICs). Among the 35 countries in scope, three have a high burden of cervical cancer.

Roche also supplies the test directly to countries not eligible to procure it through the GAP; 14 countries in scope were reached, including three lower-middle income countries. In Peru, a country not eligible for procurement through the GAP, Roche engages directly with the government, participating in the yearly public tenders. As part of its efforts in Peru, Roche has worked with third-party organisations to identify barriers and bottlenecks that prevent increases in coverage. In addition to initiatives included in the tender, such as educating healthcare professionals and distributing awareness materials to communities, Roche has made extra efforts by engaging in capacity-building activities in partnership with NGOs and supporting geographical expansion of the screening programme.

rate in high-income countries.[1,2]

Diagnostic screening for HPV is a first step to detect cancers and stands to reduce the burden of disease in LMICs. It is also important that those countries with the highest burden of disease have access to the same quality of diagnostic and health products that are available in high-income

Conclusion

Roche sets a positive example by employing various strategies, beyond supranational procurement, to increase access to diagnostics for preventing cervical cancer in women in countries.

Best Practice

Roche demonstrates Best Practice with its Cobas® HPV - diagnostic test for cervical cancer and other HPV-related

LMICs. In setting up access strategies for their products, all companies should consider multiple access pathways, tailored to the country, product and disease characteristics. This is

particularly important for diseases that disproportionately affect people in LIMCs, to ensure broader and more equitable access to treatment.

cancers, which screens for 14 high-risk HPV types – including HPV16 and HPV18 – that are responsible for most HPV-related cancers, supporting screening for earlier diagnosis in countries disproportionately affected.

Roche's Cobas® HPV test has been awarded World Health Organisation (WHO) prequalification, an evaluation that confirms the tests meet certain quality and efficacy standards required for supranational procurement by UN agencies. Importantly, the company has multiple access pathways to improve the product's availability and affordability in LMICs. Through the Global Access Program (GAP), which Roche launched in 2014, donors, multilateral organisations, inter national agencies, non-governmental organisations (NGOs) and governments can purchase its test at a standardised price across 89 LMICs. Prices are determined in consultation

For a detailed analysis of companies' access strategies, please see p.71 of the Product Delivery sub-chapter.

1. World Health Organization (WHO). Cervical cancer. Accessed September 24, 2024. https://www.who.int/news-room/fact-sheets/detail/cervical-cancer
2. World Health Organization (WHO). Global strategy to accelerate the elimination of cervical cancer as a public health problem. Published 2020. Accessed September 18, 2024. https://iris.who.int/bitstream/handle/10665/336583/9789240014107-eng.pdf?sequence=1

*Throughout the 2024 Access to Medicine Index, the term LMICs is used to denote all low- and middle-income countries in scope, except when analysing companies' access strategies, where the use of LMIC refers to lower-middle income countries as per the

World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low-income countries and upper-middle-income countries.

PRODUCT DELIVERY – ACCESS STRATEGIES

Tracking progress of access strategies against patient reach goals

ASTRAZENECA, NOVARTIS

Location: Low- and middle-income countries (LMICs)* in scope of the 2024 Index

Focus: Different products for different diseases

Action: Tracking the performance of companies' access strategies in different countries against set patient reach goals

Aim: Tracking progress and identifying areas of improvement to increase patient reach across LMICs

For equitable access to medicine to become a global reality, it is vital to determine whether companies' healthcare products are actually reaching the people that need them most – specifically people living in low- and middle-income countries. Companies can monitor progress by establishing clear, meas

For AstraZeneca, the Index analysed 25 country-specific access strategies for 10 products. Overall, AstraZeneca sets clear, product- and country-specific goals and discloses its plans on how to advance these strategies. It defines eligible and target populations, and reports related figures, for most strategies analysed. It also consistently reports patient reach approaches (based mainly on its sales and assumptions about product consumption, integrated with data from patient support programmes [PSPs] when implemented in a country strategy). AstraZeneca provides patient reach data for most strategies. In addition to sales and/or patients reached, the company reports on how it tracks overall progress by monitoring metrics, including access penetration, reimbursement in the public sector, and geographic reach. For almost half of the access strategies analysed, AstraZeneca reported an increase in the number of patients reached compared to the previous Index.

urable goals and targets, and defining methods to track patient reach and other outcomes. Then, the collected data can be used to tailor their strategies to suit country-specific needs, such as the healthcare system context and burdens of disease. This practice enables companies to more effectively address persistent access barriers and improve the success of strategies in reaching patients.

To determine how companies are tracking the outcomes of their access strategies, this iteration of the Index has placed a greater emphasis on assessing patient reach.

Companies' efforts to expand patient reach are analysed in both the Governance of Access (GA) and Product Delivery (PD) Technical Areas. As part of the assessment in GA, the Index determines whether companies have established - processes to calculate eligible and target populations, as well as the number of patients reached. Within PD, the Index assesses whether and how companies report on the number of patients reached via their product- and country-specific access strategies. Two companies stand out for demonstrating best practice in both regards.

For example, for its oncology products, durvalumab (Imfinzi®) and osimertinib (Tagrisso®), the company reports on the progress of its access strategies in different countries. In Mexico (UMIC), where both products are reimbursed in the public system and PSPs are available in the private market, the company has reported a 97% and 60% increase in patients reached for durvalumab and osimertinib respectively, between 2022 and 2023, with plans to further expand access and reach. Increased reach during the same period has been reported for both products in Egypt (LMIC), where durvalumab is not yet publicly reimbursed, however, PSPs are offered for both products. AstraZeneca engages in health-system strengthening initiatives, which are monitored and reported as part of the strategy's progress.

For Novartis, the Index assessed the outcomes of 17 country-specific access strategies across seven products. The company sets clear goals and plans for how to improve strategies, such as increasing reach through public reimbursement. It tailors goals and plans to suit context and includes health system strengthening targets in some strategies, indicating a comprehensive approach to access. It uses examples analysed, with both companies demonstrating consistent efforts to monitor the outcomes of their access strategies included in the analysis across all three country income classifications: low-income (LIC), lower-middle income (LMIC) and upper-middle-income (UMIC).

Best Practice

AstraZeneca and Novartis have established processes to calculate eligible and target populations, as well as the number of patients reached. Additionally, AstraZeneca and Novartis also report on the number of patients reached for most of the product- and country-specific access strategy

standardised methods to define eligible and target patient populations, as well as patient reach (based on volumes sold and treatment doses and duration). For all of Novartis's strategies analysed (excluding one recent launch), the company reported patient reach numbers for 2023, as well as a growth percentage in patient reach compared to 2022. For example, for sacubitril/valsartan (Entresto®), indicated for ischaemic heart disease, the company has put comprehensive access strategies in place across countries of different income classifications (Mexico, Ethiopia and India) for years.

*Throughout the 2024 Access to Medicine Index, the term LMICs is used to denote all low- and middle-income countries in scope, except when analysing companies' access strategies, where the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low-income countries and upper-middle-income countries.

It reported patient reach increases in 2023, demonstrating continued progress in reaching patients through access strategies.

Conclusion

By establishing clear, measurable goals and targets, and defining methods to track patient reach and other outcomes, companies can monitor progress to improve the success of their strategies in reaching patients. Doing so enables them to more effectively address persistent access barriers, as they can improve and tailor their strategies to suit country-specific needs, such as the healthcare system context and burden of disease faced by different countries.

AstraZeneca and Novartis exemplify best practice in monitoring and reporting progress of their access strategies, including the number of patients reached with their products, and more companies are encouraged to do so. However, there is room for improvement; sales figures are the primary metric for tracking patient reach, but these numbers do not neces sarily reflect success in reaching patients across the income pyramid. A broader perspective is needed to tailor metrics and assumptions, such as evidence of whether patients adhere to treatment, and to customise these measures for different product types, patient demographics, treatment modalities, and healthcare environments. As monitoring practices develop, the Index looks for companies to be transparent to help others adopt Best Practice.

For more on companies' efforts to measure and track patient reach, please refer to p.35 in the Governance of Access sub-chapter. Likewise, for a more detailed analy sis of companies' product-specific examples and access strategy outcomes, refer to p.71 in the Product Delivery sub-chapter.

CHAPTER 4

COMPANY REPORT CARDS

Company report cards

The 2024 Access to Medicine Index includes a set of 20 company Report Cards that provide detailed overviews of each assessed company's performance.

Companies are different in the way they operate, where they operate and in their portfolio of investigational and marketed products, all of which can have implications for access. Each Report Card includes a summary of the company's strengths and weaknesses, drivers behind changes in its ranking, as well as tailored opportunities for each company.

The Report Cards are divided into six sections, as set out below. For a detailed breakdown of how the Report Cards are set up, refer to p.124 of this section. Abbreviations and terminology used within the Report Cards are also provided on p.125.

1. Performance in the 2024 Index
Company's rank in the 2024 Index, with a summary of its access-to-medicine performance. All companies were assessed based on information that was valid in the latest period of analysis (ending on 31 May 2024). This data was either submitted by companies, found in the public domain or was accessible through other sources.

2. Opportunities
Based on the 2024 Index analysis, the Access to Medicine Foundation has set out tailored opportunities for each company to improve access to medicine, taking account of company-specific characteristics, such as business models, strategies, policies and practices, compliance system, research & development (R&D) pipeline, product portfolio, equitable pricing strategies and approach to intellectual property (IP) management.

By pinpointing specific actions companies can take to make a positive impact on access to medicine, these opportunities offer clear, practical and feasible ways in which companies can each maximise their efforts successfully.

These opportunities signal significant change-making potential for the company and are also valuable for investors and global health stakeholders as they engage with companies to expand access to medicine in low- and middle-income countries (LMICs). Between Index iterations, the Foundation continuously engages with all companies on their respective opportunities, working with them to help turn the identified potential into meaningful impact.

3. Changes since 2022
Update on where the company's access-to-medicine performance has changed most notably since the 2022 Index. It includes:
- new, expanded, or unchanged strategies, activities and programmes.
- interesting developments, initiatives or activities that can influence access to medicine.
- notable new developments that have influenced a company's performance in the Index.

4. Sales & operations
General description of the company's operations globally, including changes in its business (such as acquisitions or divestments) over the period of analysis.

5. Pipeline & portfolio summary
Analysis of the company's pipeline of R&D projects as well as portfolio of marketed products analysed in the 2024 Index. This section looks at the size and focus of the

company's pipeline and portfolio, whether the company has products that are considered first-line or are on the World Health Organization Model List of Essential Medicines and whether it is conducting priority R&D and planning for access during development.

6. Performance by Technical Area
Overview of the company's performance in each Technical Area measured by the 2024 Index: Governance of Access, Research & Development and Product Delivery.
At the start of each Technical Area, the company's sub-ranking and a summary of its performance in that area is provided. Statements within each Technical Area are a summary of a company's performance in specific indicators in that Area. Performance points measured by indicators have been structured to be comparable between companies, while still describing the company's individual programmes, initiatives and approaches.

Examples included in a company's Report Card are not exhaustive but seek to showcase the standout findings for each indicator used to measure company performance. More information can be found in the in-depth analysis included in each Technical Area sub-chapter within the 2024 Index Report. Best Practices are also listed on p.110 - 121 of the Index Report.

TABLE 1 Guide to reading company Report Cards

Section	Description	Source
Page 1		
General information (heading)	Stock exchange ticker(s) Location of headquarters Number of employees	Annual reports and/or the company's website
Opportunities (text)	See previous page	
Changes since the 2022 Index (text)	See previous page	Public domain and Index analyses
Page 2		
Sales and Operations (text)	See previous page	Annual reports, company's website, press releases and other news sources
Net revenue by segment (2023) (table)	Breakdown of the company's 2023 net sales/revenue/turnover by business segment. Depending on how the company reports the segments, this table may vary.	Company's financial statements
Sales in countries in scope (figure)	Countries in scope in which the company has sales.	Raw data submission to the Index
Sales by geographical region (graph)	Geographic breakdown of the company's gross or net sales/revenue/turnover over the last two to five years. Sales are broken down into the geographic distribution reported by the company.	Company's financial statements
Pipeline for diseases in scope (text)	The company's R&D pipeline is described according to the following: • The total number of the pipeline projects, followed by the number of projects targeting R&D priority gaps (as defined by G-FINDER and other global health organisations). A sample list of the disease in scope which the pipeline focuses on is also included, together with the number of projects in brackets. Please note this list is not exhaustive. • The total number of R&D projects targeting other diseases in scope (i.e. those that are not priority R&D), plus a sample (non-exhaustive) list of the diseases in scope which where - company is focusing their efforts, together with the number of projects in brackets. • The total number of late-stage projects for all diseases in scope (i.e., from Phase II onwards) and the percentage of these projects which have access plans in place. These numbers are derived from the verified pipelines submitted by companies.	Verified pipeline submitted by company and public sources, such as clinicaltrials.gov

Section	Description	Source
Portfolio as selected for analysis by the Index	Indicates the number of products in the company's product portfolio. It also contains details on the product types (medicine, vaccine, diagnostic etc.), as well as the patent status and number of products included in the WHO Model List of Essential Medicines (2023) and/or WHO model list of essential in vitro diagnostic (2023). The main disease types which products in the portfolio target are also listed. (Please note this is not an exhaustive list.)	Data sources for the product portfolio are products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMEA, PMDA, and the company's website.
Pipeline projects per disease category (graph)	Company's pipeline projects broken down by Index disease categories.	Company pipeline data submission
Breakdown of pipeline projects (graph)	Breakdown of active pipeline projects per phase of development.	Index analysis of products submitted by the company for scoring and analysis in the Index
Products per disease category (graph)	Total number of products in the company's portfolio within the disease scope of the Index, broken down by Index disease categories. The disease category 'Multiple categories' includes medicines that are indicated for multiple diseases within the Index scope and that cover multiple disease categories (e.g. broad-spectrum antibiotics). Contraceptive methods and devices are included under maternal and neonatal health conditions.	Products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMEA, PMDA, and the company's website
Breakdown of products (graph)	Total number of the company's products within the scope of the Index, broken down by type of products: medicines (on- and off- patent), vaccines, diagnostics, contraceptives and other (which includes vector control products and platform technologies). In addition, the figure indicates number of products included in the WHO Model List of Essential Medicines (2023) and/or WHO model list of essential in vitro diagnostic (2023).	Products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMEA, PMDA, and the company's website
Pages 3 & 4		
Report card statements	This section contains the indicator performance statements for each Technical Area: • Governance of Access • Research & Development • Product Delivery	Index analyses

TABLE 2 Abbreviations and terminology used in Report Cards

API	Active pharmaceutical ingredient
CHAI	Clinton Health Access Initiative
Country income classifications: • LMIC • LIC • UMIC	The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low-income countries and upper-middle income countries.
ESG	Environmental, social and governance
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPS	Good Practice Standards (also see Appendix V on p.226)
HPV	Human papillomavirus
'In scope'	Refers to the diseases, countries, products covered/included for analysis in the 2024 Access to Medicine Index as defined in the 2024 Access to Medicine Index Methodology.
PAHO	Pan American Health Organization
Period of analysis	For the 2024 Index, the time period for which data was analysed covers company activities which were ongoing between 1 June 2022 and 31 May 2024, as this is the cycle of the Index. Projects that ended before 1 June 2022 are not included.
TB	Tuberculosis
WHO SRA-CRP	World Health Organization Collaborative Registration Procedure using Stringent Regulatory Authorities
SMART (targets)	Specific, measurable, achievable, realistic and timely
WHO EML	World Health Organization Model List of Essential Medicines

RANK	SCORE
20	1.61
19 (2022)	

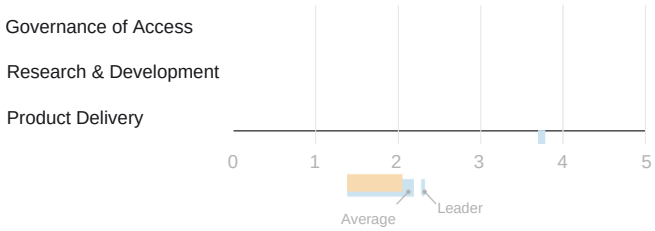
AbbVie Inc

Stock exchange: NYSE • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: ~50,000

PERFORMANCE IN THE 2024 INDEX

20th place. AbbVie performs in the lower ranks of all three Technical Areas. The company does not have an access planning framework during Research & Development, nor does it have access plans for any of its late-stage pipeline candidates. However, as assessed in Product Delivery, it is newly engaged in supply chain capacity building.

How score was achieved



OPPORTUNITIES FOR ABBVIE

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. AbbVie can develop a formal access planning framework and accordingly apply access plans that consider availability, affordability and sustainable supply for all its projects, no later than Phase II. For example, it can disclose access plans for ABBV-552, an investigational treatment for Alzheimer's disease.

Share company-specific access-to-medicine targets, goals and objectives. AbbVie has commitments for access to medicine that align with the goals of other organisations, such as the World Health Organization. In addition to this, the company can also work to implement and report on access-to-medicine goals that are specific to commitments it would like to achieve as a company.

Disclose process for measuring patient reach. AbbVie did not provide evidence of a patient reach process. The company can work to publicly share the details of its patient reach process, including the underlying equation, metrics, assumptions and limitations. AbbVie can also improve transparency by regularly publishing patient reach figures and disclosing the outcomes of its product-specific access strategies.

CHANGES SINCE THE 2022 INDEX

- Appointed Robert Michael as new CEO in 2024.
- Completed acquisition of ImmunoGen in February 2024, adding a product targeting ovarian cancer to AbbVie's portfolio and expanding its oncology pipeline.
- Completed acquisition of Cerevel Therapeutics in August 2024. Cerevel's clinical-stage assets include a next generation anti-psychotic for schizophrenia.
- Launched new initiative aimed at expanding patient access to its eyecare products from 9 to 45 African countries.

AbbVie Inc

SALES AND OPERATIONS

Therapeutic areas: Aesthetics, eyecare, immunology, neuroscience, oncology, other specialty areas

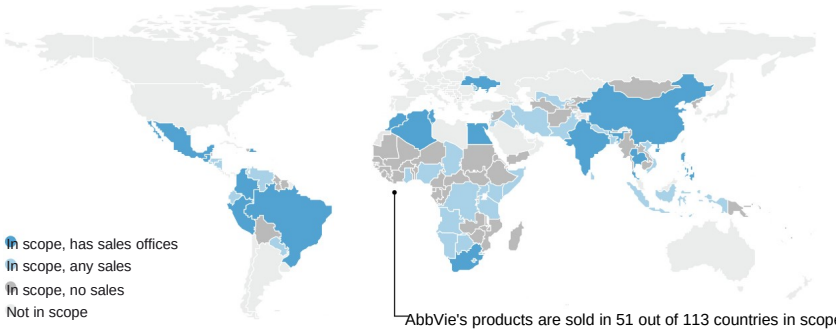
Product categories: Pharmaceuticals

M&A news: AbbVie acquired DJS Antibodies for USD 255mn and Mitokinin for USD 110mn in 2022 and 2023, respectively. In 2024, it acquired ImmunoGen for USD 10.1bn and Landos Biopharma, Inc. for USD 137.5mn respectively.

Net revenue by segment (2023) – in USD

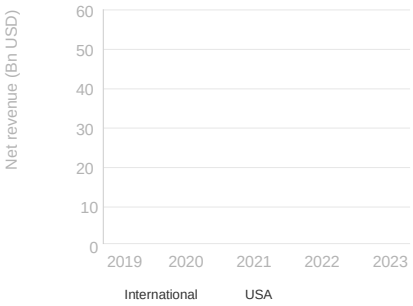
Pharmaceutical sciences	54.32 bn
Total	54.32 bn

Sales in countries in scope



AbbVie's products are sold in 51 out of 113 countries in scope of the Index. AbbVie has sales offices in 17 countries and sells via suppliers and/or pooled procurement in an additional 34 countries.

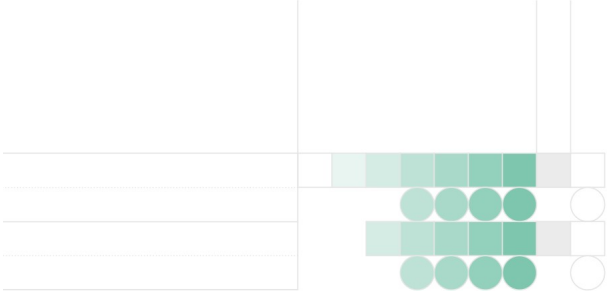
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

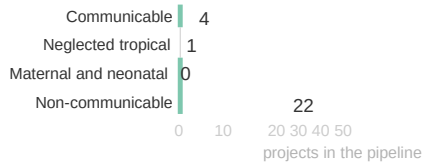
AbbVie has 27 R&D projects in scope, 5 of which target priority diseases, including HIV/AIDS (2), TB (1) and COVID-19 (1). The remaining 22 projects target other diseases in scope, including cancer (14), Alzheimer's disease (3) and migraine (2). Of the 27 R&D projects, 10 are in late-stage development, with evidence of access planning for 0% (0/10) of these.



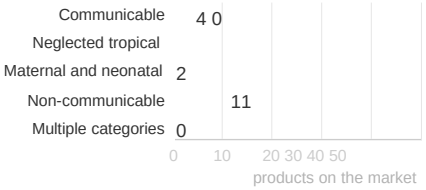
PORTFOLIO *as selected for analysis by the Index*

AbbVie has 17 products in scope, 14 of which are on patent and 5 of which are listed on the WHO EML. Most of its medicines are on patent (13) and mostly target non-communicable diseases, such as cancer (4) and migraine (2). It has several maternal and neonatal health products in scope, including contraceptives (1) and a product targeting pre-term birth complications (1). It also has medicines targeting communicable diseases, such as HIV (2) and hepatitis C (2).

27 projects in the pipeline



17 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	2	0	3	0	0	0	0	0	5
with access plan				0	0	0	0		0
Other projects in scope			12	4	3	0	3	0	22
with access plan				0	0	0	0		0

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	3	10			13
off patent	2	1			3
Vaccines	0	0			0
Contraceptives	0	1			1
Diagnostics			0		0
Other				0	0

AbbVie Inc

GOVERNANCE OF ACCESS

RANK 20 SCORE 2.52

20th place. AbbVie performs poorly in this Technical Area. The company has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as well as direct board-level responsibility for access but it does not disclose sufficient evidence of having a robust set of controls to mitigate the risk of non-compliant or corrupt activities in countries in scope. Further, AbbVie does not publicly express any support for the Doha Declaration on TRIPS and Public Health. The company did not share any processes for measuring patient reach.

The highest responsibility for access lies directly with the Board, with its Public Policy and Sustainability Committee responsible for corporate responsibility aspects, including access. AbbVie has access-related incentives for senior executives under its key material driver of Patient Affordability and Accessibility within its ESG framework.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its 'Global Integrated Access Strategy' covers all therapeutic areas in which the company is involved. AbbVie publicly discloses its commitments to access to medicine, but the reported goals, objectives and targets are linked to external global health targets and are not company specific.

Reporting is mostly clear, centrally available and updated regularly in its ESG Action Report.

Shows comparatively strong commitment to responsible business practices. AbbVie's sales agents are not solely incentivised by sales volume. Further, AbbVie commits to ensuring ethical interactions with healthcare professionals in its code of conduct and sets limits on transfers of value to healthcare professionals (e.g., payments for attending events or promotional activities). However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

with company standards. It does not disclose to the Index whether there is fraud-specific risk assessment done in countries in scope of the Index. AbbVie does not disclose sufficient evidence publicly, or to the Index, of country risk-based assessments in countries in scope. It has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

AbbVie does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available policy on 'Intellectual Property and Patient Access', but it does not align with principles embodied in the Declaration.

AbbVie did not share any processes for

Has a set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AbbVie performs moderately in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance

RESEARCH & DEVELOPMENT

RANK 20 SCORE 0.91

20th place. AbbVie performs poorly in this Technical Area. It has a small-sized priority pipeline compared to its peers and its performance across R&D has stayed the same. It is one of the few companies that does not have a framework in place for systematic access planning and does not have access plans for any of its late-stage pipeline candidates. Furthermore, it does not publicly disclose disaggregated R&D investment data, nor does it engage in R&D capacity building activities.

No structured process in place to develop access plans during R&D. The company does not make public commitments addressing its systematic approach to access planning for LMICs.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with none of its late-stage projects (0/10) covered by access plans. The company has 10 late-stage R&D projects targeting other diseases in scope

AbbVie does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

No evidence of R&D capacity building initiatives that meet inclusion criteria.

Small-sized priority R&D pipeline compared without any late-stage candidates.
pipeline of 5 projects, none of which
stage targeting a priority gap. The com
focuses on various priority areas, including
HIV/AIDS, TB and COVID-19.

that have not been established as a priority by to peers,
global health stakeholders. The projects mainly Priority R&D
target cancer, Alzheimer's disease and migraine. are late
AbbVie does not provide evidence of access plans pany
for any of the 10 late-stage projects.

AbbVie Inc

PRODUCT DELIVERY

RANK 19 SCORE 1.75

19th place. AbbVie performs poorly in this Technical Area. The company shows no evidence of manufacturing capacity building initiatives but is newly engaged in supply chain capacity building. The company also shows limited evidence of access strategies for its products, with no data on the outcomes of these strategies. However, AbbVie engages in supranational procurement agreements and non-exclusive voluntary licensing for two compounds.

AbbVie registers products in 5 countries in scope on average. There is no evidence of registering newer products* in any countries in scope. Of the products assessed, there is no evidence of registration in any low-income countries and 25% are registered in at least 1 of the 10 countries with the highest disease burden. The company's ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira®), indicated for hepatitis C, is most widely registered, totalling 13 countries in scope. AbbVie reports engaging in mechanisms to facilitate registration, for example, the European Medicines Agency EU-M4all (former Article 58).

Supplies 2 products through supranational agreements. The 2 products assessed under this category, lopinavir/ritonavir (Aluvia®/Kaletra®) and ritonavir (Norvir®), are both HIV treatments and are supplied through The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). The company has strategies to make ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

AbbVie has no public commitment to not file for or enforce patents in any countries in scope.

Publicly discloses product patent status for countries in scope. Like most peers, AbbVie publicly discloses patent information for small molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

AbbVie has 3 non-exclusive voluntary licensing agreements to enable generic supply. One of the licences is for glecaprevir/pibrentasvir, indicated for hepatitis C, and includes 79 countries in scope. The other licences are for the compounds lopinavir/ritonavir, indicated for HIV, for both adult and paediatric use. The adult licence was issued in 2015 and covers 107 countries in scope; the paediatric licence was issued in 2014 and covers 93 countries in scope.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, AbbVie's local affiliate in South Africa works with local stakeholders to ensure supply of HIV treatment lopinavir/ritonavir (Aluvia®). When a supply issue or delay is detected through regular reports, AbbVie's central planning team works with distributors, government agencies and hospitals to assess the delay, inventory levels, and to ensure coverage.

AbbVie has procedures in place for reporting substandard and falsified medicines in countries in scope. It provides evidence of reporting cases to national or local regulatory authorities and WHO. However, the company does not disclose evidence, publicly or to the Index, that it requires reporting to occur within 10 days, nor does it provide evidence of shortened timeframes for reporting cases that only require visual inspection for confirmation.

The terms for all 3 licences are publicly available.

the products available in at least one country not eligible for supply via the Global Fund and agreed non-exclusive voluntary licences with the Medicines Patent Pool for both products. Further, AbbVie engages in health system strengthening initiatives to support HIV care. For both products, outcomes data has not been disclosed.

Has access strategies for only one healthcare practitioner (HCP)-administered product, does not report outcomes. AbbVie has not disclosed, either publicly or to the Index, any new data on access strategies for its 2 HCP-administered products selected for analysis under this category. The company has strategies for 1 product, beractant (Survanta®), indicated for respiratory distress syndrome (RDS) in premature neonates. AbbVie applies a cost-plus pricing strategy for the product in Uganda (LIC) and has provided this product via donation to AmeriCares, which supplies in different countries in scope. No data on the strategies' outcomes has been reported.

Limited access strategies for its self-administered products, does not report outcomes. AbbVie has not disclosed, either publicly or to the Index, any new data on access strategies for its self-administered products. The company has a non-exclusive voluntary licence with the Medicines Patent Pool for glecaprevir/pibrentasvir (Mavyret®), which covers 10 UMICs, 42 LMICs and 24 LICs. No data related to the strategies'

No evidence of manufacturing capacity building initiatives that meet inclusion criteria.

One supply chain capacity building initiative was included for analysis, but it does not meet all Good Practice Standards (GPS). In this initiative, AbbVie developed a distributor training programme in South Africa aimed at improving demand and supply management.

that offers 2 products in 52 countries in scope. Launched in 2013, the Access to Care programme offers HIV treatments lopinavir/ritonavir (Aluvia®/ Kaletra®) and ritonavir (Norvir®) at reduced prices in countries like Lesotho and Nigeria. The model also includes training of healthcare profes sionals to help address treatment capacity.

One of four health system strengthening initiatives included for analysis meets all GPS. In this initiative, The AbbVie Foundation supports Baylor College of Medicine International Pediatric AIDS Initiative in providing HIV treatment, prevention, testing and psychosocial support in 7 countries, including 6 in scope: Botswana, Eswatini, Lesotho, Malawi, Tanzania and Uganda. The aim of the initiative is to reduce mortality and increase treatment adherence.

AbbVie remains engaged in existing IP-sharing agreements with drug discovery initiatives to accelerate drug development. The company shares IP assets through the Corona Accelerated R&D in Europe which aims to deliver new corona viral products. However, AbbVie has not made new agreements during the period of analysis.

Fulfils all criteria for ad hoc donations. AbbVie has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to outcomes has been reported.

*Products that received their first marketing authorisation within the last 5 years.

RANK	SCORE
15	2.23
16 (2022)	

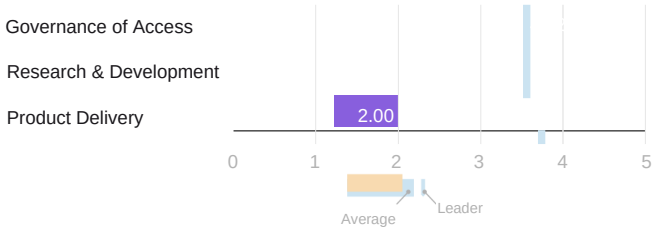
Astellas Pharma Inc

Stock exchange: TSE • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 14,754

PERFORMANCE IN THE 2024 INDEX

15th place. Astellas performs below average. It performs above average in Governance of Access but has a comparatively poor performance in Research & Development and Product Delivery, where the geographic scope of its access plans and strategies is limited.

How score was achieved



OPPORTUNITIES FOR ASTELLAS

Improve the quality and broaden the geographic reach of access plans. Currently, Astellas has access plans for 66% of its late-stage candidates in the pipeline. The depth and geographic coverage of access plans are limited, primarily focusing on supply and demand plans that include three countries in scope, on average. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus more on low- and middle-income countries.

Establish direct board-level responsibility for access to medicine. Astellas has an access-to-medicine strategy. The Sustainability Committee, responsible for this strategy,

Expand access to innovative oncology medicines. Astellas has access strategies in place for its innovative oncology medicines, but these are limited in geographic reach, with no low-income country currently covered. It can increase access to these products, such as enfortumab (Padcev®), indicated for bladder cancer, and gilteritinib (Xospata®), indicated for leukaemia, through increased registration, equitable access strategies and/or licensing, with a particular focus on countries with the highest burden of disease.

reports to the CEO. To further progress, the CEO can become a member of the Sustainability Committee, elevating the responsibility for the access-to-medicine strategy to board level.

CHANGES SINCE THE 2022 INDEX

- The Astellas Global Health Foundation announced new grants totaling USD 3.9 million in December 2022 to five organisations in the Dominican Republic, El Salvador, Guinea-Bissau, Honduras, Kenya, Senegal and Uganda. Additionally, in January 2024, it awarded USD 2.6 million to three organisations in Kenya, Yemen and Peru. These grants focus on improving access to healthcare, disaster relief and enhancing community resilience.
- In January 2023, Astellas transferred the worldwide product rights for micafungin (Mycamine®) to Sandoz AG.
- In December 2023, Astellas completed the acquisition of Propella Therapeutics, adding PRL-02 (abiraterone decanoate) for the treatment of prostate cancer to its clinical pipeline.
- In December 2023, the European Medicines Agency adopted a positive scientific opinion for a peadiatric formulation of arpraziquantel for the treatment of schistosomiasis in preschool-aged children (3 months to 6 years of age). Astellas contributed to the development as a member of the Pediatric Praziquantel Consortium.

Astellas Pharma Inc

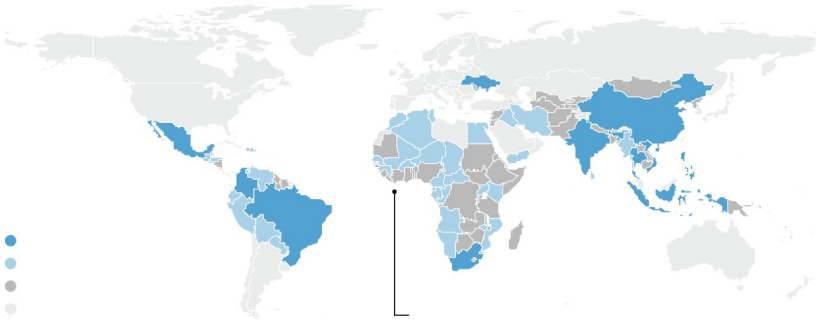
SALES AND OPERATIONS

Therapeutic areas: Oncology, nephrology, transplantation, urology

Product categories: Innovative medicines M&A news: Astellas reacquired its shares at a total value of YEN 50bn in 2023. In 2023, and Propella Therapeutics for USD 175mn, respectively.

Revenue by segment (2023) – in JPY

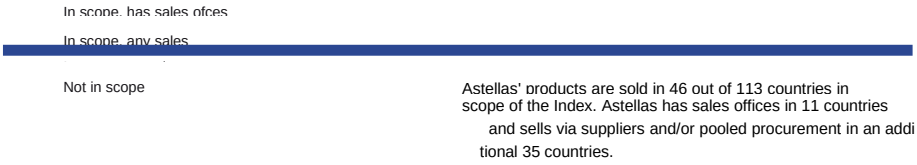
Pharmaceutical	1,603.67 bn



Total	1,603.67 bn

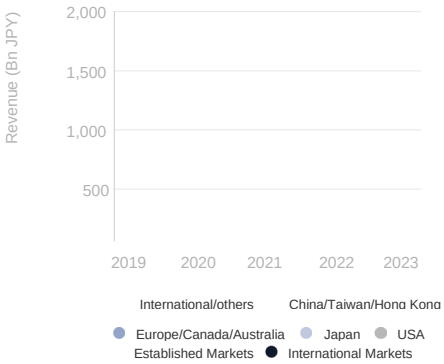
Astellas acquired IVERIC Bio, Inc. for USD 5.9bn

Sales in countries in scope



Astellas' products are sold in 46 out of 113 countries in scope of the Index. Astellas has sales offices in 11 countries and sells via suppliers and/or pooled procurement in an additional 35 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

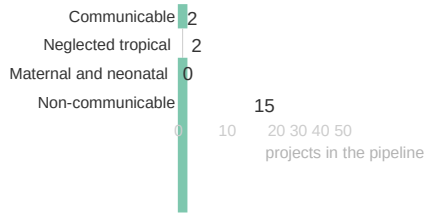
PIPELINE *for diseases in scope*

Astellas has 19 R&D projects in scope, 4 of which target priority diseases, including Chagas disease (1), leishmaniasis (1) and schistosomiasis (1). The remaining 15 projects target other diseases in scope, including cancer (14) and kidney disease (1). Of the 19 R&D projects, 6 are in late-stage development, with evidence of access planning for 67% (4/6) of these.

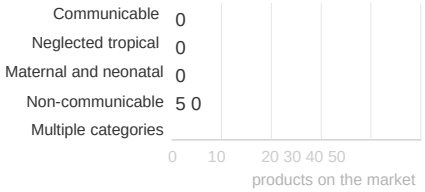
PORTFOLIO *as selected for analysis by the Index*

Astellas has 5 medicines in scope, 1 of which is listed on the WHO EML. All its medicines are on patent and exclusively target non-communicable diseases, such as cancer (4) and kidney diseases (1).

19 projects in the pipeline



5 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	3	0	0	0	0	0	1	0	4
with access plan				0	0	0	1		1
Other projects in scope			10	1	2	0	2	0	15
with access plan				1	0	0	2		3

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	1	4		5
off patent	0	0		
Vaccines	0	0		0
Contraceptives	0	0		
Diagnostics		0		0
Other			0	

Astellas Pharma Inc

GOVERNANCE OF ACCESS RANK 8 SCORE 4.12

8th place. Astellas performs above average in this Technical Area. Although the company does not have direct board-level responsibility for access to medicine, it has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy. Further, Astellas has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies indirectly with the Board, with the Sustainability Committee overseeing social activities, including access. Astellas has access-related incentives at both the executive and in-country manager levels. The CEO also has access-related incentives linked to their remuneration plan.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Astellas publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regu

not solely based on sales volume. It commits to ensuring ethical interactions with healthcare professionals in its code of conduct. It also offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for attending events or for promotional activities) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by

breaches in countries in scope were found in the period of analysis.

Astellas publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Astellas states that compulsory licensing is justified only in national emergencies or other urgent situations, in line with international regulations, and only after exhausting all other options.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For 1 process covering all its products and some countries in scope of the Index, Astellas publicly provides the metrics. The resulting patient reach numbers are published regularly and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

non-compliant or corrupt activities. Astellas performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance particularly in its Integrated Report.

Shows comparatively strong commitment to responsible business practices. Astellas sets team-level sales targets when individual-level targets are not possible, and incentives are

with company standards, fraud-specific risk assessments and region or country risk-based assessments. Astellas also has an ethical deci sion-making framework for employees. No

RESEARCH & DEVELOPMENT

RANK 16 SCORE 1.72

16th place. Astellas has a below-average performance in this Technical Area. It has a small-sized pipe line compared to its peers and engages in R&D for priority diseases and non-communicable diseases. The company has an access planning framework, and it has access plans for most late-stage pipeline candidates – although the breadth and depth of plans are limited. Astellas does not publicly disclose disaggregated R&D investment data, nor does it engage in R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

multiple components, such as WHO prequali fication, a technology transfer agreement and equitable pricing plans.

Small-sized pipeline compared to peers, that addresses other diseases in scope, with 60% (3/5) of late-stage projects covered by

Astellas does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

No evidence of R&D capacity building initiatives that meet inclusion criteria.

Small-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (1/1) of the late-stage candidates. Priority R&D pipeline of 4

projects, including 1 late-stage project targeting a priority gap. The company focuses on various priority areas, including Chagas disease, leishmaniasis and schistosomiasis. Astellas' 1 late-stage candidate targeting a priority prod

access plans. The company has 5 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer and kidney disease. Astellas provides evidence of access plans for 3 of its 5 late-stage projects. Access plans include supply and demand plans, registration preparation and post-trial access in

uct gap has evidence of an access plan, including countries in scope.

Astellas Pharma Inc

PRODUCT DELIVERY

RANK 16 SCORE 2.00

16th place. Astellas performs below average in this Technical Area. The company shows no evidence of manufacturing capacity building initiatives or of new intellectual property sharing agreements. It has access strategies in place for its products; however, geographic reach and outcomes data is limited. Astellas engages in a supply chain capacity building initiative, but it does not meet Good Practice Standards (GPS). Astellas does engage in some health system strengthening initiatives that meet all GPS.

Astellas registers products in 16 countries in scope on average. For the 1 newer product* analysed, it registers in 7 countries in scope. All products assessed are registered in at least 1 of the 10 countries with the highest disease burden; however, no products are registered in any LICs. The company's enzalutamide (Xtandi™), indicated for prostate cancer, is most widely registered, totalling 29 countries in scope. Astellas participates in regulatory reliance to facilitate registration for 1 of its products.

Astellas is not eligible for assessment of supra national access strategies because it has no products in scope that are supranationally procured.

One healthcare practitioner (HCP)-administered

Astellas publicly commits not to file for or enforce patents for all products in a subset of countries in scope. This commitment applies to least developed countries and LICs.

Publicly discloses product patent status for countries in scope. Like most peers, Astellas publicly discloses patent information for small molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

Astellas does not engage in non-exclusive vol untary licensing for products in scope.

No evidence of manufacturing capacity building

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Astellas manages buffer stocks in countries with their own warehouses. Where there are no ware-houses, Astellas supports third parties to hold sufficient stocks. However, the company lacks mechanisms, such as engaging in technology transfer agreements.

Astellas has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to both WHO Rapid Alert and/or national or local regulatory authorities within 10 business days. The company provides evidence of shortened timeframes for reporting for cases that only require visual inspection by experts for confirmation and are not contingent upon labora tory analysis.

No evidence of inclusive business models that meet inclusion criteria. However, Astellas engages in initiative(s) that address access needs of neglected populations. For example, Astellas

initiatives that meet inclusion criteria.

product, with limited access strategy and outcomes data. For its HCP-administered product indicated for bladder cancer, the company provides evidence of access strategies

is offering one of its oncology products to low-

One supply chain capacity building initiative

programme in India.

in UMIC and LMIC examples. Astellas' access strategy is in the private sector only, with plans to expand to the public sector. There

was included for analysis but it does not meet all Good Practice Standards (GPS). In this initiative, Astellas partners with PATH in Kenya to support integrated HIV and TB care. This includes conducting a supply chain assessment for contraceptive/HIV prevention supplies and designing solutions to improve their availability in health centres.

are no plans to launch it in LICs. Astellas provides evidence of engaging in health system strengthening, focused on HCP training in an LMIC. The company provides some information regarding the methodologies used to monitor the outcomes of the strategy but does not disclose the number of patients reached.

Quality of access strategies for self-administered products varies across countries, with limited information reported on the outcomes of most strategies. Astellas provides examples of access strategies in UMICs and LMICs, but none in LICs, for the 2 products analysed. For one of its products, the company has a comprehensive access strategy in Mexico (UMIC) where the product is fully reimbursed by the public health

Three of the four health system strengthening initiatives included for analysis meet all GPS. For example, The Astellas Global Health Foundation granted funds to Amref Health Africa to train health workers and improve paediatric care in 2 under-resourced regions in Senegal.

Astellas remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In a 2021 agreement, the company shared 20,000 compounds with the TB Alliance to screen against mycobacterium TB. However, Astellas has not made new agreements during the period of analysis.

system. The strategy is supported by additional strategies, such as a patient support programme and a model to shorten distribution time. The same quality is not found in the access strategies for the LMIC example for the same product, nor for the second product assessed. However, for these strategies, Astellas reports goals to expand access in the public sector. The company reports patient reach data and evidence of an increase

Fulfils most criteria for ad hoc donations. Astellas has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, the company does not make public commitments to adhere to the most recent WHO Guidelines for

only for the strategy in Mexico.

Medicine Donations.

*Products that received their first marketing authorisation within the last 5 years.

RANK	SCORE
5	3.43

3 (2022)

AstraZeneca plc

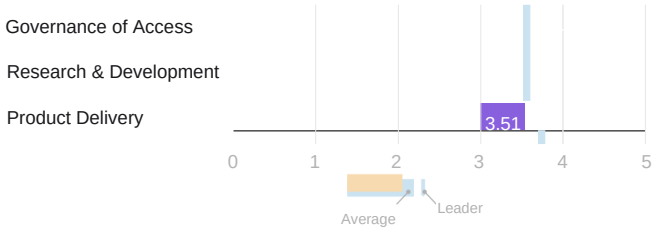
Stock exchange: LSE • Ticker: AZN • HQ: Cambridge, United Kingdom • Employees: 89,900

PERFORMANCE IN THE 2024 INDEX

5th place. AstraZeneca is a high-performing company.

It performs well in Governance of Access and Product Delivery, and above average in Research & Development. It demonstrates Best Practice in reporting outcomes for its access strategies.

How score was achieved



OPPORTUNITIES FOR ASTRAZENECA

Improve the quality and broaden the geographic reach of access plans. AstraZeneca has access plans for nearly all its late-stage projects. However, these plans predominantly focus on registration in emerging markets. For example, its late-stage oncology projects focus primarily on registration preparation and include four countries in scope, on average. The company can expand its plans, for example, by including supply and demand plans and/or licensing and broadening the geographic coverage of these plans to focus more on low- and middle-income countries.

Expand access to innovative oncology products.

AstraZeneca has comprehensive access strategies in place for most of its products targeting non-communicable diseases; however, it lacks access strategies in low-income countries for its oncology products. It can increase access to these products, such as osimertinib (Tagrisso®) – a key lung cancer medicine that is prioritised for voluntary licensing by public health organisations – through equitable access strategies or voluntary licensing.

CHANGES SINCE THE 2022 INDEX

Publicly report on patient reach of the Healthy Heart Africa (HHA) programme. Through HHA, AstraZeneca aims to address the disease burden of cardiovascular disease and, since 2024, chronic kidney disease. The programme includes awareness raising, healthcare worker trainings, screenings and treatments, where applicable. As of the end of March 2024, the company reports that HHA has identified over 10.8 million people with elevated blood pressure, to be referred for appropriate treatment. While the company annually reports the number of people screened, it does not specify the number of patients reached by its antihypertensive product specifically. Publicly reporting these details can foster accountability and clarify the impact of the model.

- Launched Cancer Care Africa in November 2022, an initiative which aims to improve patient outcomes by advocating for policy change and improved cancer screening.
- Began the worldwide withdrawal of its COVID-19 vaccine (Vaxzevria®).
- Expanded the Healthy Heart Africa (HHA) programme to additional countries including Burkina Faso, Central African Republic, The Gambia, Madagascar, Malawi, Morocco,

- Announced plans to invest GBP 650mn (USD 826.8mn) in Britain to boost research, development and manufacturing of vaccines.
- Signed agreement to invest USD 475mn to build a small-molecule drug factory in eastern China's Wuxi, the location of its first plant in China.

Mozambique, Sierra Leone, Zambia and Zimbabwe. HHA aims to improve access to end-to-end hypertension management

• Opened the Africa Health Innovation Hub, which aims to use the latest technologies to increase access to healthcare.
and was recently expanded to encompass

a broader spectrum of non-communicable diseases, such as chronic kidney disease.

- Increased its investment in a manufacturing facility in Qingdao, China, that will produce its

AstraZeneca plc

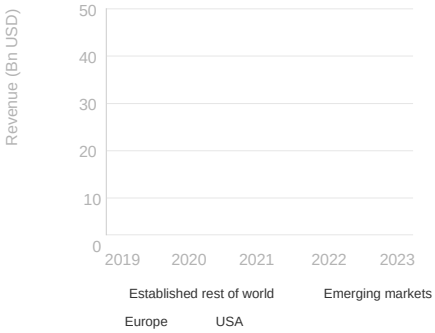
SALES AND OPERATIONS

Therapeutic areas: Biopharmaceuticals (including cardiovascular, immunology, metabolism, renal and respiratory), immune therapies, oncology, rare diseases, vaccines	In 2023, it acquired Neogene Therapeutics Inc. for USD 120mn; CinCor Pharma, Inc. for USD 1.1bn; and Pfizer's pre-clinical rare disease gene therapy portfolio for USD 1bn. In 2024, it acquired Gracell Biotechnologies Inc. for USD 1.2bn; Icosavax for USD 1.1bn; and Amolyt Pharma for USD 1.08bn.	Revenue by segment (2023) – in USD Pharmaceutical 45.81 bn Total 45.81 bn
Product categories: Innovative medicines, vaccines M&A news: AstraZeneca acquired TeneoTwo Inc. for USD 1.2bn and Logic Bio for USD 68mn in 2022.		

Sales in countries in scope

AstraZeneca's products are sold in 62 out of 113 countries in scope of the Index. AstraZeneca has sales offices in 19 countries and sells via suppliers and/or pooled procurement in an additional 43 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

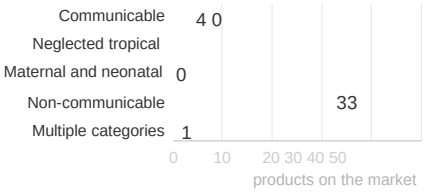
AstraZeneca has 79 R&D projects in scope, 10 of which target priority diseases, focusing on influenza (5) and COVID-19 (4). The remaining 69 projects target other diseases in scope, including cancer (44), cardiovascular diseases (6) and kidney diseases (5). Of the 79 R&D projects, 54 are in late-stage development, with evidence of access planning for 81% (44/54) of these.

PORTFOLIO *as selected for analysis by the Index*

AstraZeneca has 38 products in scope, including 36 medicines that primarily target non-communicable diseases, namely cancer (11), diabetes mellitus (7) and respiratory diseases, such as asthma and COPD (10). Most of its medicines are on patent (29). Of the 36 medicines in scope, 7 are listed on the WHO EML. In addition, it has 2 vaccines in scope that target influenza and COVID-19, 1 of which is listed on the WHO EML.

79 projects in the pipeline

38 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	5	2	0	1	1	0	1	0	10
with access plan				1	1	0	1		3
Other projects in scope			18	26	19	0	6	0	69
with access plan				18	18	0	5		41

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	3	26			29
off patent	4	3			7
Vaccines	1	1			2
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

AstraZeneca plc

GOVERNANCE OF ACCESS

RANK 4 SCORE 4.32

4th place. AstraZeneca performs well in this Technical Area. The company has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Further, AstraZeneca provides evidence of a patient reach process that covers all products and countries in scope of the Index, as well as public reporting of the underlying methodology and resulting patient reach numbers.

The highest responsibility for access lies directly with the Board, with a dedicated member of the Board of Directors responsible for sustainability, including access to healthcare. AstraZeneca incentivises select senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. Additionally, the CEO has access-related linked to their ESG performance. One of the performance indicators is the 'Contribution to society KPI', which measures progress on annual and long-term targets and includes 'Access to healthcare' as 1 of 3 pillars of sustainability.

Comprehensive access-to-medicine strategy

Shows comparatively strong commitment to responsible business practices. AstraZeneca does not disclose the level at which targets are set, but sales agents are not solely incentivised by sales volume. It has a global policy on ensuring ethical interactions with healthcare professionals. AstraZeneca offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for attending events or promotional activities) are made at fair market value. However, it only publicly discloses information on such payments in countries in assessments and region or country risk-based assessments. AstraZeneca lacks a framework, but its code of ethics guides employee decision-making. No breaches in countries in scope were found in the period of analysis.

AstraZeneca publicly supports the Doha Declaration on TRIPS and Public Health. However, it favours the use of alternative avenues ahead of compulsory licensing. AstraZeneca states that compulsory licensing should be considered only when access to patented medicines is critical to maintaining public health and no appropriate alternative is available.

Fulfils most criteria across 4 processes for measuring and reporting patient reach. For 1 process covering all its products and all countries (where the company operates) in scope of

scope if required by law or local regulation.

the Index, AstraZeneca publicly provides the

integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. AstraZeneca publicly discloses its commitments to access to medicine,

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AstraZeneca

limitations. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified.

along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated

performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance regularly in its Sustainability Report.

with company standards, fraud-specific risk

RESEARCH & DEVELOPMENT

RANK 7 SCORE 2.83

7th place. AstraZeneca performs above average in this Technical Area. It has an access planning process in place from Phase II onwards and applies this to nearly all late-stage candidates – although plans primarily focus on registration in emerging markets. Its priority pipeline is small compared to its peers, but it has the largest pipeline for non-communicable diseases of companies in scope. AstraZeneca publicly discloses disaggregated R&D investment data by phase of development and has an average performance in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (3/3) of the late-stage candidates. Priority R&D pipeline of 10 projects, including 3 late-stage projects mainly target cancer, cardiovascular diseases and kidney diseases. AstraZeneca provides evidence of access plans for 41 of its 51 late-stage projects, focusing mostly on registration preparation, post-trial access and equitable pricing plans.

Largest pipeline addressing other diseases in scope, with 78% (41/51) of late-stage projects covered by access plans. The company has 51 late-stage R&D projects targeting diseases in scope, which have not been established as focuses on various priority areas, including COVID-19 and influenza. All 3 of the late-stage projects targeting a priority gap have access plans in place, including registration preparation in countries in scope and equitable pricing plans.

AstraZeneca publicly discloses disaggregated R&D investment data for phase of development. It also discloses anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

One of the four R&D capacity building initiatives included for analysis meets all Good Practice Standards (GPS). Through the initiative that meets all GPS, AstraZeneca aims to build clinical trial capacity for cancer research in Vietnam.

projects targeting a priority gap. AstraZeneca a priority by global health stakeholders. The

AstraZeneca plc

PRODUCT DELIVERY RANK 4 SCORE 3.51

4th place. AstraZeneca performs well in this Technical Area. The company has access strategies in place for its products across different countries' income classifications. AstraZeneca shows Best Practice in reporting outcomes for these strategies. It fulfills all criteria for ensuring continuous supply of its medicines and all its health system strengthening initiatives meet all Good Practice Standards (GPS). The company engages in some manufacturing capacity building initiatives, some of which meet all GPS.

AstraZeneca registers newer products* in 15 countries in scope on average. It registers 75% of products assessed in at least 1 of the 10 countries with the highest disease burden; however, only 1 is registered in an LIC. The company's osimertinib (Tagrisso®), indicated for the treatment of lung cancer, is most widely registered, totalling 42 countries in scope. AstraZeneca reports engaging in mechanisms to facilitate registration, for example, through the WHO Collaborative Registration Procedure (SRA CRP).

One product in scope supplied through a supranational agreement. AstraZeneca's COVID-19 vaccine (Vaxzevria®)** was supplied through COVAX during the period of analysis. In addition, the company demonstrates access strategies in countries that procured the vaccine outside of COVAX. The company discloses data on doses sold and provides evidence of an additional access strategy to increase patient reach.

Most healthcare practitioner (HCP)-administered products covered by an access strategy, with comprehensive methods to track outcomes. For 2 of the 5 products selected for analysis – fulvestrant (Faslodex®), indicated for breast cancer, and goserelin acetate (Zoladex®), indicated for breast and prostate cancer and endometriosis – AstraZeneca provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC); 3 products lack access strategies in LICs. Access strategies in UMICs are more comprehensive in addressing product- and country-specific barriers to access; however, AstraZeneca shows some efforts to consider different payers' ability to pay in most of its strategies. For all of the examples analysed, the company provides evidence of health system strengthening initiatives. In general, the company shares goals to maximise patient reach and reports patient reach data, as well as details on the approaches used to track the outcomes and the progress of its strategies. For example, for its cancer treatment durvalumab (Imfinzi®), AstraZeneca reported increased patient reach both in Mexico (UMIC) and Egypt (LMIC) from 2022 to 2023, with forecasts indicating continued growth in 2024.

Majority of self-administered products are covered by an access strategy, with outcomes mostly tracked and reported. For 3 of the 5 products selected for analysis, AstraZeneca provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). Access strategies in UMICs are more comprehensive, with public reimbursement and additional support for patients paying out of pocket. For its 2 cancer products, the company provides testing support for early diagnosis in both UMIC and LMIC examples; for both its asthma products, it provides additional health system strengthening initiatives in the LMIC and LIC examples analysed. For almost all of the examples analysed, patient reach is reported, with details on the methodologies applied to measure and track the strategies' outcomes. For example, for osimertinib (Tagrisso®), indicated for lung cancer, the company has reported an increased number of patients reached from 2022 and 2023 in Egypt (LMIC), calculated through sales and reports from the patient assistance programme. The company also reported an increase in EGFR testing rate and plans to further increase patient reach.

AstraZeneca publicly commits not to file for or enforce patents for all products in over 80 countries in scope. This applies to all LICs and least developed countries, as well as many UMICs and LMICs. AstraZeneca publicly discloses the list of countries to which this commitment applies.

Publicly discloses product patent status for countries in scope. AstraZeneca publicly discloses patent information for its products on its website. The information published includes brand name, nature of the patent, patent number, expiry date and jurisdiction.

AstraZeneca has voluntary licensing agreements to enable generic supply for its COVID-19 vaccine. The agreements cover 70 countries in scope and are with multiple generic manufacturers. The terms of the licence are not publicly available. The agreement was active during the period of analysis; however, AstraZeneca subsequently withdrew the product from the market in May 2024.

Two of the three manufacturing capacity building initiatives included for analysis meet all GPS. For example, AstraZeneca is providing a technology transfer to a local manufacturer in one country in scope. The transfer will allow the manufacturer to fully produce and package two medicines in scope that are indicated for hypertension.

Two of the five supply chain capacity building initiatives included for analysis meet all GPS. For example, through United for Health II, AstraZeneca is collaborating with the Unified Procurement Authority in Egypt (LMIC) to educate pharmacists on topics such as health technology assessment, oncology burden and vaccines/immunology. So far, 200 pharmacists have been accredited.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, AstraZeneca's Young Health Programme, in partnership with Johns Hopkins Bloomberg School of Public Health and Plan International, is a global initiative aimed at preventing non-communicable diseases in youth aged 10 to 24 through advocacy, awareness and prevention.

AstraZeneca newly engaged in 2 IP-sharing agreements with public research institutions to accelerate drug development. In 1 agreement, the company shares a diverse compound library with the Liverpool School of Tropical Medicine to identify novel snake venom toxin inhibitors. AstraZeneca also remains engaged in existing agreements.

Fulfils all criteria for ad hoc donations. AstraZeneca has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, AstraZeneca is supporting an LMIC government's aim to reduce reliance on imports by assisting a local manufacturer to manufacture and supply dapagliflozin (Forxiga®), indicated for diabetes mellitus.

AstraZeneca has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to the national or local regulatory authorities within 5 days and to WHO Rapid Alert when cases are deemed significant. The company provides evidence of shortened timeframes for reporting cases that only require visual inspection for confirmation and aims to report within 3 working days when packaging is sufficient to assess the case.

AstraZeneca operates an inclusive business model that covers 1 product in 9*** countries. Launched in 2014 with a focus on cardiovascular disease (CVD), Healthy Heart Africa (HHA) includes reduced-price CVD medication felodipine (Plendil®), treatment and screening capacity, awareness, and provision of equipment. Now in 9 countries, including Kenya and Senegal, HHA also addresses chronic kidney disease and continues to expand geographically.

*Products that received their first marketing authorisation within the last

**In May 2024, AstraZeneca announced it

was withdrawing the product worldwide.
***The programme was closed in Tanzania in 2023.

5 years.

RANK	SCORE
10	3.13

9 (2022)

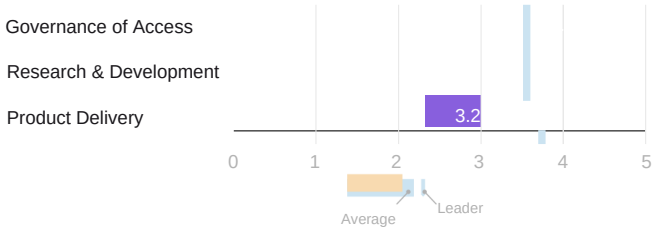
Bayer AG

Stock exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 99,723

PERFORMANCE IN THE 2024 INDEX

10th place. Bayer ranks in the top ten. It has improved its performance in Governance of Access. The company performs above average in Research & Development and Product Delivery, where it shows Best Practice in registering innovative products broadly in low- and middle-income countries (LMICs).

How score was achieved



OPPORTUNITIES FOR BAYER

Broaden the geographic reach of access plans for non-communicable diseases (NCDs). Bayer has comprehensive access plans in place for over half its late-stage R&D candidates. In general, its plans for NCDs are less comprehensive than those for neglected tropical diseases (NTDs) and include five countries in scope, on average. The company can ensure it has access plans in place for all NCD projects and broaden the geographic coverage of these plans to include more low- and middle-income countries (LMICs).

Expand access to its innovative products for NCDs. Bayer has access strategies in place for its NCD products; however, coverage in low-income countries is limited. It can improve access to these products in low-income countries through registration and equitable access strategies. For example, for its products vericiguat (Verquvo®), indicated for heart failure, and finerenone (Kerendia®), indicated for chronic kidney disease.

CHANGES SINCE THE 2022 INDEX

Publicly report on progress and outcomes of its Global Health Unit. In 2024, Bayer announced that it launched a Global Health Unit to improve access to medicines, including contraceptives, primarily – but not exclusively – in LMICs. Once the unit is operational, Bayer can report on outcomes of the model, such as patient reach and country-level implementation. This can help foster partnerships locally and drive accountability and implementation.

- Since 2022, Bayer's access-to-medicine strategy now covers all therapeutic areas the company is involved in.
- Bayer launched its Global Health Unit in May 2024 to enhance access to its medical products in countries where the company has limited or no presence.
- Signed a grant agreement with the Bill & Melinda Gates Foundation to advance research in non-hormonal contraception.
- Launched chronic kidney disease drug finerenone (Kerendia®) in India.
- Established the Pharma Sustainability Steering Board (a sub-committee of the Bayer Pharma Executive Committee) with the purpose of accelerating decision-making for cross-functional activities in the areas of ecological footprint and access to medicine.
- Opened its first cell therapy launch facility in Berkeley, California, to create the capacity to manufacture cell and gene therapies on a global scale.
- Opened its new USD 140mn Research and Innovation Center in Boston-Cambridge, Massachusetts, for precision molecular oncology research.

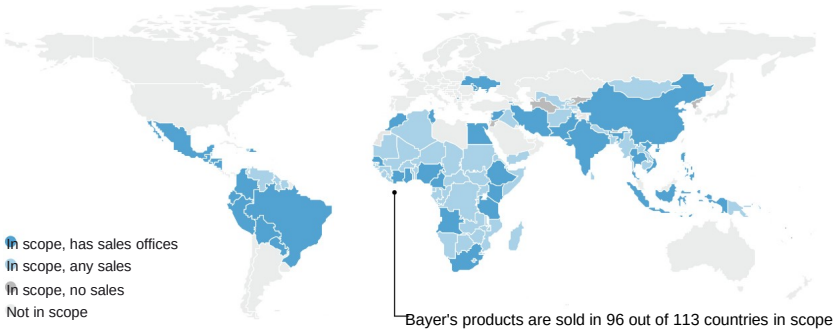
Bayer AG

SALES AND OPERATIONS

Therapeutic areas: Cardiology, chronic kidney disease, haematology, oncology, ophthalmology, healthy ageing, hormonal & reproductive health
Product categories: Innovative medicines
M&A news: In 2022, Bayer acquired Targenomix GmbH for an undisclosed amount and divested its Environmental Science Professional (BESP) business to Cinven for EUR 2.4bn, as well as its testosterone therapy (Nebido®) to Grünenthal for EUR 495mn. In 2023, it acquired Blackford Analysis Ltd and divested its right to Nimotop to Laboratoire X.O for undisclosed amounts.

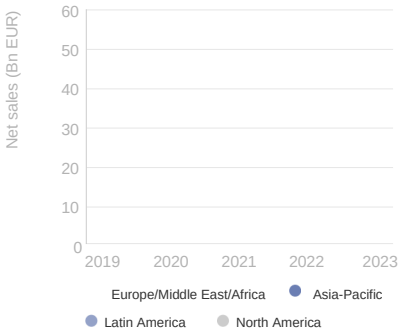
Net sales by segment (2023) – in EUR	
Crop science	23.27 bn
Pharmaceutical	18.08 bn
Consumer health	6.03 bn
Total	47.38 bn

Sales in countries in scope



Bayer's products are sold in 96 out of 113 countries in scope of the Index. Bayer has sales offices in 38 countries and sells via suppliers and/or pooled procurement in an additional 58 countries.

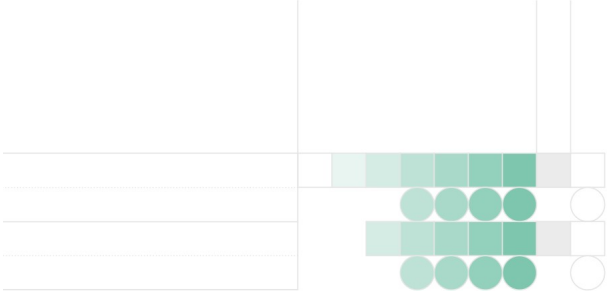
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

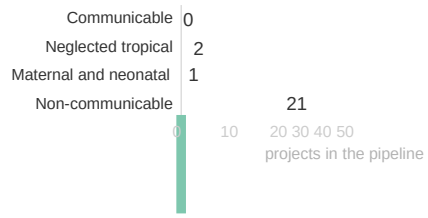
Bayer has 24 R&D projects in scope, 3 of which target priority diseases, focusing on contraceptives (1), soil-transmitted helminthiasis (1) and onchocerciasis (1). The remaining 21 projects target other diseases in scope, including cancer (12), cardiovascular diseases (5) and kidney diseases (2). Of the 24 R&D projects, 9 are in late-stage development, with evidence of access planning for 56% (5/9) of these.



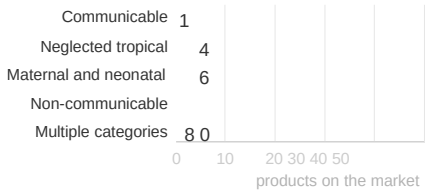
PORTFOLIO *as selected for analysis by the Index*

Bayer has 19 products in scope, 9 of which are listed on the WHO EML. Of its 13 medicines in scope, 8 are on patent. Bayer's medicines mostly target non-communicable diseases, including cancer (4), kidney diseases (2) and cardiovascular diseases (2), followed by products for maternal and neonatal health, including 6 contraceptives. Its medicines also target neglected tropical diseases, such as human African trypanosomiasis; its 1 medicine for a communicable disease targets malaria.

24 projects in the pipeline



19 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	1	0	2	0	0	0	0	3
with access plan				2	0	0	0		2
Other projects in scope			14	3	4	0	0	0	21
with access plan				0	3	0	0		3

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	1	7			8
off patent	5	0			
Vaccines	0	0			5
Contraceptives	3	3			
Diagnostics			0		0
Other				0	

Bayer AG

GOVERNANCE OF ACCESS RANK 4 SCORE 4.32

4th place. Bayer performs well in this Technical Area. The company's access-to-medicine strategy now covers all therapeutic areas in which the company is involved. It has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Further, Bayer provides evidence of a patient reach process that covers all countries in scope of the Index, as well as public reporting of the underlying methodology and resulting patient reach numbers.

The highest responsibility for access lies directly with the Board, with the CEO in their role as Chief Sustainability Officer. Furthermore, Bayer has an ESG Committee at Supervisory Board level to oversee access-related goals. Additionally, Bayer incentivises its senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. The CEO has long-term access-related incentives linked to sustainability goals.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Bayer publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regu

tives are not solely based on sales volume. For example, in Northwest Africa, Bayer incentivises qualitative key performance indicators such as presentation skills, compliance guideline knowledge and report quality and timeliness. Further, it commits to ensuring ethical interactions with healthcare professionals in its code of conduct and declares that transfers of value to healthcare professionals (e.g., payments for attending events or promotional activities) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that

sion-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Bayer supports the Doha Declaration on TRIPS and Public Health. However, it claims to support an efficient and balanced approach to intellectual property protection, aligned with the TRIPS Agreement, while highlighting a need for appropriate measures for the development of innovative products.

Fulfils most criteria with its process for measuring and reporting the patient reach of its contraceptives in LMICs. The process covers all countries in scope of the Index (where the company operates) and Bayer publicly provides the underlying equation, metrics and assumptions. The resulting patient reach numbers were published from 2019 to 2023 and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

governance efforts are not undermined by non-compliant or corrupt activities. Bayer performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance particularly in its Sustainability Report.

Shows comparatively strong commitment to responsible business practices. Bayer sets individual-level targets for sales agents, but incen

with company standards, fraud-specific risk assessments and region or country risk-based assessments. Bayer also has an ethical deci

RESEARCH & DEVELOPMENT

RANK 11 SCORE 2.40

11th place. Bayer performs above average in this Technical Area. It has an access planning framework in place, publicly commits to access planning from Phase II onwards and applies this to more than half of its late-stage pipeline candidates. The company has a small-sized priority R&D pipeline, which has declined in size. However, its access plans have a broader geographic reach, on average, compared to other companies. Bayer does not publicly disclose disaggregated R&D investment data, and it has regressed in its performance in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public mitment addressing its systematic approach to access planning for LMICs.

including registration preparation in countries in scope and equitable pricing plans.

Average-sized pipeline compared to peers, that address other diseases in scope, with 43% (3/7) of late-stage projects covered by access plans. The company has 7 late-stage projects in its pipeline, including 2 late-stage projects targeting a priority gap. The company focuses on various priority areas, including contraceptives and soil-transmitted helminthiasis.

Small-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (2/2) of the late-stage candidates. Bayer has 3 priority R&D

Bayer does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.
However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

One R&D capacity building initiative was included for analysis but it does not meet all Good Practice Standards (GPS). Bayer's collaboration with Peking University aims to build R&D capacity focused on translational drug discovery for multiple therapeutic areas.

R&D projects targeting other diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, cardiovascular diseases and kidney diseases. Bayer provides evidence of access plans for 3 of its 7 late-stage projects. Access plans include registration preparation, post-trial access and equitable pricing plans.

Bayer has access plans in place for both late-stage candidates targeting a priority product gap,

Bayer AG

PRODUCT DELIVERY

RANK 10 SCORE 3.21

10th place. Bayer performs above average in this Technical Area. The company engages in supranational agreements for its contraceptive products and has access strategies for its products across different income classifications, including low-income countries for half of the products assessed. However, data on the outcomes of some of these strategies is limited. Bayer demonstrates Best Practice by registering innovative products widely in LMICs. It newly engages in an intellectual property sharing agreement with a drug discovery initiative.

Bayer registers newer products* in 21 countries in scope on average. It registers the majority of products assessed in at least 1 of the 10 countries with the highest disease burden; 80% of products are registered in at least 1 LIC. The company's rivaroxaban (Xarelto®), indicated for stroke prevention, is most widely registered, totalling 74 countries in scope. Bayer reports engaging in mechanisms to facilitate registration, for example, through the WHO Collaborative Registration Procedure (SRA CRP) for its contraceptive device.

Supplies 3 products through supranational agreements. All 3 products assessed are contraceptives supplied through the United Nations Population Fund (UNFPA). The company demonstrates access strategies for all 3 products in at least one country not eligible for supply via UNFPA. For the non-eligible country examples, Bayer has goals to improve availability and affordability for the most vulnerable populations and demonstrates efforts in reaching these goals. Patient reach is reported for all 3 products, for both the supranational agreement and the non-eligible country example.

efforts in considering payers' ability to pay in its strategies, however, it could further refine its strategies and expand to LICs. In Colombia and China (UMICs), the company has secured public reimbursement for 4 of the 5 products analysed. For 2 cancer products – Darolutamide (Nubeqa®) and sorafenib (Nexavar®) – it implements patient assistance programmes to improve access in India (LMIC), a country where most patients pay out of pocket. Bayer only provides evidence of patient reach for a few of the examples analysed, as well as limited information on the approaches used to measure outcomes and track progress.

Bayer publicly commits not to file for or enforce patents for all products in all low-income countries in scope.

Publicly discloses product patent status for countries in scope. Like most peers, Bayer publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Bayer newly engaged in an IP-sharing agreement with a drug discovery initiative to accelerate drug development. In this agreement, Bayer shares its molecule libraries with Medicines for Malaria Venture to identify potential new therapies. The company also remains engaged in existing agreements.

Fulfils most criteria for ad hoc donations. Bayer has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, the company does not make public commitments to adhere to the most recent WHO Guidelines for Medicine Donations.

Bayer publicly commits to continue long-term donation programmes to support the control of Chagas disease and food-borne trematodiases' and elimination of human African trypanosomiasis and taeniasis. One of its programmes is active in 15 countries in scope, with the company pledging to donate nifurtimox (Lampit®) and suramin (Germanin®) for as long as needed, to achieve goals highlighted by the WHO for elimination of human African trypanosomiasis.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Bayer supplies products, mainly hormonal contraceptives

Bayer does not engage in non-exclusive volun
tary licensing for products in scope.

Algeria and Morocco. For supply in Algeria, Bayer is
currently transferring technology to Somedial for

One healthcare practitioner (HCP)-administered

product covered by access strategies in all 3 income country classifications. For the prod

Three of the four manufacturing capacity building initiatives included for analysis meet all GPS. For example, Bayer supports the Institute of Vaccine and Medical Biologicals (IVAC) in Vietnam to meet Good Manufacturing Practice standards for full production of an egg-based COVID-19 vaccine. IVAC plans to manufacture enough doses to cover 80% of the target population in Vietnam.

Both supply chain capacity building initiatives included for analysis meet all GPS. In 1 initiative, Bayer is part of the Reproductive Health Supplies Coalition's Global Family Planning Visibility and Analytics Network (GFP-VAN). GFP-VAN collects data from multiple sources, allowing reproductive health supply procurers to have visibility of the supply chain and prevent stockouts.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, since 2021, Bayer has partnered with Egypt's ministry of health to enhance screening, diagnosis and treatment of hepatocellular carcinoma.

Bayer has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 7 days for the most severe risk category and will also consider reporting to WHO Rapid Alert. The company does not provide evidence of shortened timeframes for reporting cases that only require visual inspection for confirmation.

No evidence of inclusive business models that meet inclusion criteria.** However, Bayer engages in initiatives that address access needs of neglected populations. For example, the company financially supported (convertible loan) Zuri Health, an innovative digital health company that connects underserved populations with low-cost health services. As part of its “Hospital In Your Pocket” platform, Zuri provides education, access and product delivery of modern contraceptive products (including Bayer products) to both urban and rural communities in Kenya.

uct assessed, Mirena®/LNG-IUS, a long-acting intrauterine contraceptive device, the company provides examples of access strategies in all 3 country income classifications (UMIC, LMIC, LIC), but the quality of these varies across the 3 country examples. Bayer has a comprehensive strategy in Egypt (LMIC), where a price agreement with the national reimbursement authority, and an additional supply channel via UNFPA, have enabled a considerable increase in access to the product in the public sector. In Uganda (LIC), the product is also supplied via UNFPA and via an additional donor programme. Patient reach data is reported for all 3 country examples, with evidence of increasing the number of patients reached from 2022 in Egypt (LMIC) and Brazil (UMIC). Bayer plans to continue progressing all the strategies and increase access further.

Provides evidence of access strategies for its self-administered products in some countries, though information on the outcomes is limited. For 4 of the 5 products, Bayer provides evidence of access strategies in UMIC and LMIC

The initiative aims to provide screening at 70 cen
tres nationwide, with 80% of diagnosed patients
examples. The company demonstrates some starting treatment.

*Products that received their first marketing authorisation within the last 5 years.,

**In May 2024, Bayer announced the launch of its Global Health Unit. The full strategy, product and geographic scope have yet to be disclosed, therefore it was not assessed as part of the 2024 Index cycle.

RANK	SCORE
8	3.20

13 (2022)

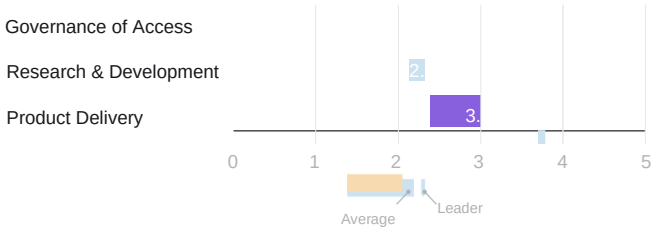
Boehringer Ingelheim

Stock exchange: N/A • HQ: Ingelheim am Rhein, Germany • Employees: 53,500

PERFORMANCE IN THE 2024 INDEX

8th place. Boehringer Ingelheim ranks in the top ten. It has improved in Product Delivery, with a strong performance in capacity building. The company has an average performance in Governance of Access. It performs above average in Research & Development, where it has access plans for all projects.

How score was achieved



OPPORTUNITIES FOR BOEHRINGER INGELHEIM

Expand the depth and breadth of access plans for investigational compounds in the pipeline. Boehringer Ingelheim has access plans for all its late-stage R&D projects. For projects testing existing treatments in new indications, these plans are comprehensive and cover a broad range of countries. However, the depth and geographic coverage of access plans for investigational compounds are more limited. For example, it can expand its access plan for BI 1358894, an investigational compound in Phase II of development for major depressive disorder, to include more countries in scope of the Index.

Expand manufacturing capacity building efforts for medicines and vaccines. Boehringer Ingelheim and the Botswana Vaccine Institute have a partnership for the production and distribution of animal vaccines, including for rabies. To support the production of medicines and vaccines and build local manufacturing capabilities, the company can build on this initiative, pursuing similar collaborations in other countries in Africa for products prioritised for local production.

CHANGES SINCE THE 2022 INDEX

Expand access to essential medicines. Boehringer Ingelheim has access strategies in place for its products that are on the WHO Model List of Essential Medicines; however, the geographic reach of these strategies is mostly limited to upper-middle and lower-middle income countries. For
example, the company can expand access to more countries in scope, particularly low-income countries for the products afatinib (Giotrif®/Gilotrif®), indicated for lung cancer, and alteplase (Actilyse®), for cardiovascular disease through equitable access strategies.

- Announced plans to invest more than CNY 3.5bn (USD 438.25mn) into R&D efforts in China over the next five years.

- Developed and implemented a new Access & Value policy that aims to provide broader and faster access for new, innovative assets.
    - Formed a joint venture (Aurobac Therapeutics SAS), together with Evotec SE and bioMérieux, to create the next generation of antimicrobials along with actionable diagnostics to fight

- Donated medicines to Afghanistan in response to aid requests from Americares in 2023.
- Inaugurated its EUR 350mn biologicals development centre in Biberach an der Riss, Germany.
- Reinforced public commitment to “Zero by 30”, the global goal to eliminate rabies by antimicrobial resistance.

- Developed and implemented a systematic approach to Human Rights and published 2030. Expanded global STOP Rabies initiative, on vaccination, education and surveillance, to additional countries in scope such as India, Indonesia and Vietnam.

several reports and statements. focusing
- Launched new “Access to Healthcare” initiative in Kenya.

Boehringer Ingelheim

SALES AND OPERATIONS

Therapeutic areas: Cardiovascular and metabolic diseases, immunology, mental health, oncology, respiratory diseases, retinal diseases

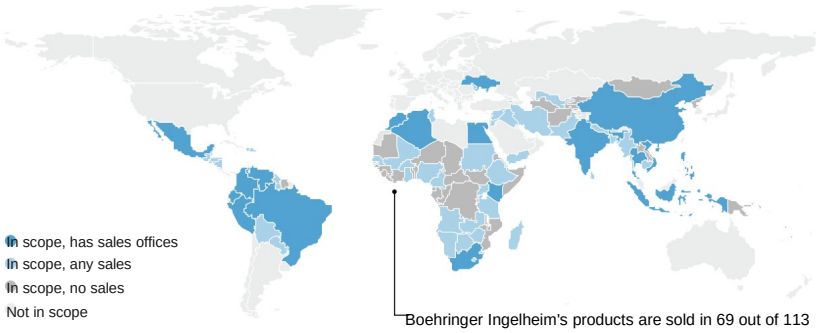
Product categories: Animal health, innovative medicines

M&A news: In 2023, Boehringer Ingelheim acquired T3 Pharmaceuticals for CHF 450mn.

Net sales by segment (2023) – in EUR

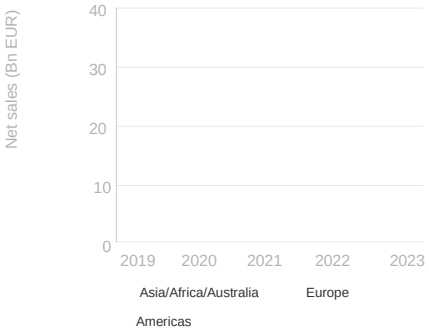
Human pharmaceutical	20.77 bn
Animal health	4.72 bn
Other sales	0.12 bn
Total	25.61 bn

Sales in countries in scope



Boehringer Ingelheim's products are sold in 69 out of 113 countries in scope of the Index. Boehringer Ingelheim has sales offices in 18 countries and sells via suppliers and/or pooled procurement in an additional 51 countries.

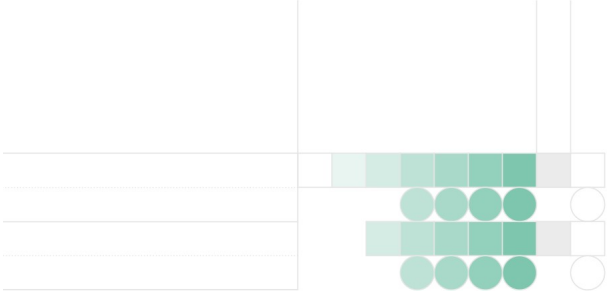
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

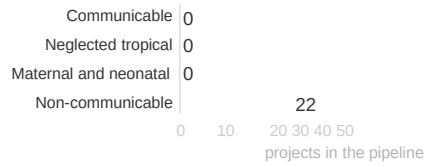
Boehringer Ingelheim has 22 R&D projects in scope, none of which target priority diseases. All 22 projects target other diseases in scope, including cancer (14), kidney diseases (3) and cardiovascular diseases (2). Of the 22 R&D projects, 7 are in late-stage development, with evidence of access planning for 100% (7/7) of these.



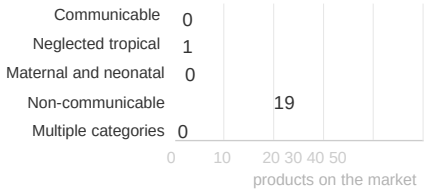
PORTFOLIO *as selected for analysis by the Index*

Boehringer Ingelheim has 20 products in scope, 11 of which are listed on the WHO EML. Of its 19 medicines, 14 are on patent, and all 19 target NCDs, including cardiovascular diseases (6), diabetes (6) and asthma and COPD (6). The company has 1 vector control product in scope for rabies.

22 projects in the pipeline



20 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	0	0	0	0	0	0	0
with access plan				0	0	0	0		0
Other projects in scope			15	4	1	0	2	0	22
with access plan				4	1	0	2		7

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	7	7			14
off patent	4	1			5
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				1	1

Boehringer Ingelheim

GOVERNANCE OF ACCESS

RANK 12 SCORE 3.80

12th place. Boehringer Ingelheim has an average performance in this Technical Area. The company provides evidence of a patient reach process that covers all countries and products in scope of the Index. However, it does not publicly provide the underlying methodology details, and no patient reach goals were identified. Boehringer Ingelheim sets individual-level sales targets for its sales agents, but it has a robust set of controls to mitigate the risk of non-compliant or corrupt activities in countries in scope.

The highest responsibility for access lies directly with the Board, specifically with the Board member responsible for Human Pharma. Boehringer Ingelheim has access-related incentives for senior executives and in-country managers.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Boehringer Ingelheim publicly discloses its commitments to access to medicine, along with company-specific targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available and updated regularly in its Annual Report.

Shows comparatively strong commitment to responsible business practices. Boehringer Ingelheim sets individual-level sales targets and incentives are not solely based on sales volume. Additionally, the company commits to ensuring ethical interactions with healthcare professionals in its code of conduct and declares that transfers of value to healthcare professionals (e.g., payments for attending events) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Boehringer Ingelheim performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country decision-making. No breaches in countries in scope were found in the period of analysis.

Boehringer Ingelheim publicly supports the Doha Declaration on TRIPS and Public Health. It views the Declaration as a mechanism offering more juridical certainty to countries that may use the system. However, the company states that protecting intellectual property (IP) is the foundation for making long-term commitments to high-risk investment decisions in the research, development and commercialisation of innovative drug products.

Fulfils some criteria across 3 processes for measuring and reporting patient reach. For its global patient reach process covering all its products and all countries (where the company operates) in scope of the Index, Boehringer Ingelheim provided the underlying equation, metrics, assumptions and limitations directly to the Index. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified.

risk-based assessments. It lacks a framework, but its code of conduct guides ethical employee

RESEARCH & DEVELOPMENT RANK 9 SCORE 2.65

9th place. Boehringer Ingelheim performs above average in this Technical Area. It has an access planning framework from Phase II onwards and applies this to all late-stage pipeline candidates. The company does not have any priority projects in its pipeline, but it has comprehensive access plans for non-communicable disease projects – although the depth and breadth of plans vary depending on the project. Furthermore, it newly discloses public R&D investment data disaggregated by phase of development and has improved its R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Boehringer Ingelheim does not have any pro jects in its R&D pipeline targeting a priority disease in scope.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 100% (7/7) of late-stage projects covered by access plans. The company has 7 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, kidney diseases and cardiovascular diseases. Boehringer Ingelheim provides evidence of access plans for all 7 late-stage projects, mostly focused on registration preparation and supply and demand plans.

Boehringer Ingelheim publicly discloses dis-aggregated R&D investment data for phase of development. However, it does not disclose disaggregated R&D investment data to global health organisations.*

Three of the four R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is a collaborative training initiative with local hospitals and universities in Brazil, focused on patient safety and pharmacovigilance. Similar programmes are being implemented in Nigeria and Kenya.

PRODUCT DELIVERY RANK 8 SCORE 3.34

8th place. Boehringer Ingelheim performs above average in this Technical Area, showing significant improvement since the last Index. The company has a comprehensive strategy to provide access to its supranationally procured product. It also implements comprehensive access strategies for its products and generally reports their outcomes, however coverage in low-income countries is limited. The company engages in multiple new intellectual property sharing agreements. Most of its capacity building initiatives across supply chain, manufacturing and health system strengthening, meet all Good Practice Standards.

Boehringer Ingelheim registers products in 23 countries in scope on average. It registers 80% of products assessed in at least 1 of the 10 countries with the highest disease burden; however, only 30% are registered in LICs. The company's empagliflozin (Jardiance®), licensed for multiple indications including diabetes

*Boehringer Ingelheim currently has no pipeline candidates within the disease scope of Impact Global Health (formerly known as Policy Cures Research), an organisation that assesses disaggregated R&D data.

Boehringer Ingelheim

mellitus, is most widely registered, totalling 43 countries in scope. The company did not report participating in any mechanisms to facilitate registration.

Has access strategies for its supranationally procured product in scope. Boehringer Ingelheim supplies its veterinary rabies vaccine (Rabisin®) through the Pan American Health Organization (PAHO). The company also demonstrates access strategies for the product in a country not eligible for procurement via PAHO. In Vietnam, the company engages in supply chain strengthening and capacity building initiatives, as well as in vaccination campaign and product donations. The company shares evidence of the strategy outcomes and plans to progress the strategy with a comprehensive goal aimed at eliminating rabies.

Access strategies for healthcare practitioner (HCP)-administered products in some countries, with outcomes tracked and reported. For both products selected for analysis, Boehringer Ingelheim provides evidence of access strategies in UMICs and LMICs, but not in any LICs. Access strategies in UMICs are more comprehensive. For example, in Mexico (UMIC), for its product tenecteplase (Metalyse®), indicated for cardiovascular disease, the company implements tailored cost-effectiveness models and budget impact analysis with the different public health institutions and the product is fully reimbursed for patients in the public sector. The second product analysed, also indicated for cardiovascular disease, is publicly reimbursed in both the UMIC and LMIC examples. The company engages in health system strengthening initiatives; for example, through the Angels Initiative, it supports the improvement of a stroke management system in Egypt (LMIC). The company has goals to increase access to its products and reported outcomes data, including patient reach for all the examples assessed.

Access strategies for its self-administered products in some countries, with outcomes mostly tracked and reported. For 2 of the 5 products selected for analysis, Boehringer Ingelheim provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC); 3 products lack access strategies in LICs. The company demonstrates efforts in reaching patients across income levels through its strategies (AtH) programme, through which the price is determined based on individual income levels and eligibility assessed by a third-party survey. For all UMIC and LMIC examples analysed, strategies' outcomes are tracked and reported, although for those under the AtH programme this is at an aggregated level.

Boehringer Ingelheim publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all products in all LICs, least developed countries and many LMICs and UMICs. The list of countries to which the commitment applies is publicly available.

Boehringer Ingelheim does not publish patent information of its products on its website or via a patent database, such as Pat-INFORMED.

Boehringer Ingelheim does not engage in non-exclusive voluntary licensing for products in scope.

All 5 manufacturing capacity building initiatives included for analysis meet all GPS. For example, Boehringer Ingelheim has partnered with the Botswana Vaccine Institute (BVI) since 1978, transferring technology for animal vaccine production. BVI is currently a distributor for the company's veterinary rabies vaccine (Rabisin®) in sub-Saharan Africa.

Three of the five supply chain capacity building initiatives included for analysis meet all GPS. For example, Boehringer Ingelheim supports Wella health, a digital platform connected with nearly 2,000 pharmacies in Nigeria that aims to address availability, affordability and adherence to treatment.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, in partnership with major stroke organisations, Boehringer Ingelheim's Angels Initiative aims to improve global stroke care by increasing the number of hospitals able to provide quality stroke care in more than 150 countries including 70 countries in scope.

Fulfils all criteria for ad hoc donations. Boehringer Ingelheim has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in 2023, The Boehringer Ingelheim Cares Foundation (BICF) responded to aid requests from Americares by donating medicines to Afghanistan. This comprised 3 products, including empagliflozin (Jardiance®), which is in scope, reaching 524 patients. BICF publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Boehringer Ingelheim publicly commits to continue long-term donation programme to support the elimination of human dog-mediated rabies. Its programme is active in 9 countries in scope, with the company pledging to donate its rabies vaccine (Rabisin®) to help ensure there are no human deaths from dog-mediated rabies by 2030.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Boehringer Ingelheim is working with Algeria's Abdi Ibrahim Remede Pharma to manufacture the antihypertensive telmisartan/hydrochlorothiazide (Micardis Plus®) and package the diabetes treatment empagliflozin (Jardiance®) for local supply.

Boehringer Ingelheim has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 7 days. The company discloses to the Index, but not publicly, whether it has shortened reporting timeframes for cases that only require visual inspection for confirmation.

Boehringer Ingelheim operates an inclusive business model that covers 2 products in 1 country. Launched in 2014, the model is a partnership with Farmacias Similares in Mexico, providing reduced cost antihypertensives telmisartan (Micardis®) and telmisartan/hydrochlorothiazide (Micardis Plus®) to low-income populations. Additionally, diabetes treatments are planned to be launched. The company also offers healthcare worker training in UMICs and LMICs. In Mexico (UMIC), the company launched a generic brand of telmisartan/hydrochlorothiazide (Micardis Plus®), supplied through a local partner, Farmacias Similares, to improve affordability for low-income populations; it plans to do the same for a second product. In Kenya (LMIC), 3 of the 5 products

Boehringer Ingelheim newly engaged in 26 IP-sharing agreements with public research institutions to accelerate drug development. The company performs well in this area. Through opnMe.com Boehringer Ingelheim shares molecules with partners, such as São Paulo State University, Brazil to accelerate preclinical research for diabetes, mental health conditions and communicable diseases, such as malaria and COVID-19. The company also remains engaged in

analysed are part of the Access to Healthcare existing agreements.

RANK	SCORE
13	2.63

15 (2022)

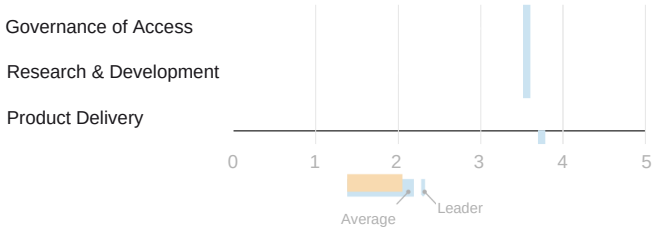
Bristol Myers Squibb

Stock exchange: NYSE • Ticker: BMY • HQ: New York, New York, United States • Employees: 32,200

PERFORMANCE IN THE 2024 INDEX

13th place. Bristol Myers Squibb performs below average. However, it has improved performance in Research & Development and Product Delivery. It demonstrates best practice by launching an inclusive business model to improve access to its products in LMICs.

How score was achieved



OPPORTUNITIES FOR BRISTOL MYERS SQUIBB

Broaden the geographic reach of access plans to include more low- and lower-middle-income countries. Bristol Myers Squibb has comprehensive access plans in place for most of its late-stage R&D candidates. However, these plans focus primarily on upper-middle-income countries (UMICs) and include an average of two countries in scope. The company can expand its plans beyond UMICs by including more low- and middle-income-countries (LMICs) within scope.

Publicly report on progress and outcomes of its inclusive business model. In May 2024, Bristol Myers Squibb announced the launch of ASPIRE (Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity), an inclusive business model supporting the company to reach more patients in LMICs. Bristol Myers Squibb can publicly report on the patient reach numbers for the various

CHANGES SINCE THE 2022 INDEX

strategies deployed through the model and can also disclose the countries where its products are being made available through these strategies. This can foster partnerships locally and drive accountability and implementation.

Expand access to oncology products. Bristol Myers Squibb has demonstrated providing access to several of its oncology products including in some low-income countries. It can continue to increase patient and geographic reach to its key products through the new access pathways outlined in its ASPIRE inclusive business model. For example, for its products dasatinib (Sprycel®), listed on the WHO Model List of Essential Medicines, and azacitidine (Onureg®), both of which are indicated for leukaemia.

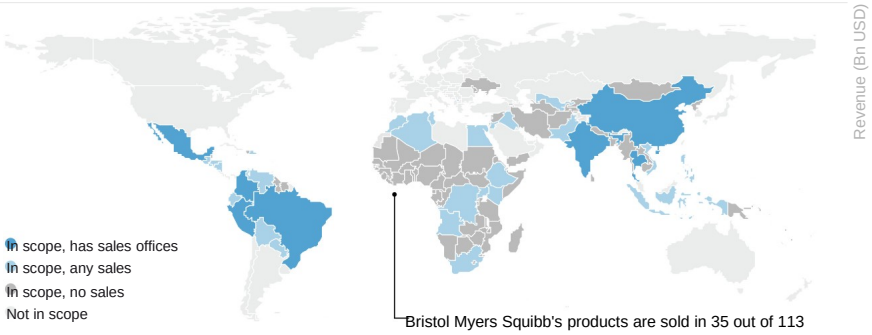
- Established its Global Health Equity Team in September 2022, with the objectives to establish sustainable access to its innovative medicines for patients, expand global partnerships and empower clinicians and patients with educational resources.
- In 2022, launched the LMIC Governance Committee to focus on addressing challenges in LMIC markets. The committee has supported the establishment and implementation of a new LMIC access strategy and governance processes with cross-functional representation to ensure enterprise-wide alignment.
- Launched ASPIRE (Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity) in May 2024, a ten-year strategy to advance access to its innovative treatments and help patients in LMICs gain access to potentially lifesaving medicines.
- Announced a collaboration with the Access to Oncology Medicines (ATOM) Coalition and their partners to make Opdivo™ (nivolumab) available via a safe, scalable and sustainable access model in select countries including Pakistan, Rwanda and Zambia while working to develop an integrated pathway that can expand access in multiple LMICs by 2026.
- Announced the official opening of its new USD 100mn drug development and IT facility in Hyderabad, India.
- Newly demonstrated a public commitment not to file patent applications or enforce patent rights in least developed countries, LICs and a vast majority of LMICs.
- Awarded an additional USD 1.8mn towards its Health Equity Grant Initiatives in March 2024. The expansion will fund an initiative to advance health equity by addressing social determinants of health in Brazil, India and Thailand (as well as the UK).

Bristol Myers Squibb

SALES AND OPERATIONS

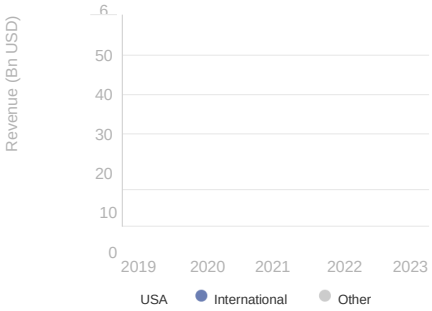
Therapeutic areas: Cardiovascular disease, haematology, immunology, neuroscience, oncology	in 2022 and Orum Therapeutics' ORM-6151 programme for USD 100mn in 2023. In 2024, it acquired Mirati Therapeutics Inc. for USD	Revenue by segment (2023) – in USD	
Product categories: Innovative medicines	5.8bn; RayzeBio Inc for USD 4.1bn; and Karuna	Pharmaceutical	45.01 bn
M&A news: Bristol Myers Squibb acquired Turning Point Therapeutics for USD 4.1bn	Therapeutics Inc. for USD 12bn.	Total	45.01 bn

Sales in countries in scope



Bristol Myers Squibb's products are sold in 35 out of 113 countries in scope of the Index. Bristol Myers Squibb has sales offices in 7 countries and sells via suppliers and/or pooled procurement in an additional 28 countries.

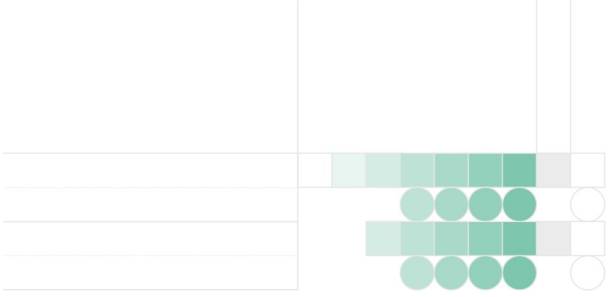
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

Bristol Myers Squibb has 34 R&D projects in scope, none of which target priority diseases. All 34 projects target other diseases in scope, including cancer (27), cardiovascular diseases (2) and Alzheimer's disease (2). Of the 34 R&D projects, 16 are in late-stage development, with evidence of access planning for 75% (12/16) of these.

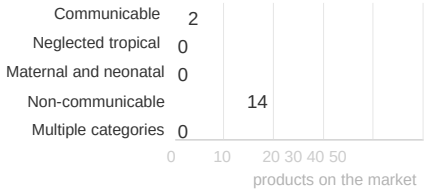


PORTFOLIO *as selected for analysis by the Index*

Bristol Myers Squibb has 16 medicines in scope, 4 of which are listed on the WHO EML. Nearly all its medicines are on patent (15). Its medicines mostly target non-communicable diseases, such as cancer (12) and thalassemia (1). Its 2 products for non-communicable diseases target HIV.

34 projects in the pipeline

16 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	0	0	0	0	0	0	0
with access plan				0	0	0	0		0
Other projects in scope			18	9	5	0	2	0	34
with access plan				6	4	0	2		12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	3	12		15
off patent	1	0		1
Vaccines	0	0		0
Contraceptives	0	0		0
Diagnostics		0		0
Other			0	0

Bristol Myers Squibb

GOVERNANCE OF ACCESS

RANK 15 SCORE 3.44

15th place. Bristol Myers Squibb performs below average in this Technical Area. The company incentivises its CEO and senior executives to act on access to medicine but does not disclose whether in-country managers are also incentivised. Bristol Myers Squibb provides evidence of a patient reach process that covers all countries and some of its products in scope but does not provide the underlying methodology publicly. Further, it does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility for access lies directly with the Board, with the Board Chair and CEO responsible for final decisions regarding the development of each product's access strategy and programmes. Bristol Myers Squibb incentivises its senior executives to act on access to medicine with financial and non-financial rewards. The CEO has incentives tied to various ESG objectives, including specific goals toward increasing access to medicine. The company, however, does not disclose whether in-country managers are also incentivised towards access goals.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Bristol Myers Squibb publicly discloses its commitments to access to medicine, along with some company-specific measurable targets, goals and objectives. Reporting is mostly clear, linked to goals, centrally available, and updated regularly in its ESG

Shows comparatively strong commitment to responsible business practices. The level at which Bristol Myers Squibb sets sales targets varies by individual, team, business unit, national and global levels, as well as by therapeutic area, and incentives are not solely based on sales volume. Incentives are also assessed against qualitative objectives, such as achievement of individual objectives (e.g., project outcomes), company strategy objectives and how the sales agent demonstrates company values. Further, the company commits to ensuring ethical interactions with healthcare professionals in its code of conduct. However, it only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bristol Myers Squibb performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. It also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Bristol Myers Squibb does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available 'Global position statement on intellectual property', but it does not align with principles embodied in the Declaration. Further, the company states that compulsory licensing beyond TRIPS provisions would weaken intellectual property framework and undermine innovation, collaboration, and access to medicine efforts.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For its LMIC process covering all countries (where the company operates) and some of its products in scope of the Index, Bristol Myers Squibb provides the underlying equation, metrics, assumptions and limitations under an NDA. The resulting patient reach numbers are published, but as 2023 was the first year of reporting, no improvements could be demonstrated. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 13 SCORE 2.06

13th place. Bristol Myers Squibb performs below average in this area. It has an access planning framework in place and publicly commits to access planning from Phase II onwards, with most late-stage candidates covered by access plans. The company does not engage in R&D for priority diseases but has comprehensive access plans for non-communicable disease projects – although mostly focused on emerging markets. It newly reports public R&D investment data disaggregated by phase of development, but it no longer engages in R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 75% (12/16) of late-stage projects covered by access plans. The company has 16 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target

Bristol Myers Squibb does not have any projects in its R&D pipeline targeting a priority including registration preparation, post-trial access and equitable pricing plans.

Bristol Myers Squibb publicly discloses disaggregated R&D investment data for phase of development. However, it does not disclose disaggregated R&D investment data to global health organisations.*

No evidence of R&D capacity building initiatives that meet inclusion criteria.

cancer, cardiovascular diseases and Alzheimer's disease. Bristol Myers Squibb provides evidence of access plans for 12 of its 16 late-stage projects, disease in scope.

*Bristol Myers Squibb currently has no pipeline candidates within the disease scope of Impact Global Health (formerly known as Policy Cures Research), an organisation that assesses disaggregated R&D data.

Bristol Myers Squibb

PRODUCT DELIVERY

RANK 14 SCORE 2.72

14th place. Bristol Myers Squibb performs below average in this Technical Area. The company demonstrates Best Practice by launching an inclusive business model to improve access to its products in multiple low-income and least developed countries. However, it no longer engages in manufacturing capacity building initiatives. It implements access strategies; however, the geographic reach is limited, and outcomes data is only available for some products. The company has a new public commitment to not file or enforce patents in the majority of countries in scope.

Bristol Myers Squibb registers newer products** in 6 countries in scope on average. None of the products assessed are registered in any LICs, however, 30% are registered in at least 1 of the 10 countries with the highest disease burden. The company's ipilimumab (Yervoy®), indicated for multiple cancer types, is most widely registered, totalling 24 countries in scope, an increase of 13 countries since the previous Index. The company reports engaging in a mechanism to facilitate registration.

Bristol Myers Squibb is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

Some access strategies for healthcare practitioner (HCP)-administered products include all country income classifications, with outcomes mostly tracked and reported. For 2 of the 4 products selected for analysis – ipilimumab (Yervoy®) and nivolumab (Opdivo®) – Bristol Myers Squibb provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). Overall, the company makes efforts to implement access strategies that consider payers' ability to pay. For 3 products, it has launched a second brand in India (LMIC). In Uganda (LIC), the company works with a local partner and supplies 2 of these products, ipilimumab and nivolumab, directly to healthcare facilities under a newly launched pathway that aims to increase access and cost efficiencies. In most examples, the company supports health system strengthening by providing HCP education. Patient reach data and approaches for measuring the strategy outcomes are reported for most examples analysed.

Some strategies to enable access to self-administered products, but limited information on outcomes. For 2 of the 3 products selected for analysis, Bristol Myers Squibb provides evidence of access strategies in UMICs and LMICs. For the third product, azacitidine (Onureg®), only a UMIC example is provided. All products lack strategies in LICs. All 3 products are indicated for (Revlimid®) by providing financial support to patients. The company also engages in donations via the Max Foundation to make its leukemia drug dasatinib (Sprycel®), available in Nepal (LMIC), where it is not registered. The company shares limited information on approaches used to track the progress of its strategies and does not report patient reach data for any of them.

Bristol Myers Squibb publicly commits not to file for or enforce patents in the majority of countries in scope. In 2023, the company newly committed to this in all least developed countries, all LICs and a vast majority of LMICs. However, the list of countries to which the commitment applies is not publicly available.

Publicly discloses product patent status for countries in scope. Like most peers, Bristol Myers Squibb publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Bristol Myers Squibb has 2 non-exclusive voluntary licensing agreements to enable generic supply. One of the licensing agreements for atazanavir, indicated for HIV, covers 96 countries in scope and was issued in 2013. The other licensing agreement for daclatasvir, indicated for hepatitis C, covers 112 countries in scope and was issued in 2015. The terms of both licences are publicly available.

No evidence of manufacturing capacity building initiatives that meet inclusion criteria.

One supply chain capacity building initiative meets all Good Practice Standards (GPS). In this initiative, Bristol Myers Squibb is supporting manufacturers and suppliers in India and China to build their supply chain capacity.

All 5 health system strengthening initiatives

Bristol Myers Squibb newly engaged in an IP-sharing agreement with a drug discovery initiative to accelerate drug development. The company shared a compound library as part of the Global Health Priority Box with the Medicines for Malaria Venture and the Innovative Vector Control Consortium to screen against neglected and zoonotic diseases and diseases at risk of drug resistance. The company also remains engaged in existing agreements.

Fulfils most criteria for ad hoc donations. Bristol Myers Squibb has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, the company does not make public commitments to adhere to the most recent WHO Guidelines for Medicine Donations.

Fulfils few criteria for mechanisms to ensure continuous supply in LMICs. Bristol Myers Squibb manages a buffer stock of relevant products but lacks other mechanisms, such as technology transfer and manufacturing products at its own sites in LMICs.

Bristol Myers Squibb has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 10 days. The company's Corporate Security coordinates with WHO Rapid Alert representatives to exchange and furnish relevant information post-alert. There is no evidence of a shortened timeframe for reporting cases that only require visual inspection for confirmation.

Bristol Myers Squibb operates an inclusive business model that covers 12*** products in 85 LMICs in scope, including 32 low-income and least developed countries. Launched in 2024, the company's 10-year LMIC strategy aims to reach more underserved patients while promoting international growth of the company. It uses managed access programmes, partnerships and emerging market brands to improve access to a selection of mostly on-patent products indicated for various cancer types, beta thalassemia and viral infections such as HIV; including nivolumab (Opdivo®), luspatercept (Reblozyl®) and atazanavir (Reyataz®).

different cancer types, with some evidence of efforts to address accessibility and affordability barriers. For example, the company implements patient support programmes (PSPs) in 3 exam

included for analysis meet all GPS. For example, Bristol Myers Squibb financially supports Baylor College of Medicine's International Pediatric AIDS Initiative, Texas Children's Hospital and ministries of health to help improve cancer and rare blood disorder treatment and diagnosis in Botswana, Malawi, Rwanda, South Africa, Tanzania and Uganda.

ples assessed, including in Lebanon (LMIC), where it addresses affordability of lenalidomide

**Products that received their first marketing authorisation within the last 5 years.

***9 of these products address diseases in scope.

RANK	SCORE
18	1.94
17 (2022)	

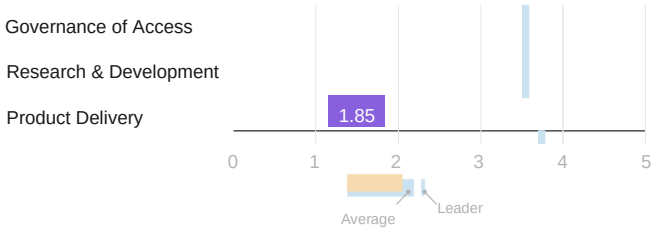
Daiichi Sankyo Co., Ltd

Stock exchange: TSE • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 18,726

PERFORMANCE IN THE 2024 INDEX

18th place. Daiichi Sankyo is in the lower ranks of all Technical Areas. It engages in health system strengthening initiatives; however, its Research & Development access plans and product access strategies are limited in geographic reach.

How score was achieved



OPPORTUNITIES FOR DAIICHI SANKYO

Develop a structured access planning framework and ensure comprehensive access plans for all late-stage R&D projects. Currently, the company has access plans for only 11% of its late-stage R&D candidates. By implementing a systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards. For example, it can improve access planning for Dato-DXd (datopotamab deruxtecan), an innovative drug for multiple cancer types, in countries which it has marketing rights.

Establish direct board-level responsibility for access to medicine. Daichii Sankyo has an access-to-medicine strategy. The company appointed a Head of Access to Healthcare, who is responsible for reporting on access to medicine to the Executive Management Committee and the Board of Directors. To further progress, Daiichi Sankyo can ensure a member of the board is directly responsible for its access-to-medicine strategy.

CHANGES SINCE THE 2022 INDEX

Expand access to its innovative products. Daiichi Sankyo has access strategies in place for products in its portfolio, but these are limited to a select number of countries in
scope. It can expand access to its products through increased registrations and/or equitable access strategies. For example, it can increase registration and reach of its access strategies for trastuzumab deruxtecan (Enhertu®), indicated for multiple cancer types, in countries where it has marketing rights.

- Since July 2022, Daiichi Sankyo has launched two new health system strengthening initiatives focused on prevention of breast and cervical cancer. One initiative works with the Japanese Organization for International
- Donated medicines to global emergencies and poverty-stricken countries in 2022 in response to aid requests from Americares.

• Received approval in Japan for its mRNA COVID-19 vaccine (Daichirona®) in November 2024.

Cooperation in Family Planning in Kenya and the other with AMDA Multisectoral and Integrated Development Services in Honduras.

• In December 2022, President and CEO, Sunao Manabe, was appointed IFPMA Vice President.

Daiichi Sankyo Co, Ltd

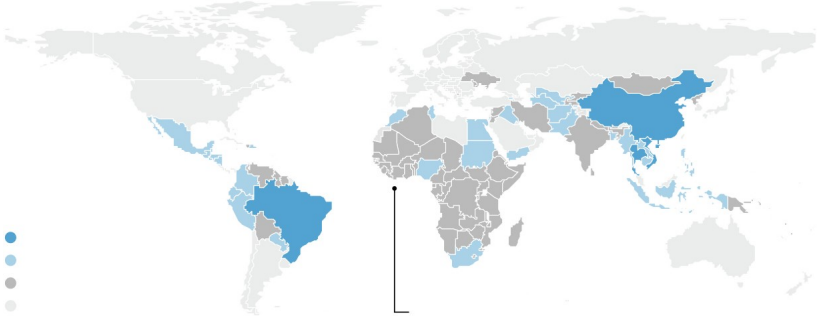
SALES AND OPERATIONS

Therapeutic areas: Oncology, cardiovascular, vaccines, other disease areas

Product categories: Consumer health, generics, innovative medicines, vaccines

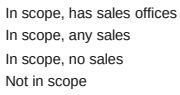
M&A news: In 2023, Daiichi Sankyo Co, Ltd divested its generics division, Daiichi Sankyo Espha, to Qol Holdings Co. Daiichi Sankyo absorbed its wholly owned subsidiaries, Daiichi Sankyo Propharma and Daiichi Sankyo Chemical Pharma, in 2023.

Revenue by segment (2023) – in JPY	
Prescription drugs	1,523.41 bn
Healthcare (OTC) products	75.90 bn
Other	2.38 bn



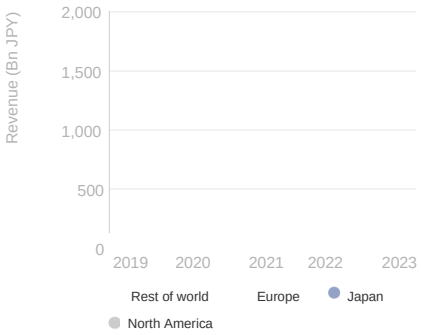
Total	1,601.69 bn

Sales in countries in scope



Daiichi Sankyo's products are sold in 35 out of 113 countries in scope of the Index. Daiichi Sankyo has sales offices in 4 countries and sells via suppliers and/or pooled procurement in an additional 31 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

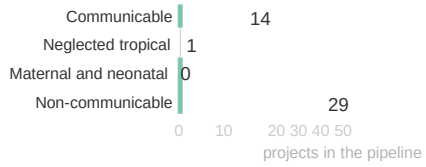
PIPELINE *for diseases in scope*

Daiichi Sankyo has 44 R&D projects in scope, 14 of which target priority diseases, including influenza (4), COVID-19 (3) and malaria (2). The remaining 30 projects target other diseases in scope, including cancer (26), respiratory infections (1) and measles (1). Of the 44 R&D projects, 18 are in late-stage development, with evidence of access planning for 11% (2/18)

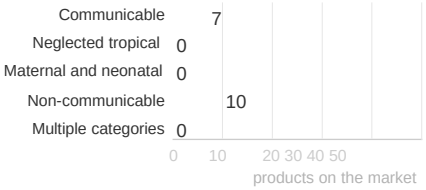
PORTFOLIO *as selected for analysis by the Index*

Daiichi Sankyo has 17 products in scope, including 12 medicines, 3 diagnostics for TB and 2 vaccines for pertussis and tetanus. Of its medicines and vaccines, 5 are listed on the WHO EML; all 3 diagnostics are listed on the WHO EDL. Its medicines target a variety of communicable and non-communicable diseases, including cardiovascular diseases (6), cancer (3) and lower respiratory infections (2).

44 projects in the pipeline



17 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	9	2	0	0	1	0	1	1	14
with access plan				0	0	0	0		0
Other projects in scope			14	7	3	0	6	0	30
with access plan				0	1	0	1		2

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	2	8			10
off patent	1	1			2
Vaccines	2	0			2
Contraceptives	0	0			0
Diagnostics			3		3
Other				0	0

Daiichi Sankyo Co, Ltd

GOVERNANCE OF ACCESS

RANK 16 SCORE 3.36

16th place. Daiichi Sankyo performs below average in this Technical Area. The company provides evidence of a patient reach process that covers one product and some countries in scope of the Index and does not publicly provide the details of the underlying methodology. Additionally, no patient reach goals were identified for this process. Further, it only has a few sets of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies indirectly with the Board. The company installed a Head of Access to Healthcare, who is responsible for reporting on access to medicine to the Executive Management Committee and the Board of Directors. Daiichi Sankyo incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards, as part of its CSR goals. The CEO also has access-related incentives.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers some of the therapeutic areas in which the company is involved, with a focus on its oncology products. Daiichi Sankyo publicly discloses its commitments to access to medicine, along with company-specific targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regularly in its Value Creation Report and directly on its website.

Shows comparatively moderate level commitment to responsible business practices. Daiichi Sankyo's incentive compensation plans vary by subsidiary. For example, in one of the countries in scope of the Index, sales agents are not solely incentivised by sales volume. Incentives are also based on behaviour assessments, such as academic interaction, training and compliance. Further, the company has a global policy on ensuring ethical interactions with healthcare professionals. It offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for speaking at events) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has a few sets of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Daiichi Sankyo performs poorly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards. However, it does not disclose sufficient evidence publicly or to the Index of fraud-specific risk assessments and region or country risk-based assessments in countries in scope. It lacks a framework, but its code of conduct guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Daiichi Sankyo publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. The company states that compulsory licensing should be carefully used in situations like public health-related national emergencies.

Fulfils some criteria with its process for measuring and reporting the patient reach of 1 of its cancer medicines. The process covers some countries in scope of the Index and Daiichi Sankyo provides the underlying equation and metrics under an NDA. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

RESEARCH & DEVELOPMENT

RANK 17 SCORE 1.41

17th place. Daiichi Sankyo performs poorly in this Technical Area. It has a general access planning process in place, rather than a systematic framework. The company has pipeline projects targeting both priority and non-communicable diseases, but only has access plans in place for a small number of its late-stage candidates – which mostly focus on registration preparation in emerging markets. Furthermore, it does not publicly disclose disaggregated R&D investment data, nor does it engage in R&D capacity building activities.

General process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects in scope. The company does not make a public commitment addressing its approach to access planning priority product gap, neither have evidence of an access plan in place.

Daiichi Sankyo does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

No evidence of R&D capacity building initiatives

Large-sized pipeline, compared to peers, addressing other diseases in scope, with for LMICs.

13% (2/16) of late-stage projects covered by access plans. The company has 16 late-stage

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 0%

(0/2) of the late-stage candidates. Priority R&D pipeline of 14 projects, including 2 late-stage projects that target a priority gap. The company focuses on various priority areas, including

R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, respiratory infections and measles. Daiichi Sankyo provides evidence of access plans for 2 of its 16 late-stage projects, including registration preparation and post-trial access.

Daiichi Sankyo's 2 late-stage candidates targeting a influenza, COVID-19 and malaria. Of

Daiichi Sankyo Co, Ltd

PRODUCT DELIVERY

RANK 18 SCORE 1.85

18th place. Daiichi Sankyo performs poorly in this Technical Area. It implements access strategies for its products; however, these are limited to upper-middle-income countries and lack data on their out comes. The company does not register its products widely or show evidence of engaging in inclusive business models or supply chain capacity building initiatives. While it does not engage in new intellec tual property sharing agreements, all health system strengthening initiatives included meet all Good Practice Standards.

Daiichi Sankyo registers newer products* in 1 country in scope on average. It did not provide evidence of registering any products assessed in LICs. Additionally, it registers only 10% of prod ucts assessed in at least 1 of 10 countries with the highest disease burden. The company's edox aban (Lixiana®), indicated for stroke prevention, is most widely registered, totalling 12 countries in scope. Daiichi Sankyo did not report participating in any mechanisms to facilitate registration.

Daiichi Sankyo is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

Access strategy in progress for one health care practitioner (HCP)-administered product, resulting in current lack of outcomes data. For trastuzumab deruxtecan (Enhertu®), indicated for multiple cancer types, Daiichi Sankyo provides evidence of a comprehensive access strategy in an UMIC. However, it lacks strategies in LMICs and LICs. In the UMIC example, the company has a clear and comprehensive strategy, working towards national reimbursement. To overcome

Africa), all least developed countries and LICs, and a subset of LMICs and UMICs. However, the list of countries to which the commitment applies is not publicly available.

Publicly discloses product patent status for countries in scope. Like most peers, Daiichi Sankyo publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Daiichi Sankyo does not engage in non-exclusive voluntary licensing for products in scope.

The 1 manufacturing capacity building initiative included for analysis meets all Good Practice Standards (GPS). Daiichi Sankyo partners with the Center for Research and Production of Vaccines and Biologicals, Vietnam to produce the Measles-Rubella vaccine from a seed stock pro vided by the company. The technology transfer was completed in 2018, but Daiichi Sankyo con

responded to aid requests from Americares, by donating medicines to global emergencies and poverty-stricken countries. The donation comprised 7 products, including 3 in scope, namely amlodipine/olmesartan medoxomil (Azor®), prasugrel (Effient®) and olmesartan medoxomil/amlodipine/hydrochlorothiazide (Tribenzor®). However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, to ensure sustainable supply in China and Latin America, Daiichi Sankyo holds meetings with its affiliates and manufacturing plants in Brazil and China to share risks and implement solutions.

Daiichi Sankyo has procedures in place at several of its subsidiaries for reporting sub standard and falsified medicines in countries in scope. It does not have a global reporting pol icy yet, but provides evidence of reporting cases to national or local regulatory authorities within 5 days, depending on the region. Further, the company aims to report cases within 3 days if the case presents a serious risk. Depending on the subsidiary, it provides evidence of shortened timeframes for reporting cases that only require visual inspection for confirmation.

tinues to provide ongoing manufacturing support.

affordability barriers prior to achieving public	No evidence of supply chain capacity building	meet inclusion criteria.
reimbursement, this strategy is complemented by a patient assistance programme. Daiichi Sankyo did not report outcomes, including patient reach, of the strategy, nor did it report its approaches for measuring and tracking future progress.	Access strategies for self-administered products are limited in geographic scope, with information on outcomes lacking. For 4 of the 5 products selected for analysis, Daiichi Sankyo provides evidence of access strategies only in UMIC examples and the data reported for these strategies is very limited. In general, the company applies a mix of strategies to set the price of its products, for most of which generic alternatives are on the market. For 1 product, edoxaban (Lixiana®), indicated for stroke prevention, it shares goals to further expand access in the public sector; for the other examples analysed, data on the outcomes, including patient reach, and	

initiatives that meet inclusion criteria.

All 5 health system strengthening initiatives included for analysis meet all GPS. For exam ple, Daiichi Sankyo financially supports Save the Children's efforts to improve the sexual and reproductive healthcare services and awareness among adolescents in 2 districts in Vietnam. In 2023, the initiative reached 2,500 adolescents through peer clubs at local high schools.

Daiichi Sankyo remains engaged in existing IP-sharing agreements with drug discovery ini tiatives to accelerate drug development. In 1 agreement, the company shared 35,000 com pounds with the Drugs for Neglected Diseases Initiative to screen against Trypanosoma cruzi. However, Daiichi Sankyo has not engaged in new agreements during the period of analysis.

plans for the strategy are lacking.

Fulfils most criteria for ad hoc donations.

Daiichi Sankyo has public policies and supply

Daiichi Sankyo publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all sub-Saharan African countries (excluding South

processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in October 2022, Daiichi Sankyo

*Products that received their first marketing authorisation within the last 5 years.

RANK	SCORE
14	2.62

12 (2022)

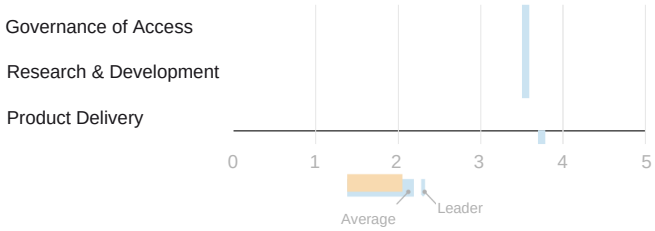
Eisai Co., Ltd

Stock exchange: TSE • Ticker: ESALY • HQ: Tokyo, Japan • Employees: 11,067

PERFORMANCE IN THE 2024 INDEX

14th place. Eisai performs below average. It engages in Research & Development for priority diseases, but many of its late-stage pipeline projects do not have an access plan. It has increased engagement in health system strengthening initiatives but has a below-average performance in Governance of Access.

How score was achieved



OPPORTUNITIES FOR EISAI

Ensure all late-stage R&D projects have comprehensive access plans. Eisai has a structured framework for access planning. However, it only has access plans in place for one of its 18 (6%) late-stage R&D projects. By implementing its systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards. For example, it can develop access plans for

Expand access to innovative products. Eisai has access strategies in place for its products targeting non-communicable diseases; however, it lacks coverage in low-income countries. The company can expand access through expanding registration and engaging in equitable access strategies, for key products such as eribulin (Halaven®), indicated for breast cancer. farletuzumab ecteribulin (FZEC), which is in Phase II trials for multiple cancers, including ovarian and endometrial.

Expand geographic scope of technology transfer initiatives. Eisai engages in technology transfer initiatives for the active pharmaceutical ingredient of its lymphatic filariasis treatment diethylcarbamazine citrate (DEC) in India and for its oncology and epilepsy treatments eribulin (Halaven®), lenvatinib (Lenvima®), perampanel (Fycompa®) and rufinamide (Inovelon®) in Mexico and Brazil. The company can engage in further technology transfer initiatives in additional countries, for example in Southeast Asia or Africa.

CHANGES SINCE THE 2022 INDEX

- Since 2022, Eisai's access-to-medicine strategy covers all therapeutic areas the

- Eisai has committed JPY 625mn to support the third phase of the Global Health Innovative Technology Fund (GHIT Fund) from FY2023
- In 2023, Eisai received FDA approval for lecanemab-irmb (LEQEMBI®), a treatment for company is involved in.

to FY2027, aimed at accelerating the development of medicines for infectious Alzheimer's disease. diseases in developing countries. This follows

- Eisai Vietnam launched a Dementia and Alzheimer awareness campaign in September 2023 to address misconceptions about Alzheimer's disease.

its previous contributions totaling JPY 1bn to the first two phases of the GHIT Fund.

Eisai Co, Ltd

SALES AND OPERATIONS

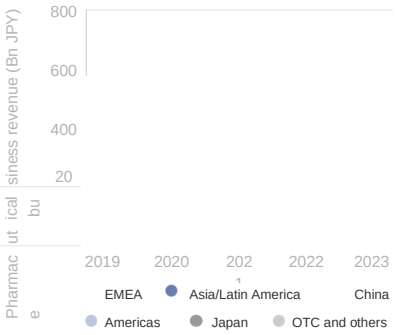
Therapeutic areas: Oncology, neurology, tropical diseases
Product categories: Innovative medicines
M&A news: In 2024 Eisai absorbed KAN Research Institute, Inc.

Revenue by segment (2023) – in JPY	
Pharmaceutical business	691.46 bn
Other business	50.29 bn
Total	741.75 bn

Sales in countries in scope

Eisai's products are sold in 47 out of 113 countries in scope of the Index. Eisai has sales offices in 9 countries and sells via suppliers and/or pooled procurement in an additional 38 countries.

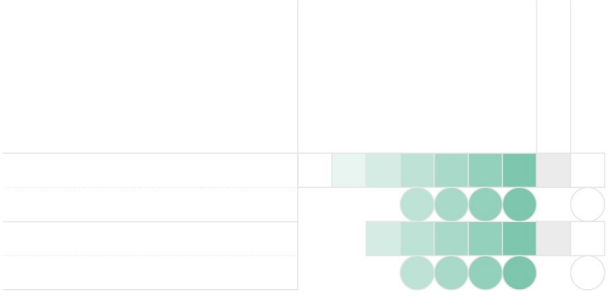
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

Eisai has 42 R&D projects in scope, 15 of which target priority diseases, including malaria (8), Chagas disease (3) and leishmaniasis (2). The remaining 27 projects target other diseases in scope, including cancer (21), Alzheimer's disease (5) and epilepsy (1). Of the 42 R&D projects, 18 are in late-stage development, with evidence of access planning for 6% (1/18) of these.

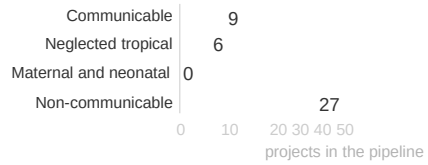


PORTFOLIO *as selected for analysis by the Index*

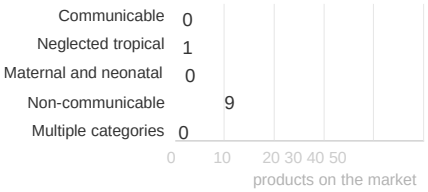
Eisai has 10 medicines in scope, 2 of which are listed on the WHO EML.

Most of its medicines are on patent (7) and treat non-communicable diseases, such as cancer (3), epilepsy (2) and Alzheimer's disease (2). Eisai has 1 neglected tropical disease medicine that treats lymphatic filariasis.

42 projects in the pipeline



10 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	5	8	0	2	0	0	0	0	15
with access plan				1	0	0	0		1
Other projects in scope			10	9	4	0	3	1	27
with access plan				0	0	0	0		0

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	0	7		7
off patent	2	1		
Vaccines	0	0		3
Contraceptives	0	0		
Diagnostics		0		0
Other			0	

Eisai Co, Ltd

GOVERNANCE OF ACCESS RANK 14 SCORE 3.52

14th place. Eisai has a below-average performance in this Technical Area. The company's patient reach process for diethylcarbamazine tablets (for treating lymphatic filariasis) covers some countries in scope of the Index. The underlying methodology details are not publicly available and the resulting patient reach numbers are not regularly published. Further, each country where Eisai operates has its own incentive compensation plans, with some individual-level targets for its sales agents.

The highest responsibility for access lies directly with the Board. Eisai incentivises its senior executives and in-country managers, including country-level corporate officers or regional managers, to act on access to medicine with financial and non-financial rewards. The CEO has long-term access-related incentives, linked, for example, to initiatives aimed at eliminating neglected tropical diseases (NTDs).

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved, including Alzheimer's disease and cancer. Eisai publicly discloses its commitments to access to medicine, along with some company-specific measurable targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available, and updated regularly in its Value Creation Report.

Shows comparatively strong commitment to responsible business practices. Eisai sets individual, team and country-level targets for sales agents, and incentives are not solely based on sales volume. Further, each country where Eisai operates has its own incentive compensation plans. For example, in Vietnam, it considers both sales and non-sales incentives. Eisai commits to ensuring ethical interactions with healthcare professionals in its Compliance Handbook. It also declares that transfers of value to healthcare professionals (e.g., payments for speaking at symposia) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eisai performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Eisai also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Eisai publicly supports the Doha Declaration on TRIPS and Public Health. It states that compulsory licensing provides a balance between protecting intellectual property (IP) and public health in appropriate circumstances.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For its process for diethylcarbamazine tablets (for treating lymphatic filariasis), which covers some countries in scope of the Index, Eisai provided the underling equation, metrics and assumptions directly to the Index. The resulting patient reach numbers are not published regularly, meaning no improvements could be demonstrated. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT RANK 15 SCORE 1.88

15th place. Eisai has a below-average performance in this Technical Area. The company has an average-sized pipeline with developments for non-communicable and priority diseases, although the number of priority projects has fallen. It has an access planning framework from Phase II onwards, but it only has access plans in place for one of its late-stage candidates. It does not publicly disclose disaggregated R&D investment data, and the company has some R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 50% (50%) has evidence of an access plan in place. This plan includes registration preparation and is a partnership with an access-oriented organisation.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 0% (0/16) of late-stage projects covered by access (1/2) of the late-stage candidates. Priority R&D pipeline of 15 projects, including 2 late-stage projects that target a priority gap. The company focuses on various priority areas, including malaria,

Eisai does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.
However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

One of the two R&D capacity building initiatives included for analysis meets all Good Practice Standards (GPS). In this initiative, Eisai provides equipment to Seeding Labs. In turn, this organisation provides this equipment to research institutions in LMICs.

plans. The company has 16 late-stage R&D projects targeting other diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer, Alzheimer's disease and epilepsy. Eisai does not provide evidence of access plans for any of its 16 late-stage projects.

Chagas disease and leishmaniasis. Of Eisai's 2 late-stage candidates targeting a priority product gap, 1

Eisai Co, Ltd

PRODUCT DELIVERY

RANK 13 SCORE 2.78

13th place. Eisai performs below average in this Technical Area. The company has access strategies in place for its products and reports on the outcomes of these strategies. However, it lacks coverage in low-income countries. Eisai shows an increase in engagement in health system strengthening initiatives, with more included initiatives now meeting all Good Practice Standards. However, it does not show evidence of new intellectual property sharing agreements.

Eisai registers newer products* in 4 countries in scope on average. It registers 66% of products assessed in at least 1 of 10 countries with the highest disease burden. The company's donepezil (Aricept®), indicated for Alzheimer's disease, is most widely registered, totalling 37 countries in scope, including 8 of the 10 countries with the highest disease burden. The company reports engaging in mechanisms to facilitate registration, for example, the WHO Collaborative Registration Procedure for WHO Prequalified finished pharmaceutical products (FPPs).

Eisai is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

One healthcare practitioner (HCP)-administered product covered by access strategies, with patient reach tracked and reported. For its product eribulin (Halaven®), indicated for breast cancer, Eisai provides evidence of access strategies in one UMIC and LMIC, but not in any LICs. In China (UMIC), the product is included in the National Reimbursement Drug List. In India (LMIC), where patients mainly pay out of pocket, Eisai implements a patient assistance programme based on annual income, demonstrating an effort to consider patients' ability to pay. The company has high-level goals to increase access to its products and provides evidence of the number of patients reached, as well as some details on the approaches for measuring this.

Access strategies for self-administered products in a few countries, which are supported by information on outcomes. For all 3 products selected for analysis, Eisai provides evidence of access strategies in UMICs and LMICs, but not in any LICs. It shows some efforts in ensuring access and affordability of its products. However, there

Eisai publicly commits not to file for or enforce patents for some products in countries in scope. This applies to some products in all least developed countries and LICs and covers infectious diseases, neglected tropical diseases and maternal and neonatal diseases.

Publicly discloses product patent status for countries in scope. Like most peers, Eisai publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Eisai does not engage in non-exclusive voluntary licensing for products in scope.

The 2 manufacturing capacity building initiatives included for analysis meet some GPS. Despite not meeting all GPS, Eisai supports Grupo Biotoscana, now acquired by Knight Therapeutics Inc., to manufacture 4 oncology and neurology products to supply in Latin American countries. Eisai transferred technology for eribulin mesylate (Halaven®), lenvatinib (Lenvima®), rufinamide (Inovelon®) and perampanel (Fycompa®).

Both supply chain capacity building initiatives included for analysis meet all GPS. In 1 initiative, Eisai is a member of the Pharmaceutical Supply Chain Initiative which audits suppliers and builds capacity across multiple areas such as ethics, human rights, health and safety, environment, and governance and management systems.

Three of the five health system strengthening initiatives included for analysis meet all GPS. For example, since 2013, Eisai has stationed staff in India and Myanmar to support efforts in eliminating lymphatic filariasis. In 2023, Eisai staff supported a mass drug administration programme in Myanmar, conducting socialisa

Fulfils most criteria for ad hoc donations. Eisai has policies and supply processes to rapidly carry out ad hoc donations in response to expressed need, with delivery monitored to ensure donations reach patients. However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Eisai publicly commits to continue long-term donation programme to support the elimination of lymphatic filariasis. Its programme is active in 25 to 26 countries in scope, with the company pledging to donate diethylcarbamazine citrate (DEC) tablets for an unlimited period until lymphatic filariasis is eliminated.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Eisai manufactures diethylcarbamazine citrate (DEC) tablets at its own site in India to supply to lymphatic filariasis elimination programmes in Nepal, Malaysia, Sri Lanka, Zambia and Zimbabwe. Eisai also supported an Indian manufacturer to supply the active pharmaceutical ingredient (API), aiming to reduce cost and sustain supply.

Eisai has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to both WHO Rapid Alert and/or national or local regulatory authorities within 24 hours to 7 days. The company provides evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation based on the company's Risk Evaluation Committee.

Eisai operates an inclusive business model supporting access to treatments for dementia, including Alzheimer's disease, in 1 country in scope. The model was launched in 2022 in partnership with Thai Life Insurance. Partners are designing insurance products, raising awareness and creating a national network for dementia care and research. The model plans to expand to an additional 5 countries in scope, including India, Vietnam and the Philippines.

is room for improvement in considering the dif
payers' ability to pay and expanding the
all 3 country income classifications.
For the LMIC examples, the company demon
efforts to improve product affordability
pay out of pocket by applying
or implementing patient assistance pro
grammes. The company has high-level goals to
access to the products and provides evi
of the number of patients reached, as well
details on approaches for measuring this.

tion with patients and raising awareness about ferent
hygiene practices to reduce transmission. strategy to

Eisai remains engaged in an existing IP-sharing strates
agreement with a public research institufor patients who
tion to accelerate drug development. In 2020, discounts
Eisai shared a target-specific compound set with
Universidad Nacional de La Plata to accelerate increase
drug discovery for Chagas disease. However, the dence
company has not entered into any new agreeas some
ments during the period of analysis.

*Products that received their first
marketing authorisation within the last
5 years.

RANK	SCORE
19	1.84
20 (2022)	

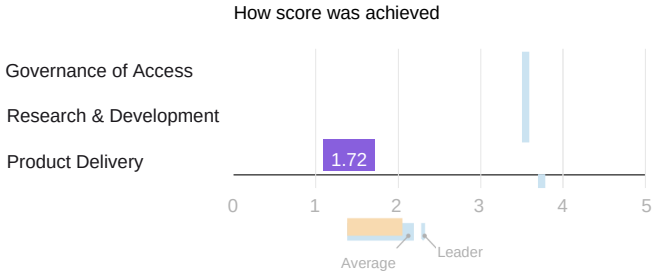
Eli Lilly & Co

Stock exchange: NYSE • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: 42,978

PERFORMANCE IN THE 2024 INDEX

19th place. Eli Lilly is in the lower ranks of all Technical Areas. It is newly engaged in technology transfer and improved in Governance of Access; however, it provides limited evidence of access strategies for products analysed in Product Delivery.

How score was achieved



OPPORTUNITIES FOR ELI LILLY

Improve the quality and broaden the geographic reach of access plans. Eli Lilly has access plans in place for most of its late-stage R&D projects. However, these plans solely focus on committing to registering in countries where clinical trials are conducted (predominantly upper-middle income countries). It can enhance these plans by considering more access provisions, such as affordability, and expand them to include more low and lower-middle-income countries within scope. For example, Eli Lilly can expand its access plan for its GLP-1 inhibitor orforglipron, which is currently in Phase III clinical trials for type 2 diabetes, beyond commitments to make it available in the three countries in scope where it is conducting trials.

Implement robust access-to-medicine incentives for senior management. Eli Lilly has an access-to-medicine strategy, and the company shows that access incentives for the CEO are in place. It could provide evidence of similar access incentives for its senior executives and in-country managers

Engage in technology transfer initiatives with manufacturers in LMICs to improve availability and affordability. In 2022, Eli Lilly entered a partnership with a local manufacturer in Egypt and in 2023 with a local manufacturer in Bangladesh to manufacture and supply human and analogue insulins to African countries and Bangladesh, respectively. The company can engage in similar initiatives to build manufacturing
capacity and improve regional availability of insulins in
countries or regions with specific access gaps.

Expand access strategies to innovative cancer products. Eli Lilly has an agreement to supply abemaciclib (Verzenio®), indicated for breast cancer, through product donations
in Kenya (LMIC), but did not report any additional access strategies for its oncology products in other countries in scope. It can expand access to its products, particularly to abemaciclib, which has been prioritised for voluntary licensing by public health organisations, through equitable pricing strategies and/or engaging in voluntary licensing to enable
in low- and middle-income countries (LMICs). generic supply.

CHANGES SINCE THE 2022 INDEX

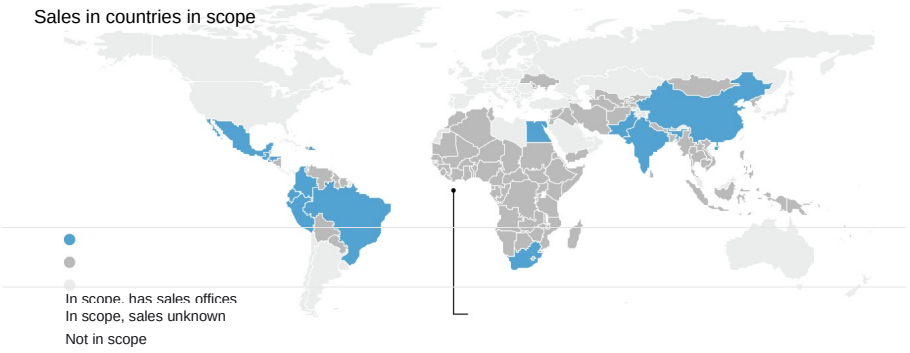
- Engaged in a new technology transfer with EVA Pharma, an Egyptian manufacturer for human and analogue insulin, since 2022. Through this collaboration, Eli Lilly supplies an API to produce insulin at a reduced price and provides a pro-bono technology transfer.
- In September 2024, after the period of analysis, Eli Lilly announced a voluntary licensing agreement and technology transfer with EVA Pharma to manufacture and supply baricitinib (indicated for rheumatoid arthritis, COVID-19 and other inflammatory conditions) in 49 LMICs in Africa.
- Donated USD 14.4mn in 2022 to address non-communicable disease (NCD) risk factors, strengthen health systems and enhance the ability of healthcare workers to care for patients in Bangladesh, Malawi, Nepal, the Philippines and Zimbabwe through the United States Fund for UNICEF; subsequently, in 2024 it expanded this commitment by donating USD 6.5mn to patients in resource limited settings in India.
- Collaborated with International Agencies (Bangladesh) Ltd. to supply its API for human insulin at a reduced price to a third-party manufacturer in Bangladesh.
- Shows publicly available evidence of conduct ing fraud-specific risk assessments to mitigate risk of non-compliant and corrupt activities.
- Joined the Coalition for Access to Oncology Medicines and Products in 2023, which aims to increase availability of affordable essential medicines and products for NCDs, starting with diabetes, hypertension and cardiovascular diseases.
- Announced a new partnership with Direct Relief in January 2023 to build cold chain capacity of Life for a Child facilities in 17 countries in Africa, Latin America, the Caribbean and Southeast Asia.
- In 2023, Eli Lilly divested its worldwide commercial rights for its entire olanzapine (Zyprexa®) portfolio to Cheplapharm for USD 1.35bn and divested glucagon (Baqsimi®) to Amphastar Pharmaceuticals for USD 1.08bn.
- Announced a collaboration with OpenAI in June 2024, after the period of analysis, through which it will leverage OpenAI's generative artificial intelligence (AI) to invent novel antimicrobials to treat drug-resistant pathogens.

Eli Lilly & Co

SALES AND OPERATIONS

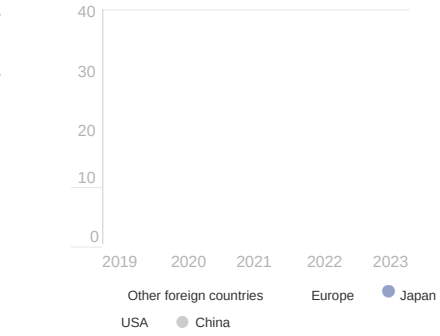
Therapeutic areas: Bone muscle joint, cancer, cardiovascular, COVID-19, diabetes, endocrine, immunology, neuroscience, obesity	and Immunitrack for undisclosed amounts; Point Biopharma Global for USD 1.4bn; Dice Therapeutics for USD 2.4bn; Versanis Bio for USD 1.93bn;	Revenue by segment (2023) – in USD Human pharmaceutical products	 34.12 bn
Product categories: Innovative medicines	Emergence Therapeutics for USD 470mn, and Sigilon	Total	34.12 bn
M&A news: In 2022 Eli Lilly acquired Akouos for USD 610mn. In 2023, it acquired Mablink Biosciences	Therapeutics for USD 309.6mn.		

Sales in countries in scope



Eli Lilly's products are sold in 72* out of 113 countries in scope of the Index. Eli Lilly has sales offices in 14 countries and sells via suppliers in 58* countries.

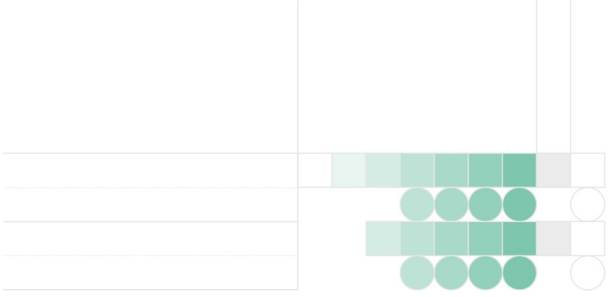
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

Eli Lilly has 25 R&D projects in scope, none of which target priority diseases. All 25 projects target other diseases in scope, including cardiovascular diseases (8), diabetes mellitus (8) and cancer (5). Of the 25 R&D projects, 16 are in late-stage development, with evidence of access planning for 75% (12/16) of these.



PORTFOLIO *as selected for analysis by the Index*

Eli Lilly has 26 medicines in scope, 6 of which are listed on the WHO EML. Most of the company's medicines are on patent (18). Its medicines mostly target non-communicable diseases, such as diabetes (15) and cancer (5). Its 2 medicines for communicable diseases treat coronaviral diseases.

25 projects in the pipeline

26 products in the portfolio

Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	0	0	0	0	0	0	0
with access plan				0	0	0	0		0
Other projects in scope			9	6	6	0	4	0	25
with access plan				4	5	0	3		12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	2	16		18
off patent	4	4		8
Vaccines	0	0		0
Contraceptives	0	0		0
Diagnostics		0		0
Other			0	0

*In 2016, Eli Lilly reported sales in 72 countries.

Eli Lilly & Co

GOVERNANCE OF ACCESS

RANK 17 SCORE 3.28

17th place. Eli Lilly performs poorly in this Technical Area. The company incentivises its CEO to act on access to medicine but does not disclose whether in-country managers and senior executives are also incentivised. It discloses information on its approach to payments to healthcare professionals. However, it does not provide evidence of a public policy that commits to ensuring ethical interactions with healthcare professionals. Further, it does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility lies directly with the Board, and specifically with Executive Committee members responsible for access strategies and reporting to the CEO. Additionally, the CEO has access-related incentives linked to its ability to drive the Lilly 30x30 initiative and ensure progress. Eli Lilly does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers some of the therapeutic areas in which the company is involved. Eli Lilly publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, updated regularly on its website.

Shows comparatively poor commitment to responsible business practices. There is evidence that Eli Lilly sets individual-level targets for sales agents, but the company does not disclose, publicly or otherwise, if incentives are solely based on sales volume. Additionally, it has a statement on payments to healthcare professionals but does not offer evidence of a public policy that commits to ensuring ethical interactions with healthcare professionals that aligns with the standards set by the Index. Further, it only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eli Lilly performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Eli Lilly lacks a framework, but its code of business conduct guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Eli Lilly does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available policy on intellectual property, but it does not align with principles embodied in the Declaration.

Fulfils most criteria with its process for measuring and reporting the patient reach of its Lilly 30x30 initiative. The process covers all its products and most countries in scope of the Index and Eli Lilly publicly provides the underlying equation, metrics and assumptions. The resulting patient reach numbers were published from 2020 to 2023 and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 19 SCORE 1.35

19th place. Eli Lilly performs poorly in this Technical Area. Eli Lilly now has an access planning framework in place for a subset of its R&D projects. The company does not engage in R&D for priority diseases but has access plans for most of its non-communicable disease projects – although plans focus on registration preparation in emerging markets. It does not publicly disclose disaggregated R&D investment data, although it newly engages in R&D capacity building initiatives.

Structured process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects in scope. The company does not make a public commitment addressing its approach to access planning

One R&D capacity building initiative was included for analysis, but it does not meet all Good Practice Standards (GPS). Through this initiative, Eli Lilly aims to build R&D capacity in Ghana through hands-on clinical training for health workers.

R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cardiovascular diseases, diabetes mellitus and cancer. Eli Lilly provides evidence of access plans for LMICs.

for 12 of its 16 late-stage projects. Access plans include registration preparation and the inclusion

Eli Lilly does not have any projects in the company pipeline that target a priority disease in

of special populations in clinical trials.

scope.

Eli Lilly does not publicly disclose R&D invest
ment data disaggregated by disease category,
Average-sized pipeline, compared to peers, addressing other diseases in scope, with 75% (12/16)
of late-stage projects covered by

product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health access plans. The company has 16 late-stage organisations.*

*Eli Lilly currently has no pipeline candidates within the disease scope of Impact Global Health (formerly known as Policy Cures Research), an organisation that assesses disaggregated R&D data.

Eli Lilly & Co

PRODUCT DELIVERY

RANK 20 SCORE 1.72

20th place. Eli Lilly performs poorly in this Technical Area. It is newly engaged in technology transfers for its products as well as supply chain capacity building; however, its access strategies for products analysed are limited. The company does not engage in non-exclusive voluntary licensing or show evi dence of engaging in inclusive business models.

Eli Lilly registers products in 20 countries in scope on average. For newer products** it reg isters in 6 countries in scope on average and it registers 66% of products assessed in at least 1 of the 10 countries with the highest disease burden. There is evidence of registration in LICs for all products assessed. The company's insulin glargine (Basaglar®), indicated for diabetes mellitus, is most widely registered, totalling 37 countries in scope. Eli Lilly did not report participating in any mechanisms to facilitate registration.

Eli Lilly is not eligible for assessment of supra national access strategies because it has no products in scope that are supranationally procured.

No evidence of access strategies for its health-care practitioner (HCP)-administered product. Eli Lilly has not reported, either publicly or to the Index, access strategies for its cancer product, ramucirumab (Cyramza®), which is assessed by molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

Eli Lilly does not engage in non-exclusive voluntary licensing for products in scope.

One of the 2 manufacturing capacity build ing initiatives included for analysis meets all GPS. For example, in 1 initiative with Egyptian manufacturer Eva Pharma, Eli Lilly is transferring technology needed to formulate, fill and finish vials and cartridges of its human and analogue insulin. Eli Lilly will work with the manufac turer to ensure that their products achieve WHO prequalification. (Bangladesh) Ltd to supply APIs at a reduced price so that the manufacturer can formulate, fill and finish insulin vials and cartridges for local distribution.

Eli Lilly has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regu-latory authorities. However, the company does not disclose evidence, publicly or to the Index, that it requires reporting to occur within 10 days. Instead, Eli Lilly reports that it follows locally mandated reporting requirements and timeframes. The company also does not provide evidence of shortened timeframes for reporting cases that require visual inspection for confirmation.

No evidence of inclusive business models that meet inclusion criteria.

None of the 3 supply chain capacity building initiatives included for analysis meet all GPS. Despite not meeting all GPS, in 1 initiative, Eli Lilly is partnering with Direct Relief to build cold chain capacity in 17 countries. Eli Lilly funding will go towards purchasing refrigeration units to support supply of quality-assured insulin products through the Life for a Child programme.

the Index in this category.

Evidence of access strategies for some self-administered products, but no data on the outcomes of these strategies. Eli Lilly has not reported to the Index access strategies for any of the 5 products assessed under this category. Of the 5 products, 4 are indicated for diabetes mellitus treatment, including 2 human insulins and 1 analogue insulin; the fifth product is a cancer treatment. The company has engaged in a collaboration to supply its active pharmaceutical ingredient (API) for human insulin at a reduced

Three of the five health system strengthening initiatives included for analysis meet all GPS. For example, Eli Lilly is supporting UNICEF through a USD 14.4mn grant to address non-communicable disease risk factors, strengthen health systems and upskill health workers. The initiative targets Bangladesh, Malawi, Nepal, the Philippines and Zimbabwe, aiming to improve health outcomes for 10mn children through 2025.

price to a third-party manufacturer in Bangladesh (LMIC). As part of the Lilly 30x30 initiative, the company has also made a similar agreement with EVA Pharma, operating in Africa, including a technology transfer for insulin vials and

Eli Lilly has not entered into any new IP-sharing agreements, nor has it continued any existing agreements, with public research institutions or drug discovery initiatives to accelerate drug development.

cartridges manufacturing. Furthermore, the com pany has announced an agreement with the Max Foundation to provide access to their oncology drug abemaciclib (Verzenio®) in Kenya (LMIC). However, the outcomes of these access strate

Fulfils most criteria for ad hoc donations. Eli Lilly has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, it does

gies are unclear.

Eli Lilly publicly commits not to file for or enforce patents for all products in all least

not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for developed countries in scope.

Medicine Donations.

Publicly discloses product patent status for countries in scope. Like most peers, Eli Lilly publicly discloses patent information for small

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Eli Lilly is partnering with International Agencies

**Products that received their first marketing authorisation within the last 5 years.

RANK	SCORE
16	2.21
14 (2022)	

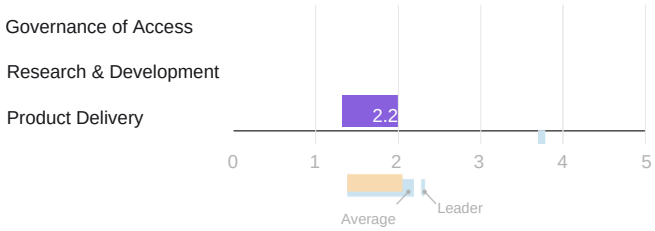
Gilead Sciences

Stock exchange: NASDAQ • Ticker: GILD • HQ: Foster City, California, United States • Employees: 18,000

PERFORMANCE IN THE 2024 INDEX

16th place. Gilead performs below average. It engages widely in voluntary licensing to enable generic supply. However, it has a comparatively poor performance in Governance of Access, and many of its late-stage pipeline projects do not have an access plan.

How score was achieved



OPPORTUNITIES FOR GILEAD

Ensure all late-stage R&D projects have comprehensive access plans. Gilead has a structured framework for access planning. However, it only has access plans in place for 10% of its late-stage R&D projects. By implementing its systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards. For example, Gilead can disclose access plans to its innovative drug domvanalimab, currently undergoing clinical trials for multiple cancer indications.

Ensure access-to-medicine strategy is integrated within its corporate strategy. Gilead's access strategy has a business

Ensure equitable access to lenacapavir in low- and middle-income countries (LMICs). Gilead's blockbuster long-acting injectable, lenacapavir, is currently approved for HIV treatment and has demonstrated promising results in clinical trials for HIV prevention. The company has publicly announced a non-exclusive voluntary licensing agreement with six generic manufacturers to make and sell generic lenacapavir in 120 LMICs (subject to regulatory approvals). It can now work (alongside the generic sublicensees) to ensure fast and equitable access to generic lenacapavir. Furthermore, it must ensure access to affordable lenacapavir, particularly for vulnerable populations living in countries outside of the

rationale, which it covers some therapeutic areas that the licensing agreement. company is involved in. The company can ensure the strategy is integrated into its corporate strategy and expand it to all therapeutic areas.

CHANGES SINCE THE 2022 INDEX

- Endorsed the Kigali Declaration on Preventing, Controlling, and Eliminating Neglected Tropical Diseases in June 2022.
- Contributed USD 85mn to the Gilead Foundation to advance health equity.
- Announced a new public-private initiative with the Partnership for Health Advancement in Vietnam to help address barriers that limit viral hepatitis diagnosis and care at primary healthcare facilities in Vietnam and the Philippines.
- Expanded its ongoing long-term donation programme of amphotericin B liposome (AmBisome®) to two additional countries in scope (Eritrea and Yemen) in 2023 to support the elimination of visceral leishmaniasis.
- In June 2024, Gilead's Phase III clinical trial PURPOSE 1, which evaluated the twice-yearly injection Lenacapavir, demonstrated 100% efficacy in preventing HIV infection in cisgender women (a group that shares a disproportionate number of new HIV infections).
- In October 2024, after the period of analysis*, announced it had signed non-exclusive voluntary licensing (NEVL) agreements with six generic manufacturers to make and sell generic lenacapavir. The licence covers lenacapavir for HIV prevention (subject to required regulatory approvals) and for HIV treatment in heavily treatment-experienced adults with multi-drug resistant HIV. The licence covers 120 countries, including 96 counties in scope of the Index.

*As the licence was announced after the period of analysis concluded, it was not assessed as part of the 2024 Access to Medicine Index.

Gilead Sciences

SALES AND OPERATIONS

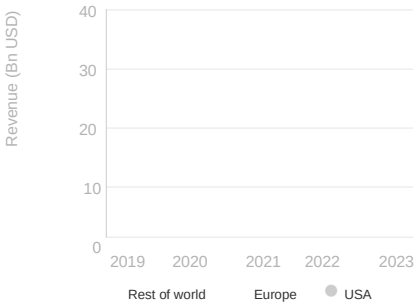
Therapeutic areas: Inflammatory diseases, oncology, viral diseases
Product categories: Innovative medicines
M&A news: Gilead acquired the remaining worldwide rights of Trodelvy® from Everest Medicines for USD 175mn and MiroBio for USD 405mn in 2022, respectively. In 2023, it acquired Tmunity Therapeutics and XinThera for undisclosed amounts. In 2024 Gilead acquired CymaBay Therapeutics Inc for USD 4.3bn.

Revenue by segment (2023) – in USD	
Pharmaceutical	27.12 bn
Total	27.12 bn

Sales in countries in scope

Gilead's products are sold in 41 out of 113 countries in scope of the Index. Gilead has sales offices in 6 countries and sells via suppliers and/or pooled procurement in an additional 35 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

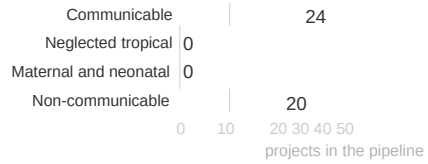
PIPELINE *for diseases in scope*

Gilead has 44 R&D projects in scope, 20 of which target priority diseases, focusing on HIV/AIDS (15) and COVID-19 (4). The remaining 24 projects target other diseases in scope, including cancer (19), hepatitis B (4) and HIV/AIDS (1). Of the 44 R&D projects, 29 are in late-stage development, with evidence of access planning for 10% (3/29) of these.

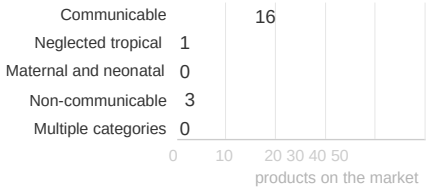
PORTFOLIO *as selected for analysis by the Index*

Gilead has 20 medicines in scope, 7 of which are listed on the WHO EML. Most of the company's medicines are on patent (17). Its medicines primarily treat communicable diseases, such as HIV (9), hepatitis B and C (5) and 1 medicine is indicated for both HIV and hepatitis B (1). Its medicines for non-communicable diseases target cancer (2) and cardiovascular diseases (1). Gilead also has 1 medicine for neglected tropical diseases that treats leishmaniasis.

44 projects in the pipeline



20 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	3	6	6	3	0	2	0	20
with access plan				1	1	0	1		3
Other projects in scope			6	11	6	0	1	0	24
with access plan				0	0	0	0		0

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	5	12			17
off patent	2	1			3
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

Gilead Sciences

GOVERNANCE OF ACCESS

RANK 19 SCORE 2.72

19th place. Gilead performs poorly in this Technical Area. The company provides a measurable patient reach goal and a measurable associated health outcomes goal for its patient reach process, but it does not publicly report the resulting patient reach numbers. Further, it does not disclose sufficient evidence of having controls to mitigate the risk of non-compliant or corrupt activities in countries in scope and does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility for access lies directly with the Board, namely with the Nominating and Corporate Governance Committee overseeing pricing and access issues. Gilead incentivises its senior executives and in-country managers to act on access to medicine. The CEO also has access-related tives, specifically related to expanding patient access and improved global health.

Access-to-medicine strategy not fully integrated within the overall corporate strategy, but it does have a business rationale. Its strategy covers some of the therapeutic areas in which the company is involved. Gilead publicly discloses its commitments to access to medicine, but the reported goals, objectives and targets are linked to external global health targets and are not company specific. Reporting is mostly clear, centrally available, and updated regularly in its ESG Report.

Shows comparatively strong commitment to responsible business practices. Gilead sets individual-level targets for sales agents, and incentives are not solely based on sales volume. For some countries in scope, it incentivises activities such as field visits and hospital seminars. The company has a public policy on ensuring ethical interactions with healthcare professionals. It also declares that transfers of value to healthcare professionals (e.g., payments for speaking at symposia) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has a set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead performs moderately in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards and region or country risk-based assessments. However, it does not disclose sufficient evidence publicly or to the Index of fraud-specific risk assessments in countries in scope. Gilead lacks a framework, but its code of conduct guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Gilead does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available policy on 'Intellectual property and patient access', but it does not align with principles embodied in the Declaration. Further, Gilead states that compulsory licensing should be used by governments as a last resort after exhausting all other options.

Fulfils some criteria with its process for measuring and reporting the patient reach of its AmBisome® donations. The process covers most countries in scope and Gilead publicly provides the metrics. The resulting patient reach numbers are not published regularly, although the company demonstrated improvements to the Index. The process also had a measurable patient reach goal and a measurable associated health outcomes goal.

RESEARCH & DEVELOPMENT

RANK 14 SCORE 1.98

14th place. Gilead performs below average in this Technical Area. It has an access planning framework from Phase II onwards, but only applies this to a small number of its late-stage candidates. It does not publicly disclose disaggregated R&D investment data, and the company has some R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach

Average-sized pipeline, compared to peers,

Two of the three R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is a programme to support an early-stage research scientist in their career, focused on the prevention, care and treatment of viral hepatitis.

addressing other diseases in scope, with 0% (0/18) of late-stage projects covered by access plans. The company has 18 late-stage R&D projects targeting other diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer and Large-sized priority R&D pipeline, compared to peers, with access plans in place for 27% to access planning for LMICs.

hepatitis B. Gilead does not provide evidence of access plans for any of its 18 late-stage projects.

(3/11) of the late-stage candidates. Priority R&D pipeline of 20 projects, including 11 late-stage projects that target a priority gap. The company focuses on various priority areas, including HIV and COVID-19. Of Gilead's 11 late-stage candidates targeting a priority product gap, 3 (27%)

Gilead does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

have evidence of an access plan in place, including equitable pricing and the inclusion of special populations in clinical trials.

Gilead Sciences

PRODUCT DELIVERY

RANK 15 SCORE 2.20

15th place. Gilead performs below average in this Technical Area. The company supplies one product through supranational procurement and engages extensively in non-exclusive voluntary licensing. Gilead does not show evidence of engaging in inclusive business models or new intellectual property sharing agreements. It does engage in supply chain and manufacturing capacity building initiatives as well as health system strengthening, but only some meet all Good Practice Standards.

Gilead registers products in 13 countries in scope on average. However, newer products* are registered in 1 country in scope on aver age. Gilead registers 56% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's tenofovir alafena mide (Vemlidy®), indicated for hepatitis B, is most widely registered, totalling 35 countries in scope. The company reports engaging in the CARICOM Joint Assessment to facilitate registration for 2 of its products.

Has access strategies for its supranationally procured product in scope. Gilead offers its anti fungal, liposomal amphotericin B (AmBisome®), at a not-for-profit price to 116 eligible countries as part of its Global Access Program. However, in 2024, Gilead increased this price by 40% per vial. well as several UMICs in scope. Gilead reports that 2.6mn sofosbuvir-based HCV treatments have been made available since 2013 through voluntary licensing. No further disaggregated information has been disclosed on the outcomes of the strategies during the period of analysis.

Gilead has no public commitment to not file for or enforce patents in any countries in scope.

Publicly discloses product patent status for countries in scope. Like most peers, Gilead publicly discloses patent information for small molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

IP assets with the Clinton Health Access Initiative and PENTA network to accelerate the develop- ment of an investigational dispersible paediatric formulation for HIV containing emtricitabine and tenofovir alafenamide (F/TAF). However, the company has not engaged in new agreements during the period of analysis.

Fulfils most criteria for ad hoc donations. Gilead has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure dona tions reach patients. However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Gilead publicly commits to continue long-term donation programme to support the elimina tion of visceral leishmaniasis. Its programme is active in 11 countries in scope, with the company extending its commitment to donate ampho

Gilead has 11 non-exclusive voluntary licens

In addition, Gilead renewed its agreement with WHO to donate 304,700 vials of AmBisome® for the years 2023-2025. As part of this renewed col laboration with WHO, the company also provides financial support to improve access to diagnosis and treatment.

Has access strategies for one healthcare practi tioner (HCP)-administered product, with some information found on the outcomes. Gilead has not reported access strategies for its HCP-administered products. For 1 product assessed under this category, remdesivir (Veklury®), indi cated for COVID-19 treatment, the company has signed non-exclusive voluntary licensing agree ments with generic medicine manufacturers in several UMICs, LMICs and LICs in scope. Gilead

ing agreements to enable generic supply, more than any other company in scope. The licences are for compounds covering multiple indications, including HIV (6), hepatitis C (4) and COVID-19 (1). The terms of all licences are pub licly available.**

One of the three manufacturing capacity build ing initiatives included for analysis meets all GPS. In this initiative, Gilead provides its licen sees with technical know-how and support to meet internationally recognised quality standards for production of HIV, hepatitis C and COVID-19 treatments. Manufacturers supported through this initiative are in China, India, Egypt, Pakistan and South Africa.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Gilead works with multiple active pharmaceutical ingre dient suppliers.

Gilead does not have a policy for reporting sub standard and falsified medicines in countries in scope. It does not disclose, publicly or to the Index, evidence of a policy to report cases of sub standard and falsified medicines to national or local regulatory authorities.

No evidence of inclusive business models that meet inclusion criteria.

reports that since its introduction in 2020, more than 8mn patients living in LMICs have received access to remdesivir for COVID-19 through voluntary licensing, up from more than 7mn in July

	One supply chain capacity building initiative was included for analysis, but it does not meet all GPS. Despite not meeting all GPS, in 1 initiative, Gilead is providing trainings on forecasting demand and supply to manufacturers in India.	2022.
	Has access strategies for its self-administered products, but no information on the outcomes available. For 3 of the 5 products selected for analysis, Gilead has access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). Of the 5 products, 4 are sofosbuvir-based	

Two of the five health system strengthening initiatives included for analysis meet all GPS. For example, Gilead is collaborating with the Partnership for Health Advancement in Vietnam within a multi-stakeholder coalition that aims to address barriers to diagnosis of viral hepatitis in primary health centres.

hepatitis C (HCV) treatments, for which the company applies a tiered pricing approach and a ceiling price for governments and NGOs in different countries in scope. In addition, for all products assessed, Gilead has non-exclusive voluntary licensing agreements covering LICs, LMICs, as

Gilead remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In 1 agreement, Gilead shared

*Products that received their first marketing authorisation within the last 5 years.

**In October 2024, Gilead announced an additional non-exclusive voluntary licensing agreement for lenacapavir. As the licence was announced after the period of analysis concluded, it was not assessed as part of the 2024 Access to Medicine Index.

RANK	SCORE
2	3.72

1 (2022)

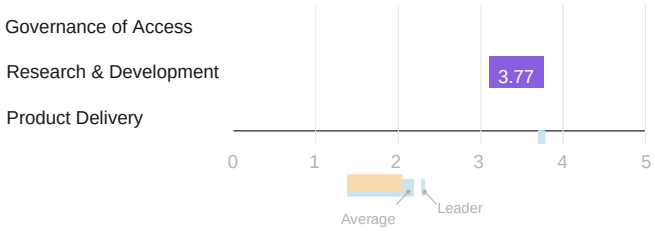
GSK plc

Stock exchange: LSE • Ticker: GSK • HQ: London, UK • Employees: 70,212

PERFORMANCE IN THE 2024 INDEX

2nd place. GSK is a leading company, ranking in the top three of all three Technical Areas and leading in Product Delivery. It shows Best Practice in Governance of Access by voluntarily disclosing information on transfers of value to healthcare professionals.

How score was achieved



OPPORTUNITIES FOR GSK

Improve the quality and broaden the geographic reach of access plans. GSK has access plans for almost all of its late-stage projects. In general, plans for communicable diseases are more comprehensive than plans for non-communicable diseases. The company can expand its plans, for example, by

to make at least two million doses of the product available for procurement for LMICs between 2025 and 2026. It can continue to expand these strategies to increase patient reach, in particular for vulnerable populations living in countries not covered by voluntary licensing or supranational procurement

including equitable pricing and/or licensing and broadening agreements.

the geographic coverage of these plans to focus more on low- and middle-income countries (LMICs). For example, it can expand its plans for depemokimab, an innovative twice-yearly drug in Phase III clinical trials for asthma, to include more than one country in scope.

Further expand access to HIV products. GSK has implemented a range of strategies to expand access to its key HIV products in LMICs. For example, for its long-acting injectable cabotegravir LA PrEP (CAB-LA), indicated for HIV prevention; it has a strategy to increase access through voluntary licensing, supranational procurement and tailored national access strategies. Recently it committed

CHANGES SINCE THE 2022 INDEX

Prioritise key markets when access is urgently needed: GSK has transitioned from a local operating model to a third-party direct distribution model in countries in scope, such as Kenya and Nigeria. It can commit to ensuring affordable access to its essential medicines in these countries by
identifying and addressing access gaps, and/or supporting local availability by engaging in technology transfers and supporting local manufacturing.

- Launched single-dose curative medicine, tafenoquine, for *P. vivax* malaria with Medicines for Malaria Venture in first endemic countries, Brazil and Thailand.
- Allocated 18 million doses of the first-ever malaria vaccine to 12 African countries for 2023 to 2025.
- Announced 10-year GBP 100mn investment to support health system strengthening and access initiatives in lower-income countries.
- Became a founding partner of the Fleming Initiative to fight antimicrobial resistance (AMR).
- Entered a partnership with Valu to offer flexible financing solutions for a range of GSK's vaccines available at pharmacies across Egypt.
- Signed voluntary licensing agreement with Medicines Patent Pool for ViiV's long-acting cabotegravir for HIV PrEP to help enable access in low, lower-middle income and sub-Saharan African countries. Programmatic supply of the original brand, Apretude® was initiated in countries in scope of the Index.
- Renewed partnership with Save the Children and investing GBP 15mn for five more years.
- Transitioned from a local operating company to a third-party direct distribution model in Kenya and Nigeria.
- Extended its long-term donation programme of albendazole (Zentel®) for soil-transmitted helminthiases, pledging up to 100 million doses annually to 2030. Also launched an echinococcosis treatment programme, committing to provide five million tablets annually until 2025.
- Partnered with Gates MRI to further develop the M72/AS01E tuberculosis (TB) vaccine candidate.
- Generic formulations of ViiV's paediatric dolutegravir-based medicines reached children living with HIV in 87 Index countries.

GSK plc

SALES AND OPERATIONS

Therapeutic areas: Infectious diseases, HIV, immunology/respiratory, oncology
Product categories: General medicines, specialty medicines, vaccines
M&A news: GSK acquired Affinivax Inc. for an upfront payment of USD 2.2bn and Sierra Oncology, Inc. for USD 1.9bn, respectively, in 2022 and 2023. It acquired BELLUS Health, Inc. for USD 2bn and Aiolos Bio for USD 1.4bn, respectively, in 2023 and 2024. It divested its remaining shares in Haleon, its consumer health business at a total value of USD 2.5bn over 2023 and 2024.

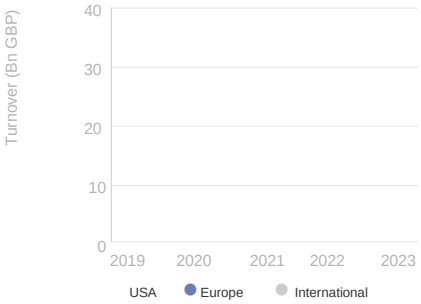
Turnover by segment (2023) – in GBP

General medicines	10.20 bn
Vaccines	9.90 bn
Specialty medicines	10.20 bn
Total	30.30 bn

Sales in countries in scope

GSK's products are sold in 82 out of 113 countries in scope of the Index. GSK has sales offices in 27 countries and sells via suppliers and/or pooled procurement in an additional 55 countries.

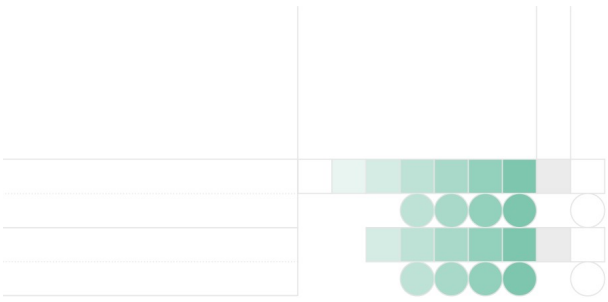
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

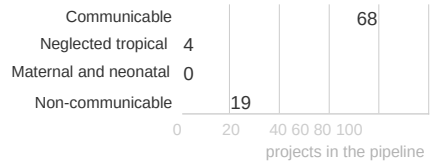
GSK has 91 R&D projects in scope, 67 of which target priority diseases, focusing on HIV/AIDS (17), TB (9) and malaria (7). The remaining 24 projects target other diseases in scope, including cancer (10), asthma (3) and COPD (2). Of the 91 R&D projects, 43 are in late-stage development, with evidence of access planning for 88% (38/43) of these.



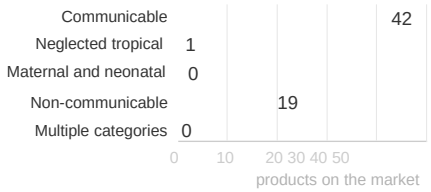
PORTFOLIO *as selected for analysis by the Index*

GSK has 62 products in scope, including 40 medicines and 21 vaccines; 37 of these products are listed on the WHO EML and most of its medicines are on patent (24). Its medicines mostly target communicable diseases, such as HIV (15) and malaria (3). Its medicines for non-communicable diseases include treatments for asthma and COPD (9), cardiovascular diseases (4) and cancer (2). Its 1 medicine for neglected tropical diseases treats leishmaniasis. GSK's vaccines include 7 for meningitis, as well as an HPV vaccine to prevent cervical cancer. In addition, GSK's 1 marketed platform technology is a vaccine adjuvant for COVID-19.

91 projects in the pipeline



62 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	1610	13	14	9	1	2	2	67
with access plan			13	9	1	2		25
Other projects in scope		7	6	9	0	2	0	24
with access plan			4	7	0	2		13

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	6	18			24
off patent	12	4			16
Vaccines	19	2			21
Contraceptives	0	0			0
Diagnostics			0		0
Other				1	1

GSK plc

GOVERNANCE OF ACCESS

RANK 3 SCORE 4.36

3rd place. GSK performs strongly in this Technical Area. It shows Best Practice by voluntarily disclosing information on transfers of value to healthcare professionals in some countries in scope, not only when required by law or local regulation. The company also has a robust set of controls to mitigate the risk of non-compliant or corrupt activities in countries in scope. Further, GSK has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as well as direct board-level responsibility for access.

The highest responsibility for access lies directly with the Board, namely with its Corporate Responsibility Committee responsible for global health and access strategies. Additionally, GSK incentivises its senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. The CEO also has long-term access-related incentives included in their annual bonus plan.

Shows comparatively strong commitment to responsible business practices. GSK's sales agents are not solely incentivised by sales volume. Individual performance is assessed on sales data, capabilities and behaviours. GSK excludes some markets from incentive compensation schemes based on risk and readiness assessments. It has a global policy on ensuring ethical interactions strongly in this regard. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessment. GSK also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

GSK publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. The company states that compulsory licensing should be used in limited situations as a last resort.

with healthcare professionals. It also declares that transfers of value for healthcare professionals

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy, embedded in its Global Health commitment, covers all therapeutic areas in which the company is involved. GSK publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Annual and ESG Reports.

Fulfils some criteria with its process for (e.g., payments for facilitating scientific work shops) are made at fair market value and sets annual cap limits per healthcare professional. Additionally, GSK voluntarily discloses information on such payments in some countries in scope, not only when required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. GSK performs measuring and reporting the patient reach of its goal to reach 1.3 billion people in lower income countries. The process covers most of its products and most countries in scope of the Index, and GSK provides the underlying equation, metrics and assumptions under an NDA. The resulting patient reach numbers are published regularly and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT RANK 2 SCORE 3.31

2nd place. GSK performs strongly in this Technical Area. It has the largest priority pipeline of all companies, with a decline in the number of projects compared to the previous Index. It publicly commits to access planning from Phase II onwards and has access plans in place for the majority of late-stage pipeline candidates, although plans for non-communicable diseases are more limited in depth and breadth. GSK does not publicly disclose disaggregated R&D investment data, but it performs strongly in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Largest priority R&D pipeline, with access plans in place for 96% (25/26) of the late-stage candidates. Priority R&D pipeline of 67 projects, including 26 late-stage projects that target a priority gap. The company focuses on various priority areas, including HIV/AIDS, TB and malaria.

Of GSK's 26 late-stage candidates targeting a priority product gap, 25 (96%) have evidence of an access plan in place, mostly focusing on registration preparation, including special populations in clinical trials and supply and demand plans.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 76% (13/17) of late-stage projects covered by access plans. The company has 17 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, asthma and COPD. GSK provides evidence of access plans for 13 of its 17 late-stage projects, mostly comprising of registration preparation, supply and demand plans and the inclusion of special populations in clinical trials.

GSK does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

All 5 R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). In one initiative, GSK builds R&D capacity in sub-Saharan Africa by providing research institutions with funds and additional in-kind support for research on non-communicable diseases.

PRODUCT DELIVERY RANK 1 SCORE 3.77

1st place. GSK leads in this Technical Area. It engages in multiple new intellectual property sharing agreements and all of its capacity building initiatives meet all Good Practice Standards. It engages in supranational agreements to supply five products and demonstrates efforts to provide access in countries outside these agreements. It has access strategies across the three country income classifications and reports outcomes of these strategies. GSK has five non-exclusive voluntary licensing agreements for three compounds, including one new license during the period of analysis.

GSK registers newer products* in 10 countries in scope on average. It registers 60% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's dolutegravir (Tivicay PD), indicated for paediatric HIV, is most widely registered, totaling 31 countries. The

*Products that received their first marketing authorisation within the last 5 years.

GSK plc

company reports engaging in various mechanisms to facilitate the registration of multiple products in multiple countries.

Ensures supply of 5 products through different supranational agreements. GSK supplies 4 products assessed in this category via supranational agreements with Gavi, The Vaccine Alliance (Gavi)/UNICEF, including RTS, S/AS01 (Mosquirix®), a vaccine recommended by WHO for malaria prevention in children. The fifth product, long acting cabotegravir (Apretude®), indicated for HIV pre-exposure prophylaxis, is supplied via different procurers, including PEPFAR via Chemonics as the procurement agent. For 3 of the products, the company demonstrates strategies to supply the product in at least one country that is not eligible for the supranational agreements. For example, after graduating from Gavi support in 2018, GSK continued to provide its rotavirus vaccine (Rotarix®) at a discounted Gavi price, committing to maintain this for 10 years (until 2028). For the 2 products not yet supplied beyond supranational mechanisms - Apretude® and Mosquirix® - GSK has provided evidence of its plans to supply Apretude® in a country outside the supranational procurement mechanism, while Mosquirix® is prioritised for supply exclusively in Gavi-eligible countries, where the burden of malaria is highest.

Quality of access strategies for healthcare practitioner (HCP)-administered products varies across products, with outcomes tracked. For 1 of the 2 products selected for analysis, its hepatitis B vaccine (Engerix® B), GSK provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). However, these strategies are for the private sector only and lack additional strategies, such as health system strengthening. For mepolizumab (Nucala®), indicated for treating severe eosinophilic asthma, the company has good access strategies for the UMIC and LMIC examples, but not for any LIC. In Colombia (UMIC), in addition to its equitable pricing strategy, GSK implements different additional strategies, such as a comprehensive patient support programme to improve adherence and decrease access barriers. The company shares how it monitors the outcomes, including patient adherence, and the progress of the access strategies for mepolizumab in increasing the number of patients reached over time.

Evidence of access strategies for most self-administered products, supported by information on outcomes. For 4 of the 5 products selected for analysis, GSK provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC), with evidence of efforts to improve most comprehensive in addressing barriers to access, with additional strategies implemented to complement pricing strategies. For example, in one UMIC, the company has launched a second brand of one of its products at a reduced price. In LMICs and LICs, GSK utilises non-exclusive voluntary licensing to enable generic supply of its dolutegravir-based products, including Tivicay® and Triumeq® (both indicated for HIV treatment). Overall, GSK reports patient reach data, including how this is measured, and provides evidence of increasing patient reach over time.

GSK publicly commits not to file for or enforce patents for all products in least developed countries and LICs.

Publicly discloses product patent status for countries in scope. Like most peers, GSK publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

ViiV Healthcare (majority-owned by GSK) has 5 non-exclusive voluntary licensing agreements to enable generic supply of 3 compounds. One compound, dolutegravir, indicated for HIV treatment, has 3 licences: 1 for paediatric use, covering 107 countries in scope, and 2 for adult use, each covering a different subset of countries, 92 of which are in scope. The company issued 1 new licence during the period of analysis for cabotegravir LA PrEP, indicated for HIV prevention. The licence covers 88 countries in scope and is the first non-exclusive voluntary licence for a long-acting injectable to prevent HIV. The terms of all licences are publicly available.

All 5 manufacturing capacity building initiatives included for analysis meet all GPS. In 1 initiative, GSK partners with a contract manufacturing organisation (CMO) in India to fully produce the single-dose malaria treatment tafenoquine (Kozenis) from API to finished product. GSK has provided ongoing support to ensure that the CMO meets environmental, health, safety and quality standards.

All 5 supply chain capacity building initiatives included for analysis meet all GPS. For example, in the Vietnam Paediatric Vaccine Supply Chain Initiative, GSK supports the Vietnam Vaccine Joint Stock Company by building the supply chain capacity of its importers and distributors to ensure timely access to paediatric vaccines.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, GSK has partnered with Save the Children since 2013, with various 5-year partnerships. pneumonia. Since 2023, the renewed partnership focuses on increasing child vaccination rates in Ethiopia and Nigeria.

GSK newly engaged in 17 IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. The company performs well in this area. In 1 agreement, the company shares a target-specific compound set with a university to accelerate drug discovery for TB. GSK also remains engaged in existing agreements.

Fulfils all criteria for ad hoc donations. GSK has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored through partners to ensure donations reach patients. For example, in February 2023, GSK responded to aid requests from Direct Relief and International Health Partners UK, by donating 57,000 units of amoxicillin and clavulanate potassium (Augmentin) to earthquake-stricken Syria. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

GSK publicly commits to continue long-term donation programme to support the elimination of lymphatic filariasis and the control of soil-transmitted helminthiasis and echinococcosis. One of its programmes is active in 29 countries in scope, with the company pledging to donate albendazole (Zentel®) for an unlimited period until lymphatic filariasis is eliminated.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, ViiV Healthcare (majority-owned by GSK), initiated a technology transfer with all 3 generic manufacturer licensees of its long-acting HIV prevention product cabotegravir (Apretude®).

GSK has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities and the WHO within 5 days. The company provides evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation. In urgent situations where there is a significant risk of patient harm, the policy is designed to enable GSK to respond quickly.

No evidence of inclusive business models that meet inclusion criteria. However, GSK engages in initiatives that address access needs of neglected populations. For example, the company is helping to ensure continuity of care for migrant populations in 1 country in scope who are awaiting regularisation and therefore lack access to HIV care.

affordability and availability of its products in most of its strategies. Access strategies in UMICs are

Between 2018 and 2023, the partnership focused on improving detection, referral and treatment of

RANK	SCORE
5	3.43
2 (2022)	

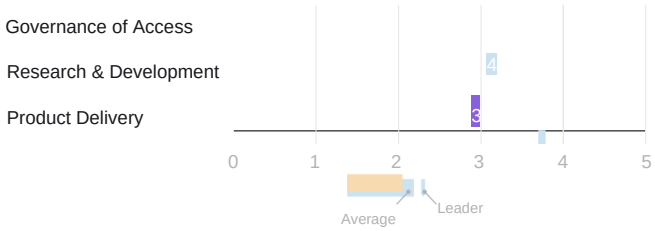
Johnson & Johnson

Stock exchange: NYSE • Ticker: JNJ • HQ: New Brunswick, New Jersey, USA • Employees: 134,400

PERFORMANCE IN THE 2024 INDEX

5th place. Johnson & Johnson is a high-performing company. It performs strongly in Research & Development, where it has access plans in place for all pipeline projects. Additionally, it performs above average in Governance of Access and Product Delivery.

How score was achieved



OPPORTUNITIES FOR JOHNSON & JOHNSON

Improve the quality and geographic reach of access plans for its non-communicable disease projects. Johnson & Johnson has access plans in place for all its late-stage R&D projects in the pipeline. These access plans focus mostly on registration in emerging markets. For example, its late-stage oncology projects focus primarily on registration preparation and include four countries in scope, on average. The company can expand these, for example, through equitable pricing and by broadening the geographic coverage of these plans to focus on more low- and lower-middle-income countries.

Expand access to its marketed products. Johnson & Johnson has access strategies in place for most of its marketed products assessed; however, these are mostly in upper-middle and lower-middle income countries. It can expand access in low-income countries through implementing access strategies and/or engaging in voluntary licensing. For example, it can increase access to ibrutinib (Imbruvica®),

CHANGES SINCE THE 2022 INDEX

indicated for multiple cancer types, and prioritised for licensing by public health organisations, through voluntary licensing and/or expanded access strategies.

Maintain a focus on diseases that impact populations in low- and middle-income countries (LMICs). Johnson & Johnson has announced the closure of its R&D infectious disease & vaccine unit, impacting R&D for diseases that disproportionately affect people living in LMICs. It can
reaffirm its commitment to enhancing access to its products that target other diseases of global health significance, such as tuberculosis, and leprosy, through R&D access planning and equitable access strategies.

- In 2023, Johnson & Johnson granted the Stop TB Partnership's Global Drug Facility (GDF) appropriate licences, allowing it to tender, pro cure and supply generic versions of bedaquiline (Sirturo®) for the majority of LMICs.
- In September 2023, Johnson & Johnson publicly reported it will not enforce any of its patents for bedaquiline (Sirturo®) in 134 LMICs.
- In August 2023, Johnson & Johnson received primary award position in the GDF open competitive tender, providing a 55% price reduction on bedaquiline (Sirturo®).
- Marked over 2.4 billion doses of mebendazole (Vermox®) donated since 2006.
- Announced an agreement with Sanofi to advance the development of a potential first-in-class vaccine against extraintestinal pathogenic *E. coli* (ExPEC).
- Extended its ongoing long-term donation programme of mebendazole (Vermox® Chewable) in 2024 for an additional five years, ensuring up to 1 billion additional doses are available through 2030, to help control soil-transmitted helminthiasis.
- Launched a new initiative to formally integrate 100,000 community health workers into the Kenyan health system, as part of the Ministry of Health’s Community Health Units for Universal Health Coverage (CHU4UHC) platform.
- Supported Empower School of Health to develop an online supply chain training curriculum for frontline health workers.
- Invested USD 15.1bn in R&D within its Innovative Medicine and MedTech sectors in 2023.

Johnson & Johnson

SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, immunology, infectious diseases & vaccines, metabolism, retina & pulmonary hypertension, neuroscience, oncology

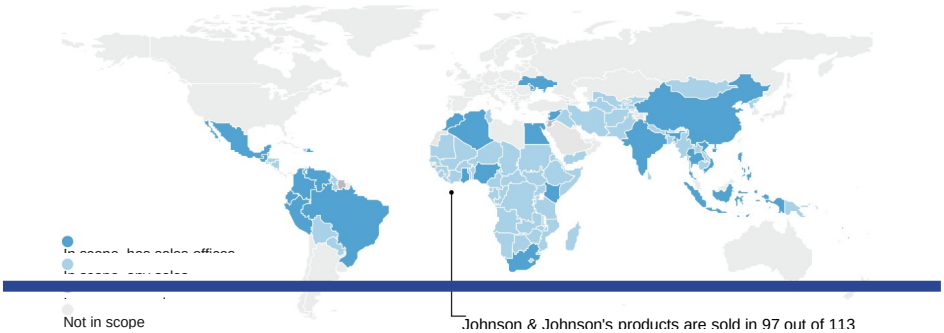
Product categories: Innovative medicines, MedTech

M&A news: Johnson & Johnson acquired Abiomed Inc. for USD 16.6bn in 2022. In 2024 it acquired Ambrx Biopharma Inc. for USD 2bn; Serotiny, Inc. for an undisclosed amount; and Shockwave Medical for USD 13.1bn USD. It divested 80% of its shares in Kenvue Inc. – formerly its consumer health business – and rights for Reminyl® to Essential Pharma in 2023 and 2024, respectively.

Sales by segment (2023) – in USD

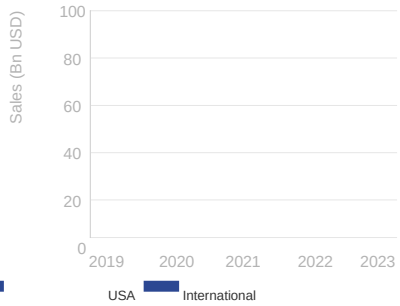
Innovative medicines	54.76 bn
MedTech	30.40 bn
Total	85.16 bn

Sales in countries in scope



Johnson & Johnson's products are sold in 97 out of 113 countries in scope of the Index. Johnson & Johnson has sales offices in 24 countries and sells via suppliers and/or pooled procurement in an additional 73 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

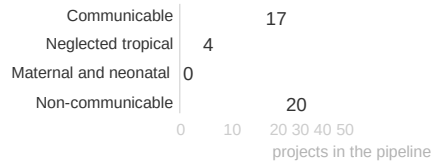
PIPELINE *for diseases in scope*

Johnson & Johnson has 41 R&D projects in scope, 21 of which target priority diseases, focusing on TB (10) and dengue (3). The remaining 20 projects target other diseases in scope, including cancer (11), cardiovascular diseases (4) and depressive disorders (4). Of the 41 R&D projects, 17 projects are in late-stage development, with evidence of access planning for 100% (17/17) of these.

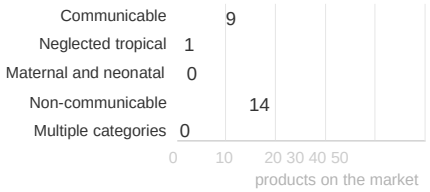
PORTFOLIO *as selected for analysis by the Index*

Johnson & Johnson has 24 products in scope, including 22 medicines that target various diseases in scope and 2 vaccines, including a vaccine targeting Ebola. Of its 22 medicines, 9 are listed on the WHO EML. Most of its medicines are on patent (18). Its medicines for communicable diseases include HIV (6) and TB (1); its medicines targeting non-communicable diseases include treatments for cancer (8) and diabetes (2).

41 projects in the pipeline



24 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	8	4	1	5	1	0	1	1	21
with access plan				5	1	0	1		7
Other projects in scope			10	2	6	0	2	0	20
with access plan				2	6	0	2		10

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	6	12		18
off patent	3	1		4
Vaccines	0	2		2
Contraceptives	0	0		0
Diagnostics			0	0
Other			0	0

Johnson & Johnson

GOVERNANCE OF ACCESS

RANK 6 SCORE 4.24

6th place. Johnson & Johnson performs above average in this Technical Area. It has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as well as direct board-level responsibility for access. The company provides a patient reach process that covers one product and all countries in scope, and has a measurable patient reach goal. Further, Johnson & Johnson has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies directly with the Board. Johnson & Johnson incentivises its senior executives and regional managers to act on access to medicine with financial and non-financial rewards. Senior management, including the CEO, have enterprise-level targets, as well as access-related performance indicators, including KPIs to improve access to medicine, as part of their annual goals and objectives.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy, embedded in its Access and Pricing Principles, covers all therapeutic areas in which the company is involved. Johnson & Johnson publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Health for Humanity Report.

Shows comparatively strong commitment to responsible business practices. Johnson & Johnson sets individual-level targets for sales agents, but incentives are not solely based on sales volume. It also incentivises sales agents on qualitative performance indicators like technical knowledge and service quality to healthcare professionals. It also does not have marketing and sales agents for some products related to diseases in scope, like HIV/AIDS medicines. The company has a global policy on ensuring ethical interactions with healthcare professionals and declares that transfers of value to healthcare professionals (e.g., payments for facilitating scientific workshops) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Johnson & Johnson performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. It also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Johnson & Johnson publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. The company states that compulsory licensing should be used in certain limited circumstances.

Fulfils some criteria across 4 processes for measuring and reporting patient reach. The process for its bedaquiline product (for the treatment of multidrug-resistant TB), which covers all countries (where the company operates) in scope of the Index, Johnson & Johnson publicly provides the metrics. The resulting patient reach numbers are published regularly and demonstrate improvements, including potential cases averted based on WHO data. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 3 SCORE 3.12

3rd place. Johnson & Johnson performs strongly in this Technical Area. It has a medium-sized priority pipeline, but the number of projects has decreased. It has access plans in place for all late-stage pipeline candidates – although plans for non-communicable disease projects mostly focus on registration preparation in emerging markets. It performs strongly in R&D capacity building and has an access planning framework, with public commitments to access planning from Phase II onwards. However, it does not publicly disclose disaggregated R&D investment data.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public mitment addressing its systematic approach to access planning for LMICs.

Large-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (7/7) of the late-stage candidates. Priority R&D pipeline of mostly focusing on registration preparation and including special populations in clinical trials.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 100% (10/10) of late-stage projects covered by access plans. The company has 10 late-stage 21 projects, including 7 late-stage projects that target a priority gap. The company focuses on various priority areas, including TB and dengue. Of Johnson & Johnson's 7 late-stage candidates targeting a priority product gap,

Johnson & Johnson does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is the Clinical Trials Community Africa Network (CTCAN). Johnson & Johnson is one of the parties involved in the initiative, which aims to build clinical trial capacity in sub-Saharan Africa.

R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, cardiovascular diseases and depressive disorders. Johnson & Johnson provides evidence of access plans for all 10 late-stage projects, including registration preparation, equitable pric ing and the inclusion of special populations in

7 (100%) have evidence of an access plan in place, clinical trials.

Johnson & Johnson

PRODUCT DELIVERY

RANK 6 SCORE 3.37

6th place. Johnson & Johnson performs above average in this Technical Area. The company has access strategies for its products and reports some information on the outcomes; however, reach in low-income countries is limited. It no longer shows evidence of new intellectual property sharing agreements with drug discovery initiatives or research institutions, but it has a non-exclusive voluntary licensing agreement for one compound. Nearly all capacity building initiatives included meet all Good Practice Standards.

Johnson & Johnson registers newer products* in 18 countries in scope on average. The company registers 67% of products assessed in at least 1 of the 10 countries with the highest disease burden.** Its COVID-19 vaccine (Johnson & Johnson COVID-19 vaccine) is most widely registered, totalling 41 countries in scope. The company reports engaging in multiple mechanisms to facilitate registration for multiple products, such as the WHO Collaborative Registration Procedure.

Supplies 3 products in scope through different supranational agreements. Johnson & Johnson supplies 3 products, indicated for MDR-TB, COVID-19 and HIV, via different procurers. For 2 of the 3 products assessed in this category, the company demonstrates access strategies in at least one country not eligible for supranational supply. For the third product, bedaquiline (Sirturo®), the company stated that as of August 2023, all countries in scope were eligible to procure via .the Stop TB Global Drug Facility supranational supply mechanism.

Quality of access strategies for healthcare practitioner (HCP)-administered products varies across products and countries, with some information on outcomes. For 2 of the 5 products selected for analysis, Johnson & Johnson provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC); 3 products lack access strategies in LICs. Access strategies in UMICs are more comprehensive in addressing product- and country-specific barriers to access, including additional strategies to complement pricing ones. However, in the majority of the LMIC and LIC examples analysed, the company provides evidence of initiatives to strengthen health systems and build capacity to ensure the continuum of care for the product. The company has high-level goals to increase access to its products and provides evidence of the number of patients reached, but did not share detailed approaches on how it measures this outcome and tracks the progress of its access strategies.

Provides evidence of access strategies for most self-administered products, supported by some information on outcomes. For 2 of the 5 products selected for analysis, Johnson & Johnson provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC); 3 products lack access strategies in LICs. The company provides evidence of considering different payers' ability to pay in setting its pricing strategies and applying patient access programmes. Furthermore, all access strategies analysed are complemented by additional strategies, such as healthcare professional education. The company has goals to increase access to its products and provides evidence of plans for advancing this. For almost all of the products analysed, it provides evidence of patient reach; in some instances, supported by more details on the approaches applied to measure outcomes.

Johnson & Johnson publicly commits not to enforce patents for only 2 products. In September 2023, Johnson & Johnson committed not to enforce patents for bedaquiline (Sirturo®), indicated for multidrug-resistant TB in 134 LMICs. Previously, in 2012, Johnson & Johnson committed not to enforce patents for darunavir (Prezista®) in sub-Saharan Africa and least developed countries and in 2015 it expanded the policy to paediatric formulations in additional countries.

Publicly discloses product patent status for countries in scope. Like most peers, Johnson & Johnson publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Johnson & Johnson has 1 non-exclusive voluntary licensing agreement to enable generic supply of rilpivirine, indicated for HIV. The licence was issued in 2011 and covers 85 countries in scope. The terms of the licence are not publicly available.

All 5 manufacturing capacity building initiatives included for analysis meet all GPS. In 1 initiative, Johnson & Johnson is transferring technology to a manufacturer in one country in scope for secondary packaging for one of the company's oncology products. The transfer includes training, expertise and pharmacological data.

Four of the five supply chain capacity building initiatives included for analysis meet all GPS. For example, Johnson & Johnson funded Empower School of Health, East, Central and Southern African College of Nursing (ECSACONM) and the Ecumenical Pharmaceutical Network (EPN) to develop a free, online supply chain management training curriculum for frontline health workers. The curriculum is available in 5 countries in scope.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, Johnson & Johnson supports multiple initiatives tackling underdiagnosis of TB in 6 countries in scope. The company and partners launched a youth TB awareness and care programme in the Philippines, targeting at-risk 15-24-year-olds for education, screening, and to support the promotion of early diagnosis and treatment.

Johnson & Johnson remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In 1 agreement, the company shared IP assets with the Clinton Health Action Initiative and PENTA to accelerate development of a paediatric fixed-dose combination HIV treatment. However, Johnson & Johnson has not engaged in new agreements during the period of analysis.

Fulfils all criteria for ad hoc donations. Johnson & Johnson has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Johnson & Johnson publicly commits to continue long-term donation programme to support the control of soil-transmitted helminthiasis. Its programme is active in 55 countries in scope, with the company extending its commitment to donate mebendazole (Vermox® Chewable) through 2030 to help control soil-transmitted helminthiasis.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Johnson & Johnson is transferring technology for the production of a product, indicated for HIV, to manufacturers in a country in scope to supply to the local market.

Johnson & Johnson has a procedure for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 5 days. The company discloses that it aims to report within 2 days if the case presents a direct and serious or life-threatening risk to a patient or healthcare professional. Further, it distinguishes quicker reporting timeframes for cases that only require visual inspection for confirmation.

No evidence of inclusive business models that meet inclusion criteria. However, Johnson & Johnson engages in initiatives that address access

needs of neglected populations, including through patient access programmes.

*Products that received their first marketing authorisation within the last 5 years.

**For one product assessed, global burden of disease data is only available for two countries.

RANK	SCORE
16	2.21
18 (2022)	

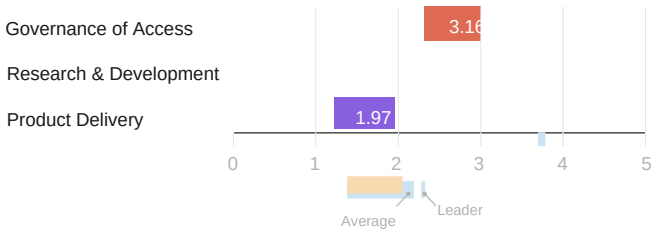
Merck & Co., Inc.

Stock exchange: NYSE • Ticker: MRK • HQ: Rahway, New Jersey, US • Employees: 72,000

PERFORMANCE IN THE 2024 INDEX*

16th place. MSD performs below average in all three Technical Areas. However, it has improved its performance in Governance of Access and Product Delivery, where it demonstrates Best Practice by sharing high-value intellectual property assets for tuberculosis and transferring technology for end-to-end manufacturing of vaccines.

How score was achieved



OPPORTUNITIES FOR MSD

Improve the quality and broaden the geographic reach of access plans. MSD has access plans that predominantly focus on registering in countries where the company is conducting clinical trials. It can expand its plans, for example, by including equitable pricing and broadening the geographic coverage of these plans to focus on more low- and lower-middle-income countries. For example, it can enhance plans for clesrovimab – a preventative treatment for respiratory syncytial virus in infants which is currently in Phase III of clinical trials – beyond the seven countries in scope where it is conducting these

Expand manufacturing capacity building efforts for vaccines.
In 2022, MSD launched a technology transfer with Bio
Farma to produce MSD's quadrivalent HPV vaccine locally in Indonesia. MSD can further expand these efforts to increase vaccine manufacturing for products prioritised for local production, such as Ebola vaccines, particularly in Africa.

Expand access strategies to key oncology products. MSD did not disclose access strategies for its cancer products in any country in scope. It can expand access by implementing

trials. equitable access strategies and/or engaging in voluntary

licensing to enable generic supply in low- and middle-

Establish direct board-level responsibility for access to medicine. MSD places the highest responsibility for access with the Policy and ESG Council reporting to the

income countries; in particular, for its key immuno-oncology therapy pembrolizumab (Keytruda®), indicated for multiple cancer types and prioritised for licensing by public health

Executive Committee. To further progress, MSD can ensure organisations.
responsibility for access to medicine lies directly with the
board.

CHANGES SINCE THE 2022 INDEX

- Entered a licensing agreement with the Gates Medical Research Institute (Gates MRI) for two pre-clinical antibacterial candidates in October 2022.
- 2022 marked 35 years of the Merck and Mectizan® donation programme, which began with the goal of eliminating onchocerciasis and later expanded to include lymphatic filariasis through the long-term donation of ivermectin (Mectizan®).
- Its HPV vaccines, Gardasil®4/Gardasil®9, were included in the Global HPV Consortium, which focuses on accelerating the prevention of HPV and eliminating cervical cancer.
- Newly entered a licensing and technology transfer agreement to have its four-valent HPV vaccine produced locally by Bio Farma in Indonesia. Merck also entered a technology transfer agreement with Chinese manufacturer Sinopharm to supply its COVID-19 treatment, molnupiravir, to the Chinese market in future.
- Signed an agreement with the faculty of medicine at Siriraj Hospital, Mahidol University, to establish a Clinical Site Partnership Project in Thailand.
- Announced that Merck for Mothers had reached more than 30 million women world wide through its programmes supporting access to high-quality maternal care.
- Published its Sustainability Bond Allocation Report in 2023, where proceeds were used to fund projects and partnerships that con tribute to the advancement of United Nations Sustainable Development Goals (SDGs), including access to health care and infec tious disease research programmes. Merck Foundation committed USD 11mn over six years (2023 – 2028) to the University of New Mexico Health in support of its new initiative to bring high-quality care to an estimated 11mn people living with cancer in underserved communities throughout India, Indonesia, Malaysia and Vietnam.

*For the 2024 iteration, MSD declined to submit data to the Access to Medicine Index.

Merck & Co, Inc

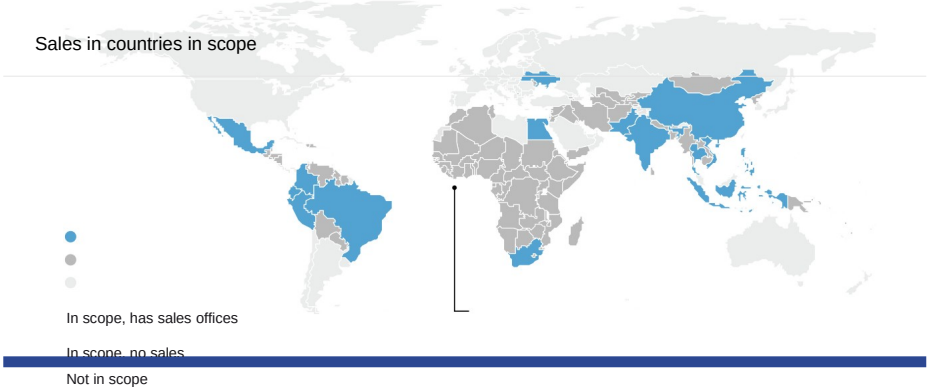
SALES AND OPERATIONS

Therapeutic areas: Cardio-metabolic diseases, immunology, infectious diseases, neuroscience, oncology, vaccines
Product categories: Animal health, innovative medicines, vaccines
M&A news: In 2023 MSD acquired Imago Inc. for USD 1.35bn; Prometheus Biosciences Inc. for USD 10.8bn; and Caraway Therapeutics Inc. for USD 610mn USD. In 2024, it acquired Harpoon Therapeutics Inc. for USD 650mn. MSD's Animal Health Division acquired Vence for an undisclosed amount and Aqua Business for USD 1.3bn USD in 2022 and 2024, respectively. In 2024, MSD acquired Abceutics, Inc. for USD 208mn.

Net sales by segment (2023) – in USD

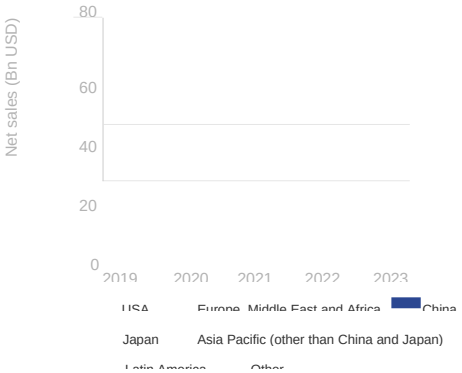
Animal health	5.63 bn
Pharmaceuticals	53.58 bn
Other segment sales	0.91 bn
Total	60.12 bn

Sales in countries in scope



MSD's products are sold in 81* out of 113 countries in scope of the Index. MSD has sales offices in 15 countries and sells via suppliers and/ or pooled procurement in 66* countries.

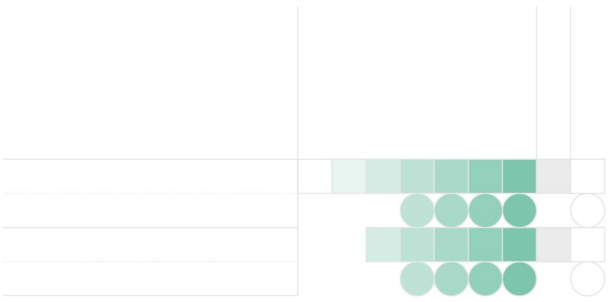
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

MSD has 36 R&D projects in scope, 5 of which target priority diseases, focusing on HIV/AIDS (3), RSV (1) and malaria (1). The remaining 31 projects target other diseases in scope, including cancer (23) and cardiovascular diseases (3). Of the 36 R&D projects, 35 are in late-stage development, with evidence of access planning for 69% (24/35) of these.

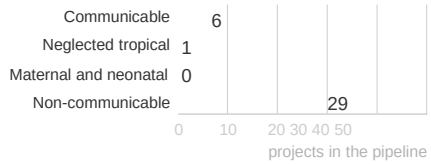


PORTFOLIO *as selected for analysis by the Index*

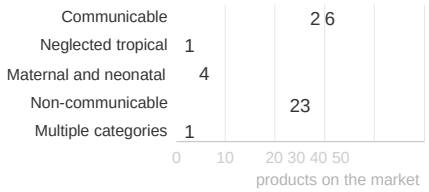
MSD has 55 products in scope, including 37 medicines and 13 vaccines; 28 of these products are listed on the WHO EML. Most of the products are on patent (30). Its medicines mostly target non-communicable diseases, such as diabetes (7), cardiovascular diseases (5) and cancer (4). Its medicines for communicable diseases include HIV (5) and hepatitis C (3), and it has a medicine that is indicated for both cancer and hepatitis (B and C). It has 1 vector control product for rabies and 4 contraceptive methods and devices.

MSD's vaccines include 2 for measles, 2 for lower respiratory infections, and 2 HPV vaccines for prevention of cervical cancer.

36 projects in the pipeline



55 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	1	1	2	0	1	0	5
with access plan				0	2	0	1		3
Other projects in scope			0	22	7	0	2	0	31
with access plan				12	7	0	2		21

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	5	19			24
off patent	9	4			13
Vaccines	12	1			13
Contraceptives	2	2			4
Diagnostics			0		0
Other				1	1

*In 2016, MSD reported sales in 81 countries.

Merck & Co, Inc

GOVERNANCE OF ACCESS

RANK 18 SCORE 3.16

18th place. MSD performs poorly in this Technical Area. The company has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy. However, the highest responsibility for access to medicine lies indirectly, rather than directly, with MSD's Board. Additionally, it does not disclose sufficient evidence of having a robust set of controls to mitigate the risk of non-compliant or corrupt activities in countries in scope. Further, the company does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility for access lies indirectly with the Board, namely with the Policy and ESG Council reporting to the Executive Committee. MSD has access-related incentives for its CEO, senior executives and in-country managers. In 2023, the company added new tainability metrics to its company scorecard, linking a percentage of employee compensation to key sustainability goals, including Access to Health.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy, guided by its Access to Health Statement of Guiding Principles, covers all therapeutic areas in which the company is involved. MSD publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and

Shows comparatively poor commitment to responsible business practices. There is evidence that MSD sets individual-level targets for sales agents, but it does not disclose, publicly or otherwise, if incentives are solely based on sales volume. Additionally, MSD does not provide evidence, publicly or otherwise, of having a global policy that commits to ensuring ethical interactions with healthcare professionals. Further, it only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

Has a set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. MSD performs moderately in this respect. It has policies

close sufficient evidence, publicly or to the Index, of fraud-specific risk assessments and region or country risk-based assessments in countries in scope. MSD has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

MSD does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available policy statement on intellectual property, but it does not align with principles embodied in the Declaration. Further, MSD states that compulsory licensing may hinder equitable access.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For MSD's process for its innovative portfolio, which covers some of its products in scope of the Index, information on country coverage was unavailable but the metrics, assumptions and limitations are publicly available. The resulting patient reach numbers are published regularly and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

Reporting is clear, linked to these goals, centrally available, and updated regularly in its Impact

to mitigate non-compliance risks, including pro cesses to ensure third-party compliance with Report.

company standards. However, it does not dis

RESEARCH & DEVELOPMENT

RANK 12 SCORE 2.17

12th place. MSD has a below-average performance in this Technical Area. The company has a public access planning framework in place from Phase II onwards but did not disclose access plans for all late-stage candidates. Its access plans comprise of commitments to register in countries where it conducts clinical trials. It has a small-sized priority pipeline, which has declined in size and does not publicly disclose disaggregated R&D investment data, but it does participate in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public com mitment addressing its systematic approach to access planning for LMICs.

of an access plan in place, including registration preparation and inclusion of special populations in clinical trials.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 68% (21/31) of late-stage projects covered by access

MSD does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (for merly Policy Cures Research).

One of the two R&D capacity building initiatives included for analysis meets all Good Practice Standards (GPS). In this initiative, MSD provides equipment to Seeding Labs. In turn, the organisation provides this equipment to research institutions in LMICs.

Small-sized priority R&D pipeline, compared to peers, with access plans in place for 75% (3/4) of the late-stage candidates. Priority R&D pipe line of 5 projects, including 4 late-stage projects that target a priority gap. The company focuses on various priority areas, including HIV/AIDS and malaria. Of MSD's 4 late-stage candidates target ing a priority product gap, 3 (75%) have evidence plans. The company has 31 late-stage R&D pro jects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer and cardiovascular diseases. MSD provides evi dence of access plans for 21 of its 31 late-stage projects, including registration preparation and the inclusion of special populations in clinical trials.

Merck & Co, Inc

PRODUCT DELIVERY

RANK 17 SCORE 1.97

17th place. MSD performs poorly in this Technical Area. The company did not report any national access strategies for its products. However, it engages in supranational agreements to supply four of its products. For two products, the company also engages in non-exclusive voluntary licensing.

It shows evidence of two new technology transfers, improving its performance in manufacturing capacity building. It engages in some supply chain capacity building and health system strengthening initiatives, but few meet all Good Practice Standards.

MSD did not disclose registration data to the Index. However, evidence in the public domain indicates that it has utilised WHO Prequalification other licence is for molnupiravir, indicated for the treatment of COVID-19, and includes 98 countries in scope and was issued in 2021.

to facilitate registration for multiple products. Supplies 4 products through supranational

donate ivermectin (Mectizan®) for as long as necessary until onchocerciasis and lymphatic filariasis are eliminated.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, MSD engages in technology transfer and supply chain capacity building. However, it does not disclose information about other mechanisms such as communication with relevant stakeholders about

Neither of the 3 manufacturing capacity building initiatives included for analysis meet all GPS. In 1 initiative, MSD is transferring technology to manufacture the HPV vaccine (NusaGard) to Bio Farma. The goal of the transfer is to allow Bio Farma to produce the full product from API to finished product for supply in Indonesia.

Two of the three supply chain capacity building initiatives included for analysis meet all GPS. For example, MSD is part of the Reproductive Health Supplies Coalition's Global Family Planning Visibility and Analytics Network (GFP-VAN). GFP-VAN collects data from multiple sources, allowing procurers of reproductive health supplies to have visibility across the supply chain and prevent stockouts.

One of the three health system strengthening initiatives included for analysis meets all GPS. MSD for Mothers is MSD's global initiative to prepare a buffer stock of relevant, finished products.

MSD does not disclose, publicly or to the Index, evidence of a policy for reporting substandard and falsified medicines in countries in scope to national or local regulatory authorities. However, it publicly discloses having a global product integrity strategy on tackling counterfeit products, and reports that it responds in alignment with local regulatory requirements.

No evidence of inclusive business models that meet inclusion criteria. However, MSD engages in initiatives that address access needs of neglected populations. The company is partnering with mPharma on their model in Nigeria and Ghana to expand access to testing for human papillomavirus (HPV) and increase access to HPV vaccinations. MSD and mPharma developed new financing options that aim to limit costs of vaccination.

agreements. MSD supplies 2 of its products, indicated for HIV and COVID-19, via different procurers, including The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), UNICEF and the US President's Emergency Plan for AIDS Relief (PEPFAR). In addition to supranational agreements, MSD has non-exclusive voluntary licensing agreements for these products to enable generic supply. The company supplies its HPV vaccine Gardasil®4 via Gavi, the Vaccine Alliance. The fourth product, its Ebola virus vaccine (Ervebo®), is supplied through UNICEF, which has created a stockpile of 500,000 doses for outbreak response.

No evidence of access strategies for its health care practitioner (HCP)-administered products. MSD has not disclosed, either publicly or to the Index, access strategies for any of the 5 products assessed by the Index in this category. The products selected include oncology medicines,

vent maternal deaths through maternity care and contraception. As of 2024, the initiative reached more than 30mn women through a range of programmes focused on improving the quality of maternity care.

antibiotics and a 9-valent HPV vaccine.

No evidence of access strategies for its self-administered products. MSD has not disclosed, either publicly or to the Index, access strategies for any of the 4 products assessed by the Index in this category. The products are indicated for dia

MSD newly engaged in 1 IP-sharing agreement with a drug discovery initiative to acceler ate drug development. In this agreement, the

betes and HIV.

company has granted Gates Medical Research

Institute an exclusive global licence for MK-7762

MSD publicly commits not to file for or enforce patents for all products in all LICs in scope.

and MK-3854 to support clinical and non-clinical research to discover new affordable treatment regimens for TB. MSD also remains engaged in an existing agreement.

Publicly discloses product patent status for countries in scope. Like most peers, MSD publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction. Additionally, on its website, MSD discloses patent numbers for countries in scope for some of

Fulfils all criteria for ad hoc donations. MSD has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure dona tions reach patients. Additionally, the company publicly commits to adhering to the most recent its products.		WHO Guidelines for Medicine Donations.

MSD has 2 non-exclusive voluntary licensing agreements to enable generic supply. One of the licensing agreements is for raltegravir for pae diatric use, indicated for HIV, which covers 89 countries in scope and was issued in 2015. The

MSD publicly commits to continuing long-term donation programmes to support the elimina tion of onchocerciasis, lymphatic filariasis and rabies. One of its programmes is active in 27 countries in scope, with the company pledging to

RANK	SCORE
7	3.27

5 (2022)

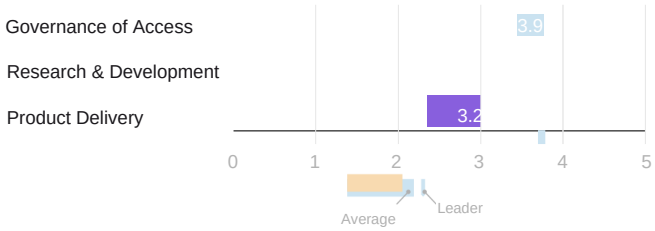
Merck KGaA

Stock exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 62,908

PERFORMANCE IN THE 2024 INDEX

7th place. Merck ranks in the top ten and performs above average in all three Technical Areas. It commits to continue its long-term donation programme to support the elimination of schistosomiasis. In Research & Development, it has access plans in place for all of its projects.

How score was achieved



OPPORTUNITIES FOR MERCK

Improve the quality and broaden the geographic reach of access plans for cancer projects. Merck has access plans in place for all late-stage R&D candidates. Currently, its access plans for oncology projects focus on registration preparation in an average of six countries in scope. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus on more low- and lower-middle income countries.

Expand access to innovative oncology products. Merck has access strategies in place for most of its innovative oncology medicines, but these are limited in geographic reach. It can increase access to key cancer medicines, such as tepotinib (Tepmetko®), indicated for lung cancer, and avelumab
(Bavencio®), indicated for bladder cancer, through increasing registration and/or engaging in equitable access strategies.

Support local availability through its supply chain model and report outcomes. In 2023 Merck launched its ‘Go-to-Market' model which aims to address distribution of the company’s products in 21 African countries through building regional stocks and conducting supply chain knowledge transfer. Merck can build manufacturing capacity in these countries by engaging, for example, in technology transfer initiatives with local manufacturers and offering technical or financial support. The company can also provide detailed reporting on outcome measurements and the sustainability of its model.

CHANGES SINCE THE 2022 INDEX

• Since 2022, Merck's access-to-medicine strategy now covers all therapeutic areas the

• Arpraziquantel was added to the World Health Organization (WHO)'s List of Prequalified company is involved in.

Medicines.

• Opened a EUR 20mn distribution centre in Brazil to serve its customers in the region.• Received a positive scientific opinion for arpraziquantel from the Committee for

- In 2023, Merck launched its ‘Go-to-Market' model, which aims to address distribution of the company’s products in 21 African countries through building regional stocks and supply chain knowledge transfer.

Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). EMA assessed arpraziquantel under the EU-M4all procedure for high-priority medicines intended

- Expanded its collaboration with Biocartis, improving patient access to RAS biomarker testing in the Middle East and North Africa for use in countries outside the EU. region.

Merck KGaA

SALES AND OPERATIONS

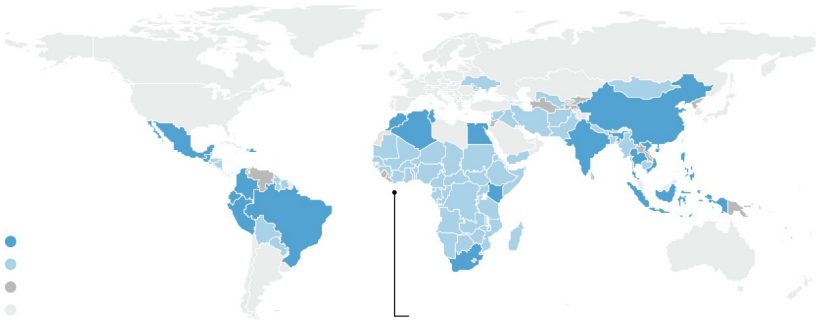
Therapeutic areas: Cardiovascular, fertility, metabolism & endocrinology, neurology & immunology, oncology

Product categories: Diagnostics, innovative medicines, medical devices

M&A news: Merck acquired M Chemicals Inc. for EUR 110mn in 2023.

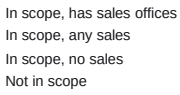
Net sales by segment (2023) – in EUR

Life sciences	9.28 bn
Healthcare	8.05 bn
Electronics	3.66 bn



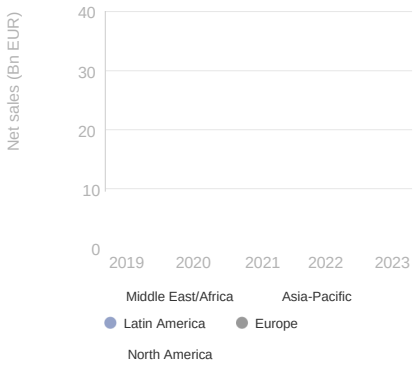
Total	20.99 bn

Sales in countries in scope



Merck's products are sold in 88 out of 113 countries in scope of the Index. Merck has sales offices in 19 countries and sells via suppliers and/or pooled procurement in an additional 69 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

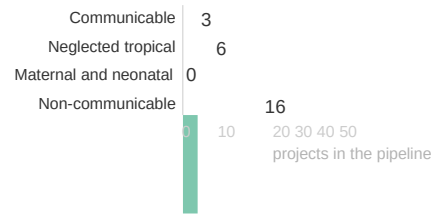
Merck has 25 R&D projects in scope, 9 of which target priority diseases, focusing on schistosomiasis (6) and malaria (3). The remaining 16 projects target other diseases in scope, namely cancer. Of the 25 R&D projects, 6 are in late-stage development, with evidence of access planning for 100%

PORTFOLIO *as selected for analysis by the Index*

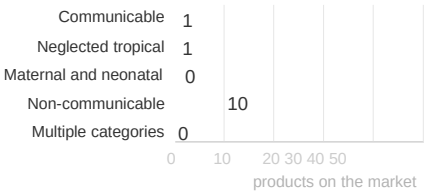
Merck has 12 products in scope, including 11 medicines; 3 of the medicines are listed on the WHO EML and 2 are on patent. In addition, the company markets one diagnostic for HIV, which is listed on the WHO EDL. Most of Merck's medicines treat non-communicable diseases, including cardiovascular diseases (4), cancer (3) and diabetes (3). In addition, it also has 1 medicine targeting neglected tropical diseases.

(6/6) of these.

25 projects in the pipeline



12 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	2	2	1	1	0	0	2	1	9
with access plan				1	0	0	2		3
Other projects in scope			11	2	1	0	0	2	16
with access plan				2	1	0	0		3

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	0	2		2
off patent	3	6		
Vaccines	0	0		9
Contraceptives	0	0		
Diagnostics			1	0
Other			0	

Merck KGaA

GOVERNANCE OF ACCESS

RANK 11 SCORE 3.92

11th place. Merck performs above average in this Technical Area. The company provides evidence of a patient reach process that covers most products and countries in scope of the Index, and has a measurable patient reach goal. However, it does not provide the underlying methodology details publicly. Further, Merck only publicly discloses information on transfers of value to healthcare professionals in countries in scope of the Index if required by law or local regulation.

The highest responsibility for access lies directly with the CEO of Healthcare at Merck, who manages Global Health on behalf of the Executive Board. Merck has financial and non-financial access-related incentives at the executive level. It has a Long-Term Incentive Plan (LTIP) in place for the CEO, senior executives, and regional managers, which includes three sustainability indicators. One of these refers to the number of people treated with Merck's products.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Merck publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Sustainability Report.

Shows comparatively moderate-level commitment to responsible business practices. Merck's sales agents are not solely incentivised on sales volume. It reports using a balanced score card approach to incentivise sales agents. Merck commits to transparency in its cooperation with healthcare professionals in its code of conduct and has a public position on responsible interactions with health systems. However, it discloses to the Index, but not publicly, the legitimate need for interactions with healthcare professionals and the limits on transfers of value to them. Further, it only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Merck lacks a framework, but its code of conduct guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Merck publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Merck states that compulsory licensing risks undermining innovation.

Fulfils some criteria across three processes for measuring and reporting patient reach. For its healthcare portfolio process, which covers most of its products and most countries in scope of the Index, Merck provided details of the methodology elements under an NDA. The resulting patient reach numbers are published, but as 2023 was the first year of reporting, no improvements could be demonstrated. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 6 SCORE 2.97

6th place. Merck performs above average in this Technical Area. The company's pipeline has both priority and non-communicable disease (NCD) projects, although the number of projects has declined. It has an access planning framework in place and publicly commits to access planning from Phase II onwards, applying this to all late-stage candidates. However, access plans for NCD projects focus mostly on registration preparation in emerging markets. Merck does not publicly disclose disaggregated R&D investment data, but it does perform strongly in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public mitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place dates targeting a priority product gap, all (100%) have evidence of an access plan in place, mostly focusing on supply and demand plans, WHO prequalification and registration preparation.

Small-sized pipeline, compared to peers, addressing other diseases in scope, with 100% for 100% (3/3) of the late-stage candidates. Priority R&D pipeline of 9 projects, including 3 late-stage projects that target a priority gap. The company focuses on schistosomiasis and malaria

Merck does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.
However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is an initiative through which Merck partners to train young scientists from LMICs through an online platform in, among others, drug discovery and development sciences.

(3/3) of late-stage projects covered by access plans. Merck has 3 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. All 3 projects target cancer and have evidence of access plans, including registration as priority areas. Of Merck's 3 late-stage candi preparation.

Merck KGaA

PRODUCT DELIVERY

RANK 9 SCORE 3.25

9th place. Merck performs above average in this Technical Area. The company has access strategies in place for its products and reports some data on their outcomes. However, strategies are mostly in upper-middle and lower-middle-income countries. It engages in some capacity building initiatives that meet all Good Practice Standards. However, it engages in fewer intellectual property sharing agreements compared with the last Index.

Merck registers products in 30 countries in scope on average. For the 1 newer product* analysed, it registers in 5 countries in scope, and it registers 78% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's bisoprolol (Concor®/Concor® COR), indicated for cardiovascular diseases such as hypertension, angina and arrythmia, is most widely registered, totalling 67 countries in scope. The company reports engaging in mechanisms to facilitate registration, for example, through the European Medicines Agency EU-M4all (former Article 58).

Merck is not eligible for assessment of supra tial pricing. For its oncology product, tepotinib (Tepmetko®), Merck has implemented a patient access programme (PAP) for self-paying patients in India (LMIC), where it also subsidises testing to support screening and early diagnosis. For the other examples assessed, additional strategies are more limited. The company has goals to increase access and affordability of all its products, and, in some cases, it shares plans to progress the strategy. For almost all products analysed, Merck provides evidence of patient reach. For tepotinib (Tepmetko®), the company also monitors and shares data on duration of treatment via its PAP

All 3 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Merck supported the Indian employees state insurance company and India Railways to increase awareness, early detection and treatment head and neck cancer. Merck educated 1,500 healthcare professionals and reached over 1mn through public awareness campaigns.

Merck newly engaged in 2 IP-sharing agreements with public research institutions to accelerate drug development. In 1 agreement, the company shares the Merck Mini Library with the University of Aberwysth to accelerate research for leishmaniasis. The company also remains engaged in existing agreements.

Fulfils all criteria for ad hoc donations. Merck has public policies and supply processes to

in India, to monitor patient adherence.

national access strategies because it has no products in scope that are supranationally procured.

Access strategies for healthcare practitioner (HCP)-administered products, with outcomes mostly tracked and shared. Merck provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC), for 1 of the 2 oncology medicines assessed, cetuximab (Erbitux®). The company demonstrates some efforts in considering payers' ability to pay in its strategies, such as implementing affordability-based patient support programmes. Merck also reports some health system strengthening initiatives. For example, in Egypt (LMIC), it provides support for improving diagnosis and treatment outcomes of colorectal cancer through molecular testing and education programs for HCPs. For all strategies analysed, the company has goals to increase access to its products and provides evidence of increasing patient reach. Merck also shows efforts in improving and monitoring patient adherence to treatment. For example, for its product avelumab (Bavencio®), it monitors duration of treatment through its patient access programme in India (LMIC) and provides evidence of increased adherence following the implementation of the programme.

Quality of access strategies for self-administered products varies across products and countries, supported by some information on outcomes. For 2 of the 5 products selected for analysis, Merck provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). The company demonstrates efforts in considering the different payers' ability to pay in its pricing strategies and applying differen

carry out ad hoc donations rapidly in response

Merck publicly commits not to file for or enforce patents for all products in 90 countries in scope. This includes all least developed countries and LICs, as well as many LMICs and UMICs. The list of countries to which the commitment applies is publicly available.

Publicly discloses product patent status for countries in scope. Merck publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction. Additionally, Merck discloses the type of patents and their expiry dates in countries in scope on its website, for a subset of products in scope.

Merck does not engage in non-exclusive voluntary licensing for products in scope.

Three of the four manufacturing capacity building initiatives included for analysis meet all GPS. For example, Merck transferred technology for formulation, fill and finish and packaging of metformin (Glucophage®) between two contract manufacturing organisations in China. Merck reports it will transfer specific manufacturing skills for the diabetes treatment as well as specifics of quality and Good Manufacturing Practice.

Three of the four supply chain capacity building initiatives included for analysis meet all GPS. For example, Merck supports Business for Health Solutions in an initiative aiming to improve access to quality-assured healthcare products for 1.2mn beneficiaries in 10 countries. The initiative will focus on building supply chain skills of employees in 4 to 6 West African health care enterprises.

ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Merck publicly commits to continue long-term donation programme to support the elimination of schistosomiasis. Its programme is active in 45 countries in scope, with the company pledging to donate praziquantel (Cesol®) until schistosomiasis is eliminated as a public health problem.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Merck is using its 'go-to-market' model to improve distribution of products in 21 countries in scope (e.g., Ethiopia, Uganda). By building warehouses in Kenya and Botswana, Merck aims to reduce time to supply products and is considering local manufacturing capacity.

Merck has a policy for reporting substandard and falsified medicines in countries in scope. It provides evidence of reporting cases to national or local regulatory authorities within 10 days, and of reporting to WHO Rapid Alert if required. When authorities request a visual assessment of an obvious counterfeit product (e.g., obvious artwork errors or a non-existing batch number), Merck commits to provide conclusions of the assessment to the relevant regulatory authorities in less than 10 days.

No evidence of inclusive business models that meet inclusion criteria. However, Merck engages in initiatives that address access needs of neglected populations. For example, Merck is partnering with Axios International to improve access to bladder cancer treatment avelumab (Bavencio®) for low-income populations in Egypt.

*Products that received their first marketing authorisation within the last 5 years.

RANK	SCORE
1	3.78

4 (2022)

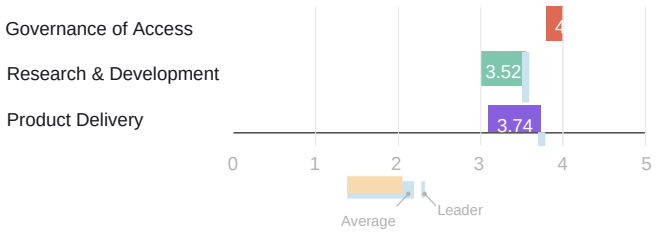
Novartis AG

Stock exchange: SWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 78,407

PERFORMANCE IN THE 2024 INDEX

1st place. Novartis is a leading company and is a top performer in the Governance of Access and Research & Development Technical Areas. It also performs strongly in Product Delivery and demonstrates Best Practices in both Research & Development and Product Delivery.

How score was achieved



OPPORTUNITIES FOR NOVARTIS

Improve the quality and broaden the geographic reach of access plans. Novartis has access plans for almost all of its late-stage projects. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus on more low- and lower-middle-income countries. For example, the access plan for EYU688, a project currently in

Expand access to innovative products. Novartis has demonstrated implementing access strategies across different income country classifications. It can continue to expand access by implementing equitable access strategies particularly in low-income countries. For example, for its innovative products ribociclib (Kisqali®), indicated for breast cancer, and inclisiran (Leqvio®), indicated for cardiovascular

Phase II for dengue, can be expanded to include more than diseases. three countries in scope.

Expand technology transfer initiatives for its products to additional countries. Novartis launched three technology transfer initiatives in 2023 and 2024 for its diabetes, epilepsy and cardiovascular disease treatments vildagliptin (Galvus®), vildagliptin/metformin (GalvusMet®), carbamazepine (Tegretol®) and amlodipine/valsartan (Exforge®). The

Publicly report on the progress and outcomes of the Sub- company can engage in additional technology transfer efforts for cardiovascular disease products in more countries, including those in sub-Saharan Africa.

CHANGES SINCE THE 2022 INDEX

Saharan Africa Business Unit. Novartis launched its inclusive business model in 2019, aiming to broaden patient reach and availability of its medicine portfolio, including 12 products in scope across 44 countries in scope. However, there is limited public information on where the products included in the model are available and how many patients the model has reached. The company can continue expanding access in these countries and report on where its products are supplied and the number of patients reached.

- Completed a 100% spin-off of its generics and biosimilars division, Sandoz, in October 2023 and merged its Pharmaceutical and Oncology business units into an Innovative Medicines unit.
- Refined its framework for equitable access to ensure continued commitment and guidance to global and local teams following the Sandoz spin-off.
- Established regular assessments of climate scenarios and the potential rise of climate-sensitive diseases (e.g., malaria, dengue, cardiovascular conditions), to inform its portfolio strategy.
- Collaborated with strategic diagnostic partners, such as PerkinElmer (Revvity), to address unmet needs of Sickle Cell Disease in sub-Saharan Africa.
- Progressed into Phase II clinical trial for an oral drug against visceral leishmaniasis in Ethiopia, together with the Drugs for Neglected Diseases initiative (DNDi).
- Announced move to Phase III study for novel ganaplacide/ lumefantrine-SDF combination in adults and children with malaria, together with Medicines for Malaria Venture.
- Signed a perpetual license agreement with Cipla to grant permission to manufacture and market its diabetes drug vildagliptin (Galvus®) and its combination brands from 1 January 2026.
- Partnered with Vision Catalyst Fund and Clinton Health Access Initiative (CHAI), Cambodia in 2023 to increase access to treatment for people living with diabetes, hypertension and eye diseases in Cambodia.
- Partnered with the General Authority for Health Insurance Mongolia, the Oddariya Foundation and Health for All to address service delivery and disease management for hypertension, diabetes and dyslipidemia at primary and secondary care levels.
- Updated its position on intellectual property (IP), which now declares support for the Doha declaration on TRIPS and Public Health.
- In August 2024, after the period of analysis, Novartis entered into an IP sharing agreement with The Kids Research Institute Australia, an Australian research institute, to accelerate development of patient-centric formulations to treat bacterial diseases in underprivileged paediatric populations.

Novartis AG

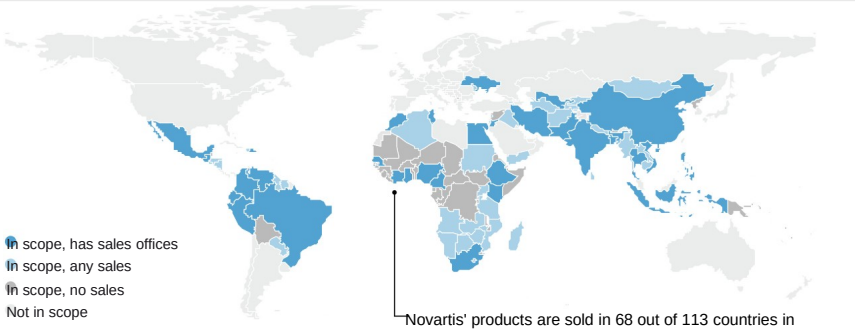
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, immunology, neuroscience, oncology, renal & metabolic
Product categories: Innovative medicines
M&A news: Novartis acquired Kedalion Therapeutics for an undisclosed amount in 2022. In 2023, it acquired DTx Pharma for USD 500mn and Chinook Therapeutics for USD 3.5bn, and divested its CGT CDMO CELLforCure to Seqens for an undisclosed amount. In 2024 it acquired Calypso Biotech for USD 425mn; SanReno Therapeutics for an undisclosed amount; IFM Due for USD 835mn; and MorphoSys AG for USD 2.89bn.

Net sales by segment (2023) – in USD

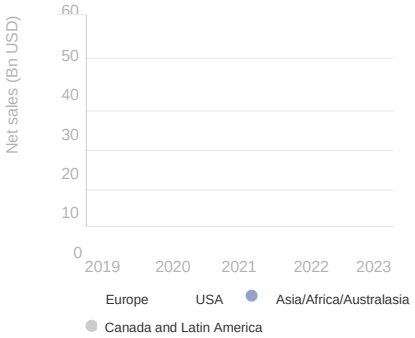
Promoted brands	31.82 bn
Established brands	13.62 bn
Total	45.44 bn

Sales in countries in scope



Novartis' products are sold in 68 out of 113 countries in scope of the Index. Novartis has sales offices in 32 countries and sells via suppliers and/or pooled procurement iin an addi tional 36 countries.

Sales by geographic region*

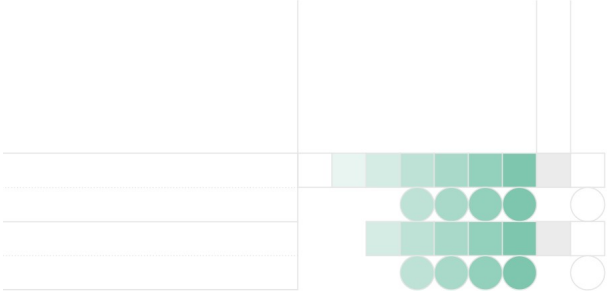


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

Novartis has 61 R&D projects in scope, 27 of which target priority diseases, focusing on malaria (10), Chagas disease (5) and dengue (5).

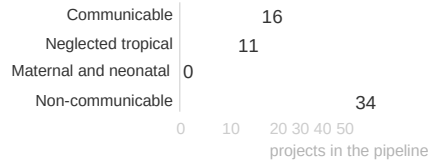
The remaining 34 projects target other diseases in scope, including cancer (15), cardiovascular diseases (9) and kidney diseases (4). Of the 61 R&D projects, 25 are in late-stage development, with evidence of access planning for 96% (24/25) of these.



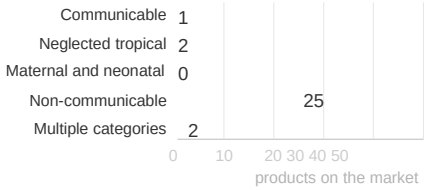
PORTFOLIO *as selected for analysis by the Index*

Novartis has 30 medicines in scope, 11 of which are listed on the WHO EML and 21 are on patent. Its medicines target mostly non-communicable diseases (25), including cancer (11), asthma and COPD (6) and cardiovascular diseases (4). It has 1 medicine for the communicable disease, malaria (1), and some medicines for neglected tropical diseases, such as leprosy (1), food-borne trematodiases (1), and 1 for both leprosy and TB (1). In addition, Novartis has 1 medicine indicated for both pregnancy hypertensive disorders and cardiovascular diseases.

61 projects in the pipeline



30 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	11	4	3	6	1	1	1	0	27
with access plan				6	1	1	1		9
Other projects in scope			18	7	9	0	0	0	34
with access plan				6	9	0	0		15

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	3	18			21
off patent	8	1			9
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

*Sales between 2019 and 2022 include Novartis' generic portfolio, Sandoz.

Novartis AG

GOVERNANCE OF ACCESS RANK 1 SCORE 4.44

1st place. Novartis leads in this Technical Area, showing a significant improvement since the last Index. It updated its intellectual property statement to express support for the Doha Declaration on TRIPS and Public Health. Further, the company provides evidence of a patient reach process that covers all products and countries in scope of the Index, as well as public reporting of the underlying methodology and resulting patient reach numbers.

The highest responsibility for access lies directly with the Board, namely with the Governance, Sustainability and Nomination Committee. Novartis incentivises its senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. The CEO and Executive Committee have long-term access-related incentives included in their performance targets.

Shows comparatively strong commitment to responsible business practices. Novartis sets individual-level targets for sales agents, but incentives are not solely based on sales volume. It also assesses whether performance is aligned with the company's Code of Ethics and Values & Behaviors. Novartis has a public policy on ensuring ethical interactions with healthcare professionals. Further, with company standards, fraud-specific risk assessments and region or country risk-based assessments. Novartis also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Novartis publicly supports the Doha Declaration on TRIPS and Public Health. The company emphasises the balances and flexibilities embedded in the agreement and states that compulsory licensing should be used in limited, exceptional circumstances for which it was designed.

it declares that transfers of value for healthcare professionals (e.g., payments for consulting) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novartis performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance

Fulfils most criteria across 4 processes for measuring and reporting patient reach. For its innovative medicines sustainability-linked bond process, which covers some of its products and all countries (where the company operates) in scope of the Index, Novartis publicly provides the underlying equation, metrics and assumptions. The resulting patient reach numbers are published regularly and demonstrate improvements. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy, embedded in its Novartis Access Principles, covers all therapeutic areas in which the company is involved. Novartis publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regularly in its Integrated Report.

RESEARCH & DEVELOPMENT

RANK 1 SCORE 3.52

1st place. Novartis leads in this Technical Area. It has a mixed pipeline including non-communicable diseases and priority diseases, with access plans in place for almost all its late-stage pipeline candidates. It demonstrates Best Practice for its malaria access plans and, on average, has access plans with greater depth and breadth compared to peers. It performs strongly in its R&D capacity building activities, and publicly discloses disaggregated R&D investment data by phase of development and for priority neglected diseases.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Large-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (9/9) of the late-stage candidates. Priority R&D pipeline of 27 projects, including 9 late-stage projects that target a priority gap. The company focuses on various priority areas, including malaria, Chagas disease and dengue. All of Novartis's 9 late-stage candidates targeting a priority product gap have evidence of an access plan in place, mostly focusing on registration preparation, equitable pricing and WHO prequalification.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 94% (15/16) of late-stage projects covered by access plans. The company has 16 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, cardiovascular diseases and kidney diseases. Novartis provides evidence of access plans for 15 of its 16 late-stage projects, mostly focusing on post-trial access, registration preparation and the inclusion of special populations in clinical trials.

Novartis publicly discloses disaggregated R&D investment data for malaria and phase of development (Phase I/II vs Phase II/III). It also discloses anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is Speaking Books, an initiative that aims to increase patients' willingness to participate in clinical trials by improving their understanding of trials.

PRODUCT DELIVERY

RANK 2 SCORE 3.74

2nd place. Novartis performs strongly in this Technical Area. It demonstrates Best Practice by registering innovative products widely in LMICs and operating an inclusive business model to improve access to its products in multiple low-income and least developed countries. It implements access strategies for which it demonstrates Best Practice in reporting outcomes. It has also launched plans for some products to increase low-income countries coverage. Novartis engaged in a new non-exclusive voluntary licensing agreement for one compound during the period of analysis.

Novartis registers newer products* in 23 countries in scope on average. It registers 80% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's sacubitril/valsartan (Entresto™), indicated for heart failure, is most widely

*Products that received their first marketing authorisation within the last 5 years.

Novartis AG

registered, totalling 50 countries. The company reports engaging in various mechanisms to facili tate the registration of multiple products.

Supplies 2 products in scope through suprana tional agreements. Novartis supplies its malaria treatment, artemether/lumefantrine (Riamet®/ Coartem®), via The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and clo fazimine (Lamprene®) for MDR-TB via the Global Drug Facility. For both products, the company demonstrates access strategies for at least 1 coun try not eligible for such supply. For example, the company offers the same price in South Africa for clofazimine as it does in Global Fund-eligible coun tries. Novartis provides patient reach data for all its strategies. For example, in Angola, a non-eli gible country, 3,204,555 patients have received artemether/lumefantrine in the public sector in the period from May 2022 to February 2024.

launch in an LIC in Africa soon. In addition, a sec ond brand for ribociclib (Kisqali®), indicated for breast cancer, has been supplied in India, with plans for launch in several LICs. Most pricing strat egies analysed are complemented by additional strategies, such as patient support programmes, that target out-of-pocket payments or other bar riers to treatment, such as screening, patient follow-up and adherence. For most of the prod ucts assessed, the company has goals to increase access to its products and patient reach. It pro vides evidence of increasing patients reached via its strategies, supported by some information on the approaches applied to measure outcomes.

Novartis publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all least developed countries and LICs, over half of UMICs

in urban environments by supporting local stake holders to roll out a set of health interventions. The interventions are tailored to the local context and can include, for example, clinical decision sup port tools and data collection. This CARDIO4Cities approach is actively scaling in Brazil to more municipalities, is transitioning to government ownership in Senegal, and has transitioned to gov ernment ownership in Mongolia. It is now being scaled to additional countries, such as Rwanda.

Novartis remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In 1 agreement, in collaboration with the Wellcome Trust, Novartis has shared IP assets aiming to discover treatments for Chagas disease. However, the company has not engaged in new agreements during the period of analysis.

and most LMICs. However, the list of countries to which this commitment applies is not publicly available.

Publicly discloses product patent status for countries in scope. Novartis publicly discloses patent information for all small molecules via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Novartis has 1 non-exclusive voluntary licensing agreement to enable generic supply of nilotinib, indicated for chronic myeloid leukaemia. The licence was issued in October 2022, shortly before the expiration of the primary patent, and covers 43 countries in scope. It is the first non-exclusive voluntary licence for a non-communicable disease.

Access strategies for its healthcare practitioner (HCP)-administered products in some countries, supported by information on outcomes. For the 2 products selected for analysis, Novartis provides access strategy examples in UMICs and LMICs that show some efforts in improving affordability and availability. For example, in Brazil (UMIC), the company launched a second brand of its product inclisiran (Leqvio®), indicated for atherosclerotic cardiovascular disease (ASCVD), and plans to launch the second brand also in an LIC. Pricing strategies are complemented by additional strategies and health system strengthening initiatives. For inclisiran, the company has a comprehensive approach in Egypt (LMIC), including microfinancing solutions, to support out-of-pocket expenses,

Fulfils all criteria for ad hoc donations. Novartis has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Novartis publicly commits to continuing long-term donation programmes to support the elimination of leprosy and control the outbreak of food-borne trematodiases. One of its programmes is active in approximately 80 countries in scope, with the company pledging to donate the combination of clofazimine (Lamprene®), dapsone (Dapsone®) and rifampicin (Rimactane®) through 2025 to help eliminate leprosy.

capacity building and public-private partnerships to strengthen healthcare systems and improve

ASCVD patient reach. Whereas for its asthma product, omalizumab (Xolair®), the company launched patient support programmes in Egypt to cover the costs of IgE testing and administration. The company has goals to increase access and advance its strategies. Novartis shares reach data, with evidence of increasing reach, ported by information on the approaches used to track the strategies' outcomes.

Access strategies for most self-administered products, supported by information on outcomes. For 3 of the 5 products selected for analysis, Novartis has implemented access strategies in all 3 country income classifications (UMIC, LMIC, LIC). The remaining 2 products have strategies in UMICs and LMICs, with launches planned in LICs. In all the strategies analysed, the company demonstrates efforts to consider different payers' ability to pay, aiming to improve the affordability of its products. For example, in India (LMIC) and South Africa (UMIC), a second brand of erenumab-aooe (Aimovig®), indicated for migraine, was launched with a reduced price compared to the original global brand; it will also

None of the 3 manufacturing capacity building initiatives included for analysis meet all GPS. Despite not meeting all GPS, in 1 initiative, Novartis is transferring technology to Moroccan manufacturer Sothema to fully produce diabetes treatment vildagliptin (Galvus® 50mg) and conduct primary and secondary packaging for epilepsy treatment (Tegretol® CR 200mg & 400mg). Novartis will support Sothema to improve the level of Good Manufacturing Practice compliance to supply to the local market.

Three of the four supply chain capacity building initiatives included for analysis meet all GPS. For example, Novartis developed Authentifield, a testing device that aims to reduce the time needed to detect and report falsified medicines. The devices have been deployed to 70 countries, 24 of which are in scope. Novartis is exploring the feasibility of empowering external stakeholders with the solution in the long term.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Novartis aims to reduce cardiovascular risks

tinuous supply in LMICs. For example, Novartis is transferring technology to Indian manufacturer Medreich for primary and secondary packaging of the diabetes treatment vildagliptin/metformin chlorydrate (GalvusMet FCT).

Novartis has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to both national or local regulatory authorities and the WHO within 7 days. The policy classifies incidents into categories according to the impact or potential impact and degree of severity, which may enable faster action.

Novartis operates an inclusive business model that covers 19** products in 46*** countries, including 30 low-income and least developed countries. Launched in 2019, the sub-Saharan Africa Unit currently offers medicines for indications, such as cardiovascular disease, sickle cell, neurology, malaria and diabetes†. The model addresses affordability (e.g., through second brands, social business), healthcare professional training, and health system strengthening through partnerships.

**12 in scope.
***44 in scope.

†On 4 October 2023, Novartis completed its spin-off of Sandoz, transferring its generic portfolio to the newly independent company.

RANK	SCORE
12	2.88
11 (2022)	

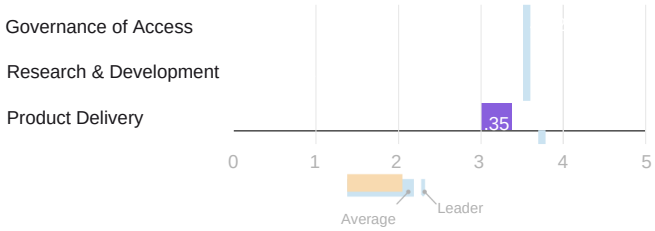
Novo Nordisk A/S

Stock exchange: Nasdaq Copenhagen • Ticker: NOVO-B • HQ: Bagsværd, Denmark • Employees: 64,319

PERFORMANCE IN THE 2024 INDEX

12th place. Novo Nordisk is a middle-performing company. It has an above average performance in Governance of Access and Product Delivery, where it demonstrates Best Practice for its inclusive business model, but performs comparatively poorly in Research & Development.

How score was achieved



OPPORTUNITIES FOR NOVO NORDISK

Improve the quality and broaden the geographic reach of access plans. Novo Nordisk has access plans for half of its late-stage R&D candidates. However, these plans predominantly focus on registering in a limited number of upper-middle-income countries and emerging markets. It can enhance these plans by considering more access provisions such as affordability and expand them to include more low- and middle-income countries within scope. For example, it can improve its access plan for CagriSema, a once-weekly

Expand access to analogue insulins listed in the WHO Model List of Essential Medicines. Novo Nordisk has comprehensive access strategies for its human insulins – Mixtard®, Actrapid®, Insulatard® – in countries in scope, whereas access strategies for its analogue insulin Tresiba® are more limited. Through increasing registrations and implementing equitable pricing strategies in more countries in scope of the Index, the company can bridge this gap and ensure that analogue insulins are as accessible as human insulins to diabetes treatment for type 2 diabetes currently in Phase II of clinical trials, by expanding it beyond registration preparation in six countries in scope.

Expand technology transfer agreements for insulin products. In 2022, Novo Nordisk signed a technology transfer agreement with Aspen in South Africa to manufacture and supply its human insulin. The company can expand partnerships with more manufacturers in LMICs to build manufacturing capacity and improve availability of insulin products, including essential analogue insulins.

CHANGES SINCE THE 2022 INDEX

Increase frequency of public reporting on progress and outcomes of its inclusive business model. iCARE was launched in 2021, aiming to improve access to diabetes products in 49 countries in Africa. Novo Nordisk reported on the list of countries where the model is active as well as the patient reach for 2023. Continuing to publicly report on country implementation and patient reach, and doing so frequently, can drive accountability and implementation. It can also help foster further partnerships and expand the model in further countries within iCARE's scope.

- In 2023, Novo Nordisk entered a
- In June 2024, Novo Nordisk became a manufacturing partnership with Aspen to improve availability and affordability of human

member company of Access Accelerated, a cross-industry collaboration that seeks to reduce barriers to prevention, treatment and insulin on the African continent.

• In August 2023, Novo Nordisk acquired Inversago Pharma, extending the company's

care for non-communicable diseases in LMICs.
Access Accelerated focuses specifically on pipeline for obesity and metabolic disorders.

NCD financing.

- Received approval for its once-weekly basal insulin icodec (Awiqli®) from the European Medicines Agency, Canada, Australia, Japan and Switzerland for type 1 and type 2 diabetes,

- Since June 2022, the Changing Diabetes in Children programme expanded to an additional seven countries: Columbia, Malaysia, Morocco, Nigeria, the Philippines, Tunisia and Vietnam.

and for type 2 from China.

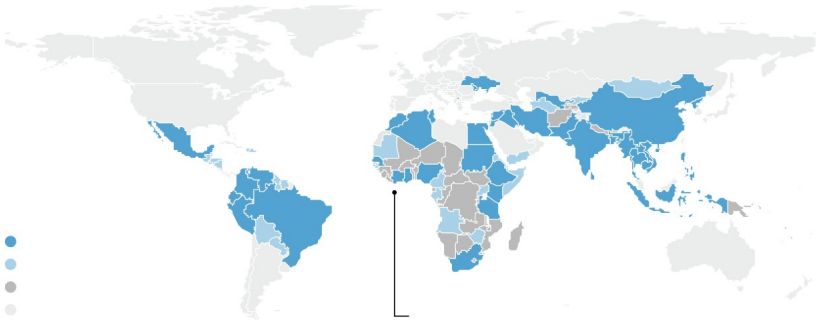
Novo Nordisk A/S

SALES AND OPERATIONS

Therapeutic areas: Biopharmaceuticals, diabetes, obesity, other serious chronic diseases
Product categories: Innovative medicines
M&A news: Novo Nordisk acquired Forma Therapeutics Holding Inc. for USD 1.1bn in 2022. Inversago Pharma for USD 1.1bn; Embark Biotech for USD 496mn; Paratek Pharmaceuticals for USD 462mn. In 2023, it acquired Biocorp for USD 165mn;

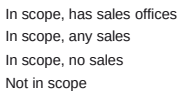
Net sales by segment (2023) – in DKK

Diabetes and obesity care	215.10
Rare diseases	17.16



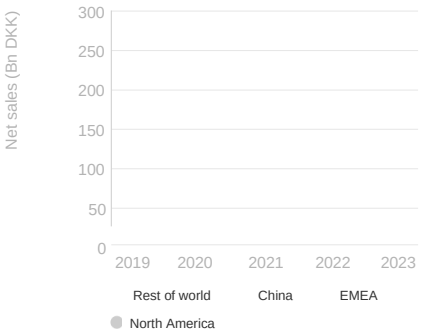
Total	232.26 bn

Sales in countries in scope



Novo Nordisk's products are sold in 69 out of 113 countries in scope of the Index. Novo Nordisk has sales offices in 41 countries and sells via suppliers and/or pooled procurement in an additional 28 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

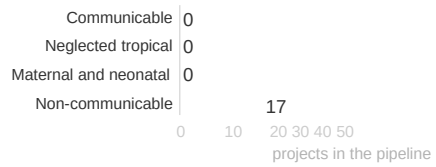
PIPELINE *for diseases in scope*

Novo Nordisk has 17 R&D projects in scope, none of which target priority diseases. All 17 projects target other diseases in scope, including diabetes mellitus (8), cardiovascular diseases (4) and sickle cell disease (2). Of the 17 R&D projects, 12 are in late-stage development, with evidence of access planning for 50% (6/12) of these.

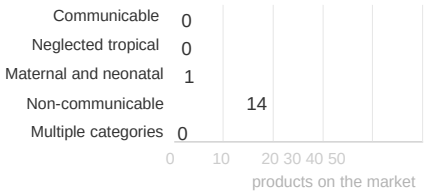
PORTFOLIO *as selected for analysis by the Index*

Novo Nordisk has 15 medicines in scope, 5 of which are listed on the WHO EML, and 9 are on patent. The company's medicines mainly target non-communicable diseases and are indicated for the treatment of diabetes (14). It has 1 medicine indicated for maternal haemorrhage.

17 projects in the pipeline



15 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	0	0	0	0	0	0
with access plan			0	0	0	0		0
Other projects in scope		5	5	6	0	1	0	17
with access plan			1	4	0	1		6

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	1	8			9
off patent	4	2			
Vaccines	0	0			6
Contraceptives	0	0			
Diagnostics			0		0
Other				0	

Novo Nordisk A/S

GOVERNANCE OF ACCESS RANK 8 SCORE 4.12

8th place. Novo Nordisk performs above average in this Technical Area. The company has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as well as direct board-level responsibility for access. Further, Novo Nordisk has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies directly with the Board, namely with the CEO, under the supervision of the Board of Directors. Novo Nordisk has financial and non-financial access-related incentives at the executive level. It also incentivises its in-country leaders to act on its social sustainability objectives. The CEO has access-related incentives, linked to long-term social targets.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Novo Nordisk publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Annual Report.

incentives are not solely based on sales volume. The company's incentive compensation plan includes guardrails, like limiting the proportion of the incentive plan that can be allocated to sales targets in specific therapeutic areas. The company commits to ensuring ethical interactions with healthcare professionals in its code of conduct. Further, it reports that transfers of value for healthcare professionals (e.g., payments for consulting) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novo Nordisk performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes

Shows comparatively strong commitment to responsible business practices. Novo Nordisk sets individual-level targets for sales agents, but has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Novo Nordisk does not publicly share explicit support for the Doha Declaration on TRIPS and Public Health. However, the company publicly states that health emergencies requiring exceptions to intellectual property rights can and should be accommodated under the international legal framework and under extraordinary circumstances. Further, it does not support the routine use of compulsory licensing.

Fulfils some criteria across 4 processes for measuring and reporting patient reach. For its diabetes care products process, which covers most of its products and most countries in scope of the Index, Novo Nordisk publicly provides the underlying equation, metrics, assumptions and limitations. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. It also

RESEARCH & DEVELOPMENT

RANK 18 SCORE 1.38

18th place. Novo Nordisk performs poorly in this Technical Area. It does not engage in R&D for priority diseases and has a small-sized R&D pipeline compared to its peers. The company has a new access planning framework in place, with evidence of access plans for half its late-stage projects – focusing predominantly on registration preparation in emerging markets. Novo Nordisk does not publicly disclose disaggregated R&D investment data, but it has improved its R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Small-sized pipeline, compared to peers, addressing other diseases in scope, with 50% (6/12) of late-stage projects covered by access plans. The company has 12 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target

Novo Nordisk does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.*

One R&D capacity building initiative was included for analysis, but it does not meet all Good Practice Standards (GPS). In this initiative, Novo Nordisk aims to build R&D capacity by training young scientists in India, focusing on innovative R&D.

Novo Nordisk does not have any projects in its R&D pipeline targeting a priority disease in

diabetes mellitus, cardiovascular diseases and sickle cell disease. Novo Nordisk provides evi

scope.

dence of access plans for 6 of its 12 late-stage projects, including registration preparation and post-trial access.

*Novo Nordisk currently has no pipeline candidates within the disease scope of Impact Global Health (formerly known as Policy Cures Research), an organisation that assesses disaggregated R&D data.

Novo Nordisk A/S

PRODUCT DELIVERY

RANK 7 SCORE 3.35

7th place. Novo Nordisk performs above average in this Technical Area. The company has access strategies for its self-administered products across countries with different income classifications, and it consistently reports their outcomes. It demonstrates Best Practice by operating an inclusive business model to improve access to its products in multiple low-income and least developed countries. Novo Nordisk does not engage in new or ongoing intellectual property sharing agreements or non-exclusive voluntary licensing agreements.

Novo Nordisk registers products in 47 countries in scope on average. For the 1 newer product** analysed, it registers in 18 countries in scope and it registers 60% of products assessed in at least 1 of the 10 countries with the highest disease burden. There is evidence of registration in LICs for all products assessed. The company's isophane human insulin (Insulatard®), indicated for diabetes, is most widely registered, totalling 87 countries, including 21 LICs. The company

Publicly discloses product patent status for countries in scope. Novo Nordisk publicly discloses patent information for products in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Novo Nordisk does not engage in non-exclusive

September 2023, Novo Nordisk responded to aid requests from the International Committee of the Red Cross, by donating 413,200 vials of human insulin to earthquake-stricken Syria. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Novo Nordisk is transferring technology to Eskayef Bangladesh Limited to manufacture and supply insulin to the local market. In 2022, the partnership expanded to include cartridge manufacturing and export to additional countries.

voluntary licensing for products in scope.

reports engaging in regulatory reliance to facili tate registration for multiple products.

Novo Nordisk is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

Novo Nordisk is not eligible for assessment of access strategies for healthcare practitioner (HCP)-administered products because it has no HCP-administered products in scope.

Access strategies for most self-administered products, supported by information on out comes. For 4 of the 5 products selected for analysis, Novo Nordisk provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). The 3 human insulins assessed – Insulatard®, Actrapid® and Mixtard® – are covered by the Access to Insulin Commitment in several LMICs and LICs. This is complemented by other initiatives, such as the company's Changing Diabetes® in Children programme, which helps provide comprehensive care to children and youth with type 1 diabetes. For the other 2 diabetes products assessed – Liraglutide (Victoza®) and Insulin degludec (Tresiba®) – the company also demonstrates efforts in improving the product's affordability for patients. In both UMIC and LMIC examples for both products, the company implements patient support programmes to provide financial support in mainly out-of-pocket

All 3 manufacturing capacity building initiatives included for analysis meet all GPS. For exam ple, Novo Nordisk is transferring technology to South African manufacturer Aspen to fill and fin ish human insulin vials. The collaboration aims to supply over 4m patients on the African conti nent in 2026.

Three of the four supply chain capacity build ing initiatives included for analysis meet all GPS. For example, Novo Nordisk provided funds to develop the non-communicable disease (NCD) Forecasting Methodology/Tool under the Coalition for Access to NCD Medicines and Products. The tool has been introduced in Ghana, Kenya and Uganda and supports demand fore

standard and falsified medicines in countries in scope. It reports cases to the relevant regional, national, or local regulatory authorities within 7 days. The company does not provide evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation.

Novo Nordisk operates an inclusive business model that covers 9 products in 49*** countries in middle Africa, including 33 LICs and least developed countries. iCARE aims to improve access to diabetes products in 49 countries in middle Africa. The model, initially launched in 2021, includes supply chain and health sys tem capacity building and patient education and affordability plans.

casting for various essential NCD medicines.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initia tive, Novo Nordisk partners with the International Committee of Red Cross and Red Crescent, Danish Red Cross and London School of Hygiene and Tropical Medicine on chronic care in human itarian settings, focusing on best practices for diabetes care in crises. Between 2022 and 2024, partners integrated NCD management and trained peer support groups in Lebanon and Iraq.

Novo Nordisk has not entered into any new IP-sharing agreements, nor has it continued any existing agreements, with public research institutions or drug discovery initiatives to accelerate drug development.

markets. The company consistently shares patient reach data and the approaches applied to meas ure the outcomes of all strategies assessed.

Novo Nordisk publicly commits not to file for or enforce patents for all products in least devel

Fulfils all criteria for ad hoc donations. Novo Nordisk has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in oped countries and LICs in scope.

**Products that received their first marketing authorisation within the last 5 years.

***46 in scope.

RANK	SCORE
4	3.50
6 (2022)	

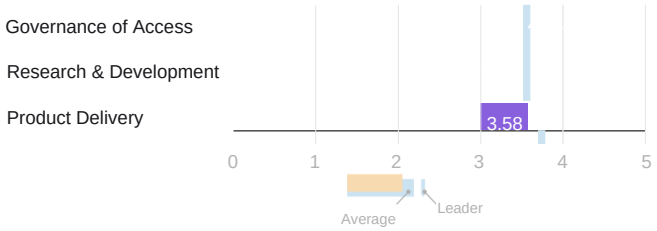
Pfizer Inc

Stock exchange: NYSE • Ticker: PFE • HQ: New York, New York, United States • Employees: 88,000

PERFORMANCE IN THE 2024 INDEX

4th place. Pfizer is a high-performing company. It performs strongly in Product Delivery, demonstrating Best Practice with its inclusive business model, 'Accord for a Healthier World'. It performs well in Research & Development and above average in Governance of Access.

How score was achieved



OPPORTUNITIES FOR PFIZER

Improve access planning for R&D projects for non-communicable diseases. Pfizer has access plans in place for less than half of its non-communicable diseases projects. These plans primarily focus on registration preparation in countries in scope. It can enhance existing plans to incorporate more access components, such as equitable pricing and sustainable supply. For example, it can improve its access plans for danuglipron, an oral GLP-1 agonist, for type 2 diabetes currently undergoing Phase II clinical trials.

Engage in technology transfer initiatives for additional products. Pfizer engages in technology transfer initiatives for its COVID-19 vaccine (Comirnaty®) in Brazil and South Africa and sterile injectable products in India. The company has previously transferred technology for its pneumococcal conjugate vaccine (Prevenar 13®) in South Africa. Pfizer can broaden these technology transfer efforts beyond the COVID-19 vaccine to include other vaccines prioritised for local manufacturing, such as its meningitis vaccine, Nimenrix®.

CHANGES SINCE THE 2022 INDEX

Expand access to its respiratory syncytial virus (RSV) vaccine. Pfizer's vaccine (Abrysvo®), is indicated for the prevention of RSV in infants (through maternal immunisation) and adults over 60 years. The product was approved in 2023 and is currently registered in 12 countries in scope. Pfizer can increase access to this product in low- and middle-income countries through supranational supply and/or equitable access strategies, with a particular focus on countries with the highest burden of disease.

Publicly report on the progress and outcomes of its inclusive business model. Pfizer launched 'An Accord for a Healthier World' (the Accord) in 2022, committing to supply its entire portfolio of on- and off-patent products (for which it has global rights) in 45 lower-income countries on a not-for-profit basis. The company has provided evidence of supplying three of the products analysed by the Index in one low-income country during the period of analysis. Pfizer can continue to expand access in low-income countries and publicly report where the products are supplied, as well as the respective number of patients reached.

- Expanded its Accord for a Healthier World to offer its full product portfolio for which it holds global rights, with the aim to benefit 1.2bn people in 45 lower-income countries. These products include essential medicines and vaccines, as well as innovative prevention and treatment options for both infectious and non-communicable diseases.
- Received FDA approval for the RSV vaccine (Abrysvo®) to protect infants.
- Partnered with Flagship Pioneering, a biotech company, to develop new innovative medicines for unmet needs.
- Collaborated with the Malawi Ministry of Health and bioMérieux to further the ministry's work in preventing antimicrobial resistance.

trainings on country-specific supply chain needs.

- Extended its on-going long-term donation programme of azithromycin (Zithromax®) in 2022 for an additional five years, through 2030, to support the elimination of trachoma.

- As of August 2024, Pfizer signed ten bilateral agreements with Accord-eligible countries to help enable access to Pfizer products (for which it holds global rights) on a not-for-profit basis, including, for example, Ethiopia, Ghana,

- Reported three new supply chain capacity building initiatives through the Accord for a Healthier World in Rwanda and one other country in sub-Saharan Africa. These initiatives include developing a track-and-trace system, improving cold chain capacity and providing Malawi, Rwanda and Senegal.

Pfizer Inc

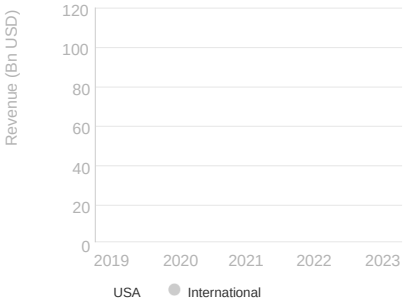
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, inflammation & immunology, internal medicine, oncology, rare diseases and vaccines	Therapeutics Inc. for USD 5.4bn; and Biohaven Pharmaceutical Holding Company Ltd. for USD 11.6bn. In 2023 Pfizer acquired Seagen Inc. for USD 43bn.	Revenue by segment (2023) – in USD	
		Biopharmaceutical products	57.19 bn
Product categories: Biosimilars, generics, innovative medicines, vaccines		Total	57.19 bn
M&A news: In 2022 Pfizer acquired ReViral for USD 525mn; ResApp for USD 116mn, Global Blood			

Sales in countries in scope

Pfizer's products are sold in 86 out of 113 countries in scope of the Index. Pfizer has sales offices in 7 countries and sells via sup pliers and/or pooled procurement in an additional 79 countries.

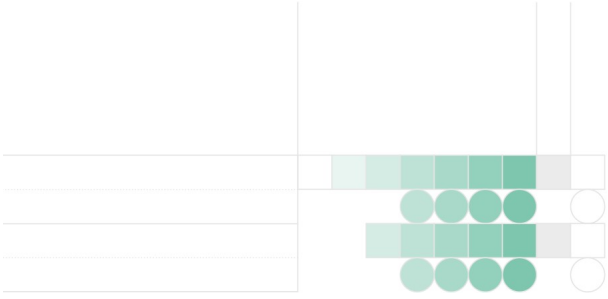
Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

Pfizer has 55 R&D projects in scope, 22 of which target priority diseases, focusing on coronaviral diseases (7), lower respiratory infections (7) and other prioritised antibacterial-resistant infections (4). The remaining 33 projects target other diseases in scope, including cancer (20) and cardiovascular diseases (4). Of the 55 R&D projects, 34 are in late-stage development, with evidence of access planning for 59% (20/34) of these.

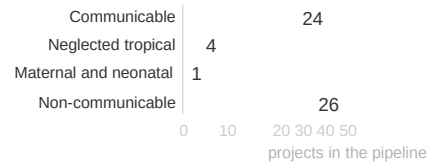


PORTFOLIO *as selected for analysis by the Index*

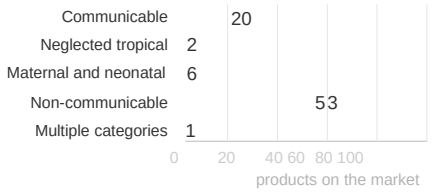
Pfizer has 82 products in scope, including 69 medicines and 8 vaccines; 46 of these products are listed on the WHO EML and 19 medicines are on patent.

Pfizer's medicines mainly target non-communicable diseases (53), including cancer (36) and cardiovascular diseases (7). Its medicines for communicable diseases (13) include treatments for lower respiratory infections (3), TB (3), HIV (2) and 1 for both HIV and TB. In addition, Pfizer has products for neglected tropical diseases (3), and maternal and neonatal health conditions (6), such as contraceptive methods (5) and 1 maternal haemorrhage product. Its vaccines target meningitis (4), lower respiratory infections (3) and coronaviral diseases (1).

55 projects in the pipeline



82 products in the portfolio



Breakdown of projects

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	1	3	4	4	4	0	6	0	22
with access plan				3	3	0	6		12
Other projects in scope			13	13	6	0	1	0	33
with access plan				2	5	0	1		8

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	2	17		19
off patent	35	15		50
Vaccines	5	3		8
Contraceptives	4	1		5
Diagnostics			0	0
Other			0	0

Pfizer Inc

GOVERNANCE OF ACCESS

RANK 10 SCORE 4.04

10th place. Pfizer performs above average in this Technical Area. The company has a global patient reach process that includes all countries and products in scope of the Index, for which it publishes the resulting patient reach numbers regularly. However, the underlying equation and metrics are not publicly available, and a measurable patient reach goal was not identified. Further, Pfizer only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

The highest responsibility for access lies directly with Pfizer's Executive Management Team with Board oversight, namely with the Corporate Governance & Sustainability Committee. Pfizer incentivises its senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to the Purpose Blueprint goals, including improving access through partnerships.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy, embedded in its Purpose Blueprint, covers all therapeutic areas in which the company is involved. Pfizer publicly discloses its commitments to access to medicine, along with some company-specific targets, goals and objectives. Reporting is mostly clear and linked to these goals, centrally available, and updated regularly in its Impact Report.

Shows comparatively strong commitment to responsible business practices. Pfizer does not set individual-level targets for sales agents and incentives are not solely based on sales volume. Sales agents are also incentivised by non-sales components (e.g., manager feedback or number of training sessions). Pfizer has a global policy on ensuring ethical interactions with healthcare professionals. It also offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Pfizer performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Pfizer also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Pfizer publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Pfizer states that compulsory licensing may be appropriate to use in national health emergencies after exhausting all other options and if the problem is truly urgent.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For its global patient reach process covering all its products and all countries (where the company operates) in scope of the Index, Pfizer publicly provides the assumptions and limitations. The resulting patient reach numbers are published regularly and demonstrate improvements. The process has a patient reach goal, although this is not measurable, and no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 5 SCORE 3.07

5th place. Pfizer performs well in this Technical Area, retaining 5th position. Pfizer has an access planning framework, access plans for the majority of late-stage candidates in its pipeline. The company has a mixed pipeline with non-communicable and priority projects – with more comprehensive plans for its priority projects. Pfizer does not publicly disclose disaggregated R&D investment data, but it performs strongly in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Large-sized priority R&D pipeline, compared to peers, with access plans in place for 86% (12/14) of the late-stage candidates. Priority R&D pipeline of 22 projects, including 14 late-stage projects that target a priority gap. The company focuses on various priority areas, including coronaviral diseases, lower respiratory infections and other prioritised antibacterial-resistant infections. Of Pfizer's 14 late-stage candidates targeting a priority product gap, 12 (86%) have evidence of an access plan in place, mostly focusing on equitable pricing plans, supply and demand plans and registration preparation.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 40% (8/20) of late-stage projects covered by access plans. The company has 20 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer and cardiovascular diseases. Pfizer provides evidence of access plans for 8 of its 20 late-stage projects, mostly focusing on registration preparation, equitable pricing and supply and demand plans.

Pfizer does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is a consortium that seeks to identify novel genetic drivers of cancer disparities in African and Caribbean populations, with partners in 5 LMICs in scope.

PRODUCT DELIVERY

RANK 3 SCORE 3.58

3rd place. Pfizer performs strongly in this Technical Area. It demonstrates Best Practice by operating an its inclusive business model, 'Accord for a Healthier World'. to improve access to its products in multiple low-income and least developed countries. Through the model, it has supplied three of its products analysed by the Index in a low-income country; however, the remaining access strategies focus on upper-middle- and lower-middle-income countries. It engages in supranational agreements for five of its products and provides access to countries outside these agreements.

Pfizer registers newer products* in 14 countries in scope on average. It registers 50% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's COVID-19 mRNA vaccine (Comirnaty®), is most widely registered, totalling 39 countries in scope.

*Products that received their first marketing authorisation within the last 5 years.

Pfizer Inc

The company reports engaging in the WHO Collaborative Registration Procedure (SRA-CRP) to facilitate registration for 2 products.

Supplies 5 products through different supranational agreements. For example, Pfizer supplies its pneumococcal vaccine, Prevnar 13®, through Gavi, the Vaccine Alliance/UNICEF. The company also provides evidence of supplying the vaccine outside of this agreement in Algeria. For all products assessed in this category – 2 vaccines, 2 contraceptives and 1 medicine – Pfizer demonstrates access strategies for at least one non-eligible country. For all products, the company shares the outcomes (e.g. doses supplied) of the supranational agreement and the non-eligible country's access strategy.

reach data, but it does not report much detail on the approaches used to track the strategies' outcomes.

Pfizer publicly commits not to enforce patents for all products in least developed countries.

Publicly discloses product patent status for countries in scope. Like most peers, Pfizer publicly discloses patent information for all small molecules via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction. Additionally, on its website Pfizer discloses patent information and basic product patent expiry for products it considers most significant to its business.

carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Pfizer publicly commits to continue long-term donation programme to support the elimination of trachoma. Its programme is active in 20 countries in scope, with the company extending its commitment to donate azithromycin (Zithromax®) through 2030 to help eliminate trachoma.

Fulfils all criteria for mechanisms to ensure

Access strategies for healthcare practitioner (HCP)-administered products in place in UMICs and LMICs, supported by some information on outcomes. For all 5 products selected for analysis, Pfizer reports access strategies in UMIC and LMIC examples. During the period of analysis, one product, ceftazidime/avibactam (Zavicefta®), was supplied to an LIC at a not-for-profit price as part of the Accord for a Healthier World. In Colombia (UMIC), 4 products – 3 antibiotics and 1 antifungal – are listed in the national formulary and thus covered by the public system. In this country, the company also engages in health system strengthening initiatives, such as an educational programme for HCPs to improve antimicrobial stewardship. For the LMICs examples analysed, mainly out-of-pocket markets, Pfizer also demonstrates efforts in improving availability and affordability of its products, for example, by offering discounts or implementing strategies to reduce mark-ups. The company has goals to increase access, especially in the public sector, and shares some information about the strategies' outcomes, as well as evidence of increasing patient reach.

Access strategies for self-administered products in some countries, with some information on outcomes. For 3 of the 5 products selected for analysis, Pfizer provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). In the UMIC and LMIC examples assessed, the company demonstrates efforts in considering barriers to access, as well as payers' ability to pay across different countries. For example, in Egypt (LMIC), it offers different solutions, such as microfinancing and co-payments support for its cancer drugs, palbociclib (Ibrance®) and sunitinib (Sutent®), to enable affordability. During the period of analysis, the company supplied sunitinib and another cancer drug, crizotinib (Xalkori®), in Sudan (LIC) via donations to the Max Foundation. For most of the strategies assessed, the company shares patient

Pfizer has 1 non-exclusive voluntary licensing agreement to enable generic supply. The licence is for nirmatrelvir, indicated for the treatment of COVID-19, and includes 93 countries in scope, including 66 UMICs. The terms of the licence are publicly available.

All 5 manufacturing capacity building initiatives included for analysis meet all GPS. For example, Pfizer supports Zeiss Pharma Ltd. in India to build its capacity for manufacturing sterile injectable products. Pfizer is supporting this manufacturer in meeting current Good Manufacturing Practice.

Two of the five supply chain capacity building initiatives included for analysis meet all GPS. For example, Pfizer supported Zipline in Ghana by providing funding and cold chain expertise aimed at improving supply of mRNA COVID-19 vaccines to rural areas. Additionally, Pfizer has provided funding to support Zipline's Zero Dose project in Nigeria.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, The Pfizer Foundation provides funding to Partners in Health, which works in partnership with the Rwanda Biomedical Center and the ministries of health in Malawi and Rwanda to improve access to quality care for cancer. In Rwanda, Partners in Health is working to decentralise care through, for example, offering oral breast cancer therapy in district hospitals.

is working with the Rwandan ministry of health and local hospitals and distributors to enable them to implement a track-and-trace project, which currently covers 7 Pfizer products. Pfizer plans to scale the initiative to cover 45 countries in scope.

Pfizer has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities, but does not specify reporting timeframes. Instead, the company reports that it follows locally mandated timeframes. It does not provide evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation.

Pfizer operates an inclusive business model that covers 144* products in scope of the Index in 45 LMICs, including 40 LICs and/or least developed countries. The company's Accord for a Healthier World, launched in May 2022, aims to enable access to the full portfolio of both on- and off-patent essential medicines and vaccines that it has global rights to on a not-for-profit basis in these countries. Through bilateral agreements, now ongoing with 10 countries** (e.g., Ghana, Senegal), Pfizer collaborates with governments to assess health system needs in order to supply its medicines and vaccines and also to co-create solutions that can help strengthen supply chain and logistics, develop healthcare workforce capabilities and enable more efficient regulatory

Pfizer remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to acceler ate drug development. In 1 agreement Pfizer shared 2 compounds with a University of Tokyo researcher for screening against targets for malaria. However, the company has not engaged in new agreements during the period of analysis.

Fulfils all criteria for ad hoc donations. Pfizer has public policies and supply processes to

*There are additional products included in the Pfizer Accord listing that are not in the scope of the 2024 Index analysis.

**For two of the ten countries, agreements were signed after the period of analysis.

RANK	SCORE
11	3.07
10 (2022)	

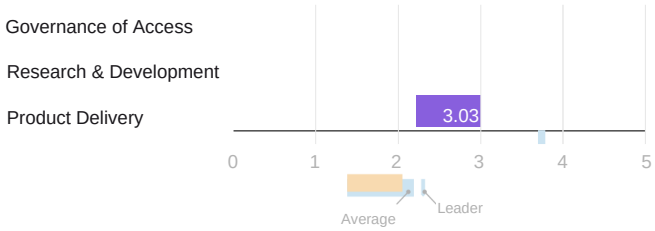
Roche Holding AG

Stock exchange: SIX • Ticker: ROG.SW • HQ: Basel, Switzerland • Employees: 103,605

PERFORMANCE IN THE 2024 INDEX

11th place. Roche is a middle-performing company. It performs above average in both Research & Development and Product Delivery, where it demonstrates Best Practice for registering its products widely and supplying its World Health Organization (WHO)-prequalified human papillomavirus (HPV) test to nearly 50 countries in scope of the Index. However, it performs below average in Governance of Access.

How score was achieved



OPPORTUNITIES FOR ROCHE

Ensure all late-stage R&D projects have comprehensive access plans. Roche has access plans in place for one third of its late-stage projects. The company's access plans currently predominantly focus on plans for registration filings. To enhance the quality of these plans, the company can go beyond commitments to register in countries where clinical trials are conducted, incorporating additional access components, such as equitable pricing and licensing. For example, it can improve its access plans for giredestrant, in development for uterine and breast cancer, with clinical trials in Phase II and Phase III, respectively.

Engage in technology transfer initiatives for additional oncology products. Roche is engaged in technology transfer initiatives with manufacturers in China and Egypt for bevacizumab (Avastin®), a product indicated for multiple cancer types. The company can expand such initiatives to further products in its oncology portfolio, such as atezolizumab (Tecentriq®) and pertuzumab (Perjeta®).

CHANGES SINCE THE 2022 INDEX

Expand access to its innovative products. Roche has access strategies in place for its assessed products, but mostly focuses on upper-middle- and lower-middle-income countries and lacks access strategies in low-income countries. For example, it can expand access to two of its key products – trastuzumab/hyaluronidase (Herceptin®SC), indicated for breast cancer, and baloxavir marboxil (Xofluza®), indicated for influenza A and B – both of which are prioritised for licensing by public health organisations, through equitable access strategies and/or voluntary licensing to enable generic supply.

- Received WHO prequalification for the Cobas® HPV Test, which is supplied at a standardised price to eligible LMICs as part of Roche's Global Access Program.
- Partnered with Jhpiego and the government of Ghana to enhance women's cancer care as part of the Ghana National Strategy for Cancer Control.
- Signed a memorandum of understanding with the Egyptian Drug Authority to shape the regulatory environment and undergo digital transformation.
- Signed a co-promotion agreement with Radiant Pharmaceuticals to provide medicines for severe diseases, including cancer, ophthalmology, and neurology in Bangladesh.
- Entered a five-year collaboration and licensing agreement with Moma Therapeutics to use its KnowledgeBase platform to identify novel cancer drug targets.
- Co-founded the Biospecimen Management Consortium to advance complex clinical research.
- Developing the first antibiotic to show progress against drug-resistant bacteria, Carbapenem-resistant *Acinetobacter baumannii* (CRAB).
- Donated medicines to earthquake-stricken Morocco in 2023 in response to requests from Morocco’s Ministry of Health.
- Newly disclosed evidence of conducting fraud-specific risk assessments to mitigate risk of non-compliant and corrupt activities.
- Expanded the list of eligible countries in its Global Access Program from 82 to 89.

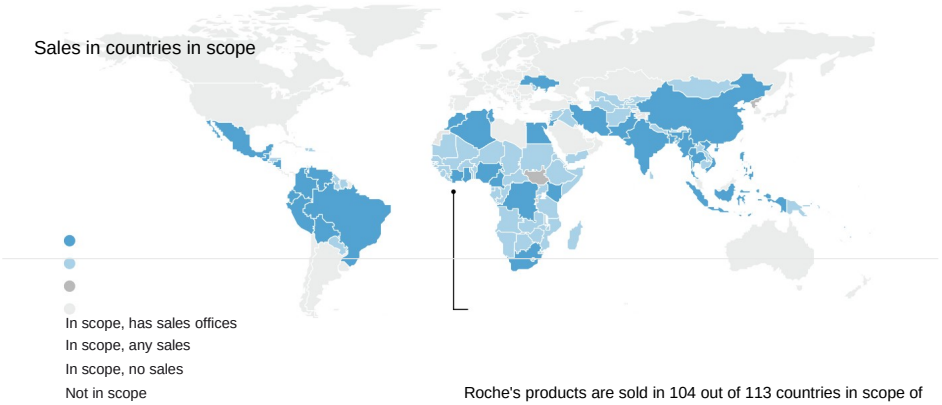
Roche Holding AG

SALES AND OPERATIONS

Therapeutic areas:Cardio-metabolic, diabetes, haematology, infectious diseases, inflammatory bowel diseases, neuroscience, oncology, ophthalmology, rare disease, respiratory, women's health	M&A news: Roche acquired Good Therapeutics' PD-1 programme for USD 250mn, Televant Holdings for USD 7.1bn, and Carmot Therapeutics for USD 2.7bn in 2022, 2023 and 2024, respectively.	Sales by segment (2023) – in CHF	
		Pharmaceuticals	44.61 bn
		Diagnostics	14.1 bn
		Total	58.71 bn

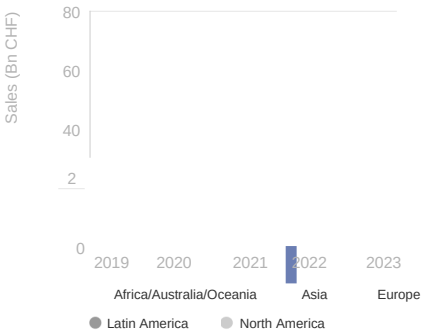
Product categories: Diagnostics, innovative medicines

Sales in countries in scope



Roche's products are sold in 104 out of 113 countries in scope of the Index. Roche has sales offices in 33 countries and sells via sup pliers and/or pooled procurement in an additional 71 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

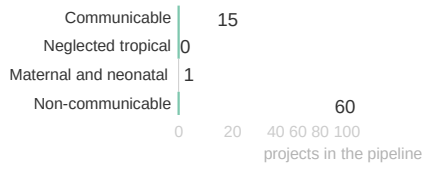
Roche has 76 R&D projects in scope, 13 of which target priority diseases, focusing on hepatitis B (3), coronaviral diseases (3) and other prioritised antibacterial-resistant infections (2). The remaining 63 projects target other diseases in scope, including cancer (46), Alzheimer's disease (6) and lower respiratory infections (3). Of the 76 R&D projects, 30 projects are in late-stage development, with evidence of access planning for 30% (9/30) of these. In addition, 4 diagnostics have been approved during the period

PORTFOLIO *as selected for analysis by the Index*

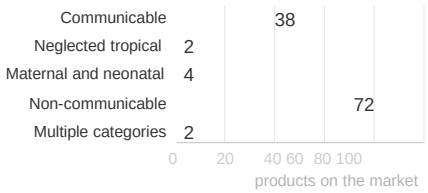
Roche has 118 products in scope, including 25 medicines, 9 of which are listed on the WHO EML and 19 are on patent. In addition, the company has 81 diagnostics, all of which are on the WHO EDL, as well as 12 platform technologies. Roche's medicines mostly target non-communicable diseases (19), specifically cancer (16). Some of its medicines target communicable diseases (6), such as coronaviral diseases (2) and lower respiratory infections (2). Its platform technologies are for diseases such as respiratory infections (3), diabetes (3), cancer (2) and other diseases in scope. The diagnostics are for diseases such as cancer (35), hepatitis (B and C) (10), cardiovascular diseases (9) and HIV (8).

of analysis.

76 projects in the pipeline



118 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	1	3	0	0	4	5	13
with access plan				2	0	0	1		3
Other projects in scope			33	12	9	0	6	3	63
with access plan				1	4	0	1		6

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	3	16			19
off patent	6	0			6
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			81		81
Other				12	12

Roche Holding AG

GOVERNANCE OF ACCESS

RANK 13 SCORE 3.68

13th place. Roche performs below average in this Technical Area. The company incentivises its in-country managers to act on access to medicine; however, it does not disclose whether the CEO and senior executives are also incentivised towards access goals. Roche has a public policy that commits to ensuring ethical interactions with healthcare professionals in its code of conduct. However, it does not align with the standards set by the Index.

The highest responsibility for access lies directly with the Board, namely with the Corporate Governance and Sustainability Committee. Roche incentivises its in-country managers to act on access to medicine with financial and non-financial rewards. It does not disclose, however, whether the CEO/senior executives are also incentivised towards access goals.

Comprehensive access-to-medicine strategy integrated within the overall corporate strat egy. Its strategy covers all therapeutic areas in which the company is involved. Roche publicly discloses its commitments to access to medicine, along with some company-specific measurable targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available and updated regularly in its Annual Report.

Shows comparatively moderate level commit ment to responsible business practices. Roche sets sales targets at the individual, division and company levels and incentives for agents are not solely based on sales volume. It incentivises both financial and non-financial goals. Roche commits to ensuring ethical interactions with healthcare professionals in its code of conduct. It discloses to the Index, but not publicly, the legitimate need for interactions with healthcare professionals and the limits on transfers of value to them. However, it declares that transfers of value to healthcare professionals (e.g., payments for exchanging sci entific information or consulting) are made at fair market value. Finally, Roche only publicly dis closes information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Roche performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Roche also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Roche publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Roche states that compulsory licensing should be considered on its own merits on a case-by-case basis.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For 1 process covering most of its products and most countries in scope of the Index, Roche provides the metrics and assumptions publicly and provided the underlying equation and limitations directly to the Index. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

RESEARCH & DEVELOPMENT

RANK 8 SCORE 2.82

8th place. Roche performs above average in this Technical Area. It has some priority projects, but its pipeline is mostly focused on non-communicable diseases. The company has an access planning framework, with access plans in place for some of its late-stage pipeline candidates. Although Roche's access plans do have a relatively wide geographic scope, plans often focus on registration preparation. It does not publicly disclose disaggregated R&D investment data, but it performs strongly in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 75% (3/4) of the late-stage candidates. Priority R&D pipeline of 13 projects, including 4 late-stage projects that target a priority gap. The company focuses on various priority areas, a priority product gap, 3 (75%) have evidence of an access plan in place, mostly focusing on registration preparation, as well as equitable pricing and WHO prequalification. In addition, 3 diagnostics targeting a priority product gap were approved during the period of analysis.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 23% (6/26) of late-stage projects covered by access plans. The company has 26 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global plans for 6 of its 26 late-stage projects, mostly focusing on registration preparation, equitable pricing and the inclusion of special populations in clinical trials. In addition, 1 diagnostic was approved during the period of analysis.

Roche does not publicly disclose R&D invest ment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggre gated R&D investment data to global health organisations.

Four of the five R&D capacity building ini tiatives included for analysis meet all Good Practice Standards (GPS). One of these initia tives, the African Genomics Programme, aims to develop an open African-led biobank, through multiple collaborations, including African universi ties and research centres.

including hepatitis B, coronaviral diseases and other prioritised antibacterial-resistant infections. Of Roche's 4 late-stage candidates targeting

health stakeholders. The projects mainly target cancer, Alzheimer's disease and lower respiratory infections. Roche provides evidence of access

Roche Holding AG

PRODUCT DELIVERY

RANK 12 SCORE 3.03

12th place. Roche performs above average in this Technical Area. The company demonstrates Best Practice by registering innovative products widely in LMICs. However, it does not engage in non-exclusive voluntary licensing. All its health system strengthening initiatives meet all Good Practice Standards, but its supply chain and manufacturing capacity building initiatives do not. It engages in supranational agreements for four products, providing access to countries outside these agreements. It implements access strategies and reports data on their outcomes; however, it lacks coverage in low-income countries.

Roche registers newer products* in 30 countries in scope on average, more than any other company in scope. It registers 67% of products assessed in at least 1 of the 10 countries with the highest disease burden, with one of its diagnostics registered in 8 of 10 countries with the highest burden. The company's trastuzumab/hyaluronidase-oysk (Herceptin Hylecta®), indicated for breast cancer, is most widely registered, totalling 63 countries in scope. The company reports engaging in several mechanisms to facilitate registration, for example, through the WHO Collaborative Registration Procedure (SRA-CRP) and for WHO Prequalified products.

Supplies 4 products via supranational agreements. Roche supplies 4 diagnostics for HIV and HPV-related cervical cancer testing assessed in this category via international partners, including the Clinton Health Access Initiative, the US President's Emergency Plan for AIDS Relief (PEPFAR), United States Agency for International Development, Unitaid and The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). For 3 of the 4 diagnostics, the company demonstrates access strategies for at least one country not eligible for such supply. Access strategies also include additional initiatives aimed at strengthening health systems, focusing on testing capabilities. The company shares outcomes of the supranational agreement and the non-eligible country's access strategies.

Access strategies in place for healthcare practitioner (HCP)-administered products, supported by data to track outcomes and progress. For the 5 products selected for analysis, all oncology medicines, Roche provides access strategy examples in UMICs and LMICs but not for any LICs. Roche demonstrates efforts to improve the accessibility and affordability of its products. For example, it negotiated a managed entry agreement based on a cost-sharing scheme for its oncology medicine, artezolizumab (Tecentriq®), to be included in the national fund in Tunisia (LMIC), which covers approximately 60-70% of the population. The rest of the population is covered by free medical assistance, whereby Roche provides the products for free. The company also provides evidence of health system strengthening initiatives in most of the strategies analysed. The company shares goals to expand access to its products, sometimes sharing more detailed future plans. For most examples assessed, the company shares the number of patients reached with its strategies and has approaches in place to track the strategies' outcomes and progress over time. For example, Roche provided evidence of increasing patients reached with artezolizumab from 2022 to 2024 through its strategy in Tunisia.

Access strategies for self-administered products in limited countries, supported by some information on outcomes. For 1 of the 4 medicines selected for analysis, Roche provides evidence of access strategies in UMIC and LMIC examples. For the other 3 products, it provides a UMIC example. The company did not provide any example in LICs. Roche provides evidence of considering country-specific barriers to access, as well as product affordability in its strategies. However, this is mainly limited to UMIC examples. In China (UMIC), 3 of the 4 products assessed achieved national reimbursement, which covers much of the population. In Peru (UMIC), in the absence of public reimbursement for its cancer medicine erlotinib (Tarceva®), Roche implements different support programmes, such as one for uninsured patients, covering both medicines and testing prices, and another supporting co-payment costs for insured patients. The company provides evidence of increasing patient reach over time and shares plans to advance some of its strategies.

Roche publicly commits not to file for or enforce patents for all products in some countries in scope. This applies to all least developed countries and LICs. Additionally, it does not file for or enforce patents for its antiretroviral HIV medicines in sub-Saharan Africa.

Publicly discloses product patent status for countries in scope. Like most peers, Roche publicly discloses patent information for small molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

Roche does not engage in non-exclusive voluntary licensing for products in scope.

Neither of the 2 manufacturing capacity building initiatives included for analysis meet all GPS. In 1 initiative, Roche is transferring technology to Egyptian manufacturer Gypto Pharma for secondary packaging of oncology product bevacizumab (Avastin®). Roche shares know-how to support the partner in meeting requirements regarding technical capabilities, quality and safety, health and environmental standards.

Two of the three supply chain capacity building initiatives included for analysis meet all GPS. For example, Roche is continuing its Global Philanthropic Secondment Program in Namibia. So far, 14 Roche employees have gone to the Namibia University of Science and Technology to share knowledge on supply chains and logistics.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Roche is supporting the City Cancer Challenge Foundation to improve access to cancer care where essential healthcare services, diagnostics and treatments remain limited. Roche provides both financial and technical support, as well as sharing information about local health systems where the initiative operates.

Roche has not entered into any new IP-sharing agreements, nor has it continued any existing agreements, with public research institutions or drug discovery initiatives to accelerate drug development.

Fulfils all criteria for ad hoc donations. Roche has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in September 2023, Roche responded to aid requests from Morocco's ministry of health, by donating 4,000 vials of ceftriaxone (Rocephin®) to the earthquake-stricken country. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Roche is building a warehouse and distribution centre in Morocco where secondary packaging of 5 biological products will take place. The project aims to improve access for patients in the country.

Roche has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities, but it does not strictly specify the reporting timeframe. However, the company states that reporting typically occurs within 24 hours once a case is confirmed. Further, it reports that earlier reporting prior to the investigation's end is possible when visual inspection is sufficient for confirmation.

Roche operates an inclusive business model that offers diagnostics** to 89 eligible countries. The Global Access Programme (GAP), launched in 2014, allows governments, local healthcare facilities and international organisations to procure reduced-price hepatitis, TB, HPV and COVID-19 diagnostics. The model includes pricing for eligible organisations and governments, R&D for innovative collection methods and health worker training and education.

*Products that received their first marketing authorisation within the last 5 years.

**Through GAP, Roche also offers various reagents, controls, consumables and instruments used in molecular diagnostics.

RANK	SCORE
3	3.52

8 (2022)

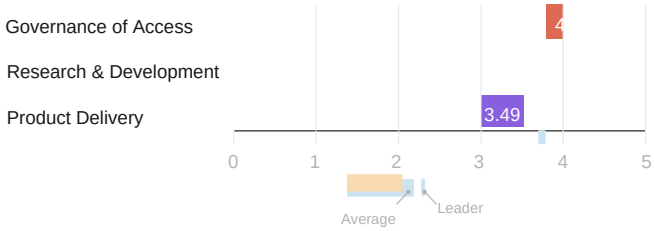
Sanofi

Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 86,088

PERFORMANCE IN THE 2024 INDEX

3rd place. Sanofi ranks in the top three, leading in Governance of Access. It performs strongly in Research & Development and Product Delivery, demonstrating Best Practice for its inclusive business model to improve access to products in LMICs.

How score was achieved



OPPORTUNITIES FOR SANOFI

Improve the quality and broaden the geographic reach of access plans. Sanofi has access plans for almost all of its late-stage projects. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus on more low and lower-middle-income countries. For example, it can improve its access plan for SP0125, an intranasal respiratory syncytial virus vaccine for infants, currently in Phase III of clinical trials, by expanding it beyond

Expand access to analogue insulins. Sanofi has demonstrated progress in expanding access to insulin; for example, it has supplied its Impact® brand's insulin glargine in 10 low-income countries through its Global Health Unit (GHU). It can continue to build on this progress by expanding this access strategy to additional countries and also applying these strategies to other analogue insulins in its portfolio, such as insulin lispro (Admelog®) and insulin glargine/lixisenatide (Suliqua™) (a combination of insulin glargine and GLP-1 registration preparation in nine countries in scope. receptor agonist).

Continue to publicly report on the progress and outcomes of its inclusive business model. In 2021, Sanofi launched its Global Health Unit (GHU), which aims to increase access to 30 products across 40 countries with the highest unmet medical needs. Since 2021, the company has publicly and annually reported on the number of countries where the model operates as well as overall patient reach. To further strengthen transparency and partnerships, Sanofi can continue regular reporting on patient reach and country-level implementation. Sanofi can track and share the outcomes of country-specific strategies and patient reach for specific products.

CHANGES SINCE THE 2022 INDEX

Expand access to nirsevimab (Beyfortus®). Sanofi's preventative medicine nirsevimab (Beyfortus®) is indicated for the prevention of respiratory syncytial virus (RSV) complications in newborns and children. The product was approved in 2022 and is currently registered in two countries in scope. As the holder of marketing rights in low- and middle-income countries (LMICs), Sanofi can increase access to this product through increasing registration, implementing equitable access strategies and engaging in voluntary licensing.

- In October 2023, the first medicines from the Global Health Unit's (GHU) not-for-profit Impact brand portfolio were delivered to the Republic of Djibouti. Sanofi plans to scale operations to more GHU countries, aiming to expand deliveries to 10 more countries in scope of the Index.
- Signed two strategic training collaborations (through its GHU) with the International Diabetes Federation in July 2023 to build capacity for healthcare practitioners across 40 LMICs; as of Q2 2024, GHU had 42 active healthcare partnerships in 21 countries in place.
- Signed a memorandum of understanding with Ghana's Ministry of Health in April 2023, aimed at improving the management of diabetes in Ghana, including access to Sanofi's analogue insulin products.
- Signed a two-year collaboration agreement with the Delta State Government in Nigeria in September 2023 to improve access to analogue insulin products and care.
- Entered an agreement with Johnson & Johnson to advance the development of a potential first-in-class vaccine against extraintestinal pathogenic E. coli (ExPEC).
- Signed a manufacturing and supply agreement with Minapharm in December 2023 for the local manufacturing of enoxaparin (Clexane®) in Egypt, an anticoagulant medicine indicated for the treatment of venous thromboembolism.
- Signed a technology transfer agreement with The Biovac Institute (Biovac) in South Africa in 2024 to manufacture its inactivated polio virus vaccine for supply to African countries through UNICEF.
- Discontinued direct operations in Nigeria in 2024, switching to a third-party distribution model.

Sanofi

SALES AND OPERATIONS

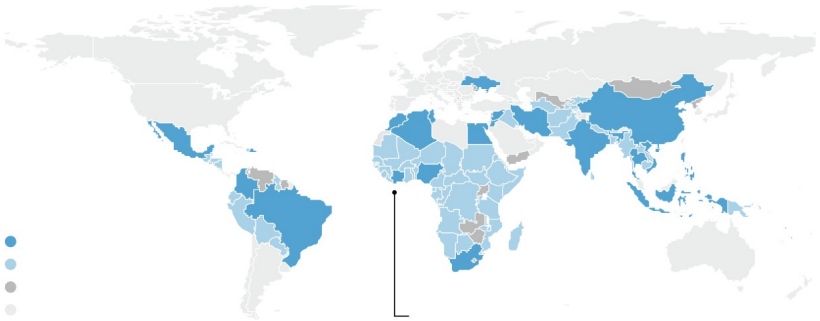
Therapeutic areas: Cardiovascular diseases, diabetes, immunology & inflammation, infectious diseases, oncology, neurology, rare blood disorders, rare diseases, vaccines

Product categories: Consumer health, generics, innovative medicines, vaccines

M&A news:In 2023, Sanofi acquired Provention Bio Inc. for USD 2.9bn and QRIB Intermediate Holdings, LLC for USD 1.4mn. In 2024, Sanofi acquired Inhibrx Inc. for USD 1.7bn.

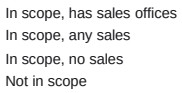
Net sales by segment (2023) – in EUR

Biopharma	37.89 bn
Consumer healthcare	5.18 bn



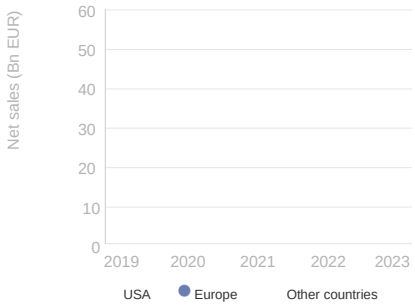
Total	43.07 bn

Sales in countries in scope



Sanofi's products are sold in 92 out of 113 countries in scope of the Index. Sanofi has sales offices in 22 countries and sells via distributors in an additional 70 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

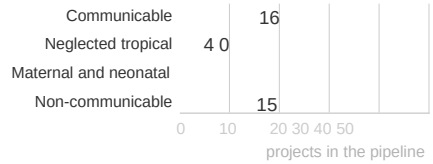
PIPELINE *for diseases in scope*

Sanofi has 35 R&D projects in scope, 15 of which target priority diseases, including lower respiratory infections (8), human African trypanosomiasis (3) and meningitis (2). The remaining 20 projects target other diseases in scope, including cancer (8), asthma (3) and lower respiratory infections (3). Of the 35 R&D projects, 21 are in late-stage development, with evidence of access planning for 86% (18/21) of these.

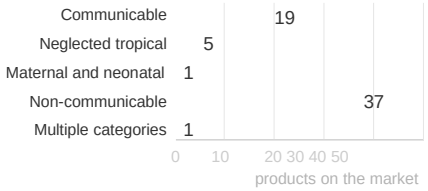
PORTFOLIO *as selected for analysis by the Index*

Sanofi has 63 products in scope, including 43 medicines and 16 vaccines; 35 of these products are listed on the WHO EML and 11 medicines are on patent. In addition, the company has 4 platform technologies targeting diabetes mellitus. Sanofi's medicines mostly target non-communicable diseases, such as cardiovascular diseases (9) diabetes (9) and cancer (6), with some for communicable diseases, including malaria (2) and TB (2). In addition, it has 1 medicine for maternal and neonatal conditions, 5 products for neglected tropical diseases (NTDs) and 1 medicine indicated for both NTDs and lower respiratory infections. Sanofi's vaccines target diseases such as lower respiratory infections, tetanus and meningitis.

35 projects in the pipeline



63 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	1	3	1	4	5	0	1	0	15
with access plan				2	5	0	1		8
Other projects in scope			9	6	2	0	3	0	20
with access plan				5	2	0	3		10

Breakdown of products

	WHO EML		Non-EML	WHO EDL	Total
Medicines *on patent*	1	10			11
off patent	21	11			32
Vaccines	13	3			16
Contraceptives	0	0			0
Diagnostics			0		0
Other				4	4

Sanofi

GOVERNANCE OF ACCESS

RANK 1 SCORE 4.44

1st place. Sanofi leads in this Technical Area. It has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Further, the company provides public reporting of the underlying methodology, patient reach goal and resulting patient reach numbers of its Sanofi Global Health NCD product delivery process.

The highest responsibility for access lies directly with board-level members seated on the Corporate Governance and Sustainability Committee. Sanofi incentivises its senior executives and in-country managers to act on access to medicine with financial and non-financial rewards. The CEO has long-term incentives tied to various access objectives, such as the number of access plans developed, and patients reached through the Global Health Unit.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Sanofi publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regularly in its Corporate Social Responsibility Report.

Shows comparatively strong commitment to responsible business practices. Sanofi sets national-level targets for sales agents in most countries in scope when individual level information is unavailable, and incentives are not solely based on sales volume. It also commonly draws national-level incentive compensation plans for vaccines and therapeutic areas like rare diseases. Sanofi has publicly available guidelines on service engagements with scientific experts to ensure ethical interactions with healthcare professionals. Further, it offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for consulting or speaking at events) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Sanofi performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Sanofi also has an ethical decision-for employees. No breaches in countries in scope were found in the period of analysis.

Sanofi publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Sanofi states that compulsory licensing should only be used in extraordinary and very limited circumstances such as a health emergency, when no appropriate alternative is available.

Fulfils most criteria across 2 processes for measuring and reporting patient reach. As part of its sustainability-linked bond for its Sanofi Global Health NCD product delivery process, which covers some of its products and some countries in scope of the Index, Sanofi publicly provides the underlying equation, metrics and assumptions. The resulting patient reach numbers are published regularly and demonstrate improvements. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT

RANK 3 SCORE 3.12

3rd place. Sanofi performs strongly in this Technical Area. The company has maintained an average-sized mixed pipeline, with both priority projects and non-communicable diseases. It publicly commits to access from Phase II onwards and has access plans for most late-stage pipeline candidates. Sanofi has improved its R&D capacity building activities, and it publicly discloses disaggregated R&D investment data for phase of development. It does also disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 80% (8/10) of the late-stage candidates. Priority R&D pipeline of 15 projects, including 10 late-stage projects that target a priority gap. The company focuses on various priority areas, including lower respiratory infections, human African trypanosomiasis and meningitis. Of Sanofi's 10 late-stage candidates targeting a priority product gap, 8 (80%) have evidence of an access plan in place, mostly focusing on registration preparation, including special populations in clinical trials and WHO prequalification.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 91% (10/11) of late-stage projects covered by access plans. The company has 11 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, asthma and lower respiratory infections. Sanofi provides evidence of access plans for 10 out of 11 late-stage projects, mostly focusing on registration preparation in countries in scope and the inclusion of special populations in clinical trials.

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standard (GPS). One of these initiatives, The Global Influenza Hospital Surveillance Network (GIHSN), aims to improve laboratory capacity for detection of respiratory viral pathogens and build know-how on whole-genome sequencing in multiple countries globally.

PRODUCT DELIVERY

RANK 5 SCORE 3.49

5th place. Sanofi performs well in this Technical Area. It demonstrates Best Practice by operating an inclusive business model to improve access to its products in multiple low-income and least-developed countries. For all of its products, the company has access strategies in place in at least one low-income country. The company reports outcomes data of its strategies; however, for some at an aggregated level. The company does not engage in non-exclusive voluntary licensing.

Sanofi registers newer products* in 4 countries in scope on average. It registers 22% of products assessed in at least 1 of the 10 countries with the highest disease burden; only 2 products are registered in LICs. The company's tetanus

*Products that received their first marketing authorisation within the last 5 years.

Sanofi

booster vaccine (Tetraxim®), is most widely reg istered, totalling 31 countries in scope. The company reports engaging in multiple mecha nisms to facilitate registration, specifically, the WHO Collaborative Registration Procedure for WHO Prequalified products and the European Medicines Agency EU-M4all (former Article 58).

Supplies a variety of products through differ ent supranational agreements. The 5 products analysed include a yellow fever vaccine, a hexava lent vaccine and 3 medicines for TB, leishmaniasis and malaria, respectively. For 4 products, Sanofi demonstrates strategies, both in countries eligible for supply from such procurers and in at least one non-eligible country. For its leishmaniasis treat ment, meglumine antimoniate (Glucantime®), the company does not provide a non-eligible country example but reports having direct sales in different countries at the same price negotiated with WHO for the supranational agreement. For its antibi otic rifapentine (Priftin®) and its malaria medicine amodiaquine/artesunate (ASAQ Winthrop®), the company reports offering the same price to non-eligible countries as the supranational agree ment. However, it did not share data on the outcomes of these countries' strategies.

Access strategy examples in LICs for 5 health care practitioner (HCP)-administered products, with some information on outcomes. For all 5 products assessed, Sanofi provides access strat egy examples in LICs and LMICs. For 3 of these products, access strategy examples are also in place in UMICs. Through its strategies, the com pany demonstrates some efforts in addressing product- and country-specific barriers to access. For example, Sanofi supplies it rabies vaccine, Verorab, in Brazil (UMIC) via an agreement with a local producer, the Butantan Institute, and the product is available free of charge in the public sector. In the Central African Republic (LIC), the company supplies its rabies vaccine via the Pasteur Insitute, which provides access to patients of all socio-economic backgrounds. Strategies for this product across all 3 country examples are also supported by health system strengthening initiatives. Access strategies for the other products are not as comprehensive. Sanofi shares information on patient reach, or volumes sold, for some of the strategies assessed, but overall data on the outcomes of the strategies is quite limited.

Access strategies for self-administrated products across all country income levels, with limited information on outcomes. For all 4 products selected for analysis, Sanofi provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). Products include 2 analogue insulins and 2 cardiovascular

reimbursed in Brazil and China (UMICs). Products are supplied in LMICs and LICs and made available at affordable prices through Sanofi's Global Health Unit, which is also committed to strengthening health systems. As part of this strategy, the company engages with international partners to reduce margins and the number of intermediates within the supply chain and has launched second brands of 3 of these products at a lower price (including one launch expected in 2024). The company reports on the outcomes of the LMIC and LIC strategies at an aggregated level, but no information was shared on the outcomes of the strategies in UMICs.

Sanofi publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all least-developed countries and LICs, and several LMICs and UMICs. The list of countries to which the commitment applies is publicly available.

Publicly discloses patent status of some prod ucts for countries in scope. Sanofi publishes the patent status of its vaccines and its products on the WHO Model List of Essential Medicines via its website.

Sanofi does not engage in non-exclusive volun tary licensing for products in scope.

Three of the five manufacturing capacity building initiatives included for analysis meet all GPS. For example, Sanofi is transferring technology to South African manufacturer Biovac to formulate, fill and finish and package it's inactivated poliomyelitis vaccine. The partnership serves to support Biovac's manufacturing capacity in, for example, aseptic filling processes.

Two of the four supply chain capacity building initiatives included for analysis meet all GPS. For example, the Sanofi Global Health Unit and the ministry of health in Tanzania are working on an initiative that aims to improve supply man agement of non-communicable disease (NCD) medicines. The partners are building capacity of health facility staff through a codeveloped train ing curriculum.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initia tive, the Sanofi Global Health Unit partners with the Organization for Public Health Interventions and Development in Zimbabwe to offer compre hensive NCD services to adults, including at-risk people living with HIV.

Medicines for Malaria Venture to accelerate dis covery of a novel malaria treatment. However, the company has not engaged in new agreements during the period of analysis.

Fulfils most criteria for ad hoc donations. Sanofi has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure dona tions reach patients. For example, in 2023, Sanofi's Foundation S responded to aid requests from Direct Relief, by donating 600,000 kits of enoxaparin (Clexane®) to crisis inflicted Sri Lanka. However, the company does not make public commitments to adhere to the most recent WHO Guidelines for Medicine Donations.

Sanofi publicly commits to continue long-term donation programme to support the elimination of human African trypanosomiasis. Its programme is active in 21 countries in scope, with the company pledging to donate pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole Winthrop®) to achieve goals highlighted by the WHO for elimination of human African trypanosomiasis.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Sanofi is transferring technology to Egyptian manu facturer Minapharm Pharmaceuticals for its anticoagulant enoxaparin (Clexane®). Minapharm will perform full manufacturing and supply to the Egyptian market.

Sanofi has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 7 days and to WHO Rapid Alert depending on local regulations. The company does not provide evidence of shortened report ing timeframes for cases that only require visual inspection for confirmation.

Sanofi operates an inclusive business model that covers 30** products in 40 LMICs, includ ing 35 LICs and/or least developed countries. The Sanofi Global Health Unit (GHU), launched in April 2021, offers reduced prices for a selection of essential medicines, including those for cardi ovascular disease, diabetes, malaria, and cancers. Sanofi collaborates with local health authorities and care providers to train health care professionals, raise disease awareness, and cultivate sustainable healthcare systems. So far, Sanofi has made products available in 38 coun tries in scope.

Sanofi remains engaged in existing IP-sharing agreements with drug discovery initiatives to accelerate drug development. In 2020, Sanofi

medicines, with all 4 products nationally shared its SAR441121/MMV533 compound with

**One hyperthyroidism treatment is not in scope.

RANK	SCORE
9	3.16

7 (2022)

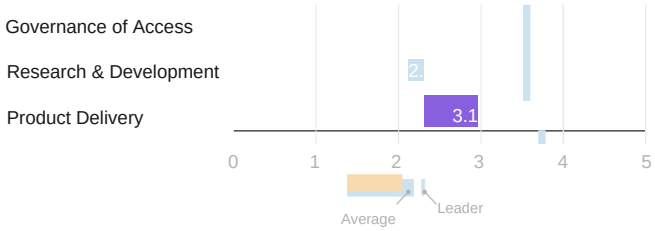
Takeda Pharmaceutical Co. Ltd

Stock exchange: NYSE • Ticker: TAK • HQ: Tokyo, Japan • Employees: 47,347

PERFORMANCE IN THE 2024 INDEX

9th place. Takeda ranks in the top ten, performing above average across the three technical areas: Governance of Access, Research & Development and Product Delivery. The company demonstrates Best Practice in Product Delivery for transferring technology for end-to-end vaccine manufacturing.

How score was achieved



OPPORTUNITIES FOR TAKEDA

Broaden the geographic reach of access plans to include more low- and lower-middle-income countries. Takeda has comprehensive access plans in place for all its late-stage R&D candidates. These plans focus primarily on upper-middle-income countries. It can expand these plans to include more low- and middle-income countries within scope, in particular those with a high burden of disease.

Expand access to its oncology products. Takeda has access strategies for its oncology medicines, including on-patent products brentuximab vedotin (Adcetris®), indicated for non-Hodgkin lymphoma, and brigatinib (Alunbrig®), indicated for lung cancer, in upper-middle-income countries and lower-middle-income countries. The company can increase access in low-income countries and improve the affordability of these medicines through increasing registration and/or implementing equitable access strategies.

CHANGES SINCE THE 2022 INDEX

Expand access to its dengue vaccine QDENGA® (TAK-003).

Takeda's dengue vaccine was approved in 2022 and is currently registered in six countries in scope. In 2024, the World Health Organization recommended the use of QDENGA® (TAK-003) in children aged 6-16 years in settings with high dengue transmission intensity. In line with this recommendation, Takeda can expand access to the vaccine in countries where dengue is endemic, through increased registration, equitable access strategies and/or supranational procurement mechanisms.

- Launched dengue fever vaccine QDENGA® in multiple LMICs and achieved WHO prequalification to facilitate its potential procurement by UN agencies, including UNICEF and the Pan American Health Organization (PAHO).
- Engaged in a technology transfer agreement with Biological E. Limited to manufacture and supply up to 50mn doses annually of its dengue vaccine, QDENGA®.
- Evolved its integrated business approach for access to medicines (ATM) in LMICs with the
- Integrated access metrics within the Corporate Philosophy metrics in its Annual Integrated Report and increased the publication frequency of its Access to Medicines Progress Report from bi-annual to annual.
- Announced five new partnerships in its global corporate social responsibility programme to strengthen health systems in LMICs, aiming

establishment of ATM Units and implemented these units in six countries in scope of the Index, with a focus on oncology, rare diseases and gastroenterology products.

to reach 25.2 million people in 92 countries by 2028.

Takeda Pharmaceutical Co, Ltd

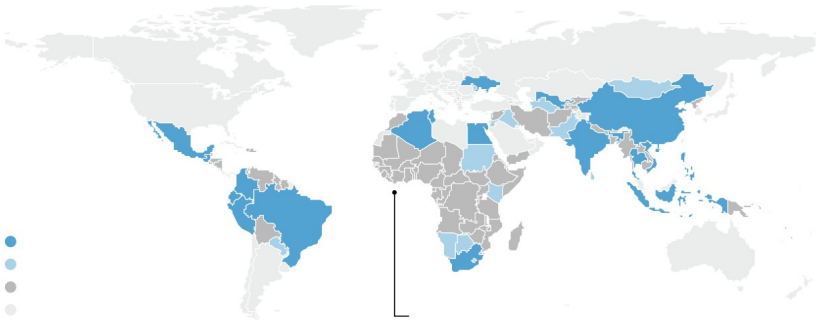
SALES AND OPERATIONS

Therapeutic areas: Gastroenterology, neuroscience, oncology, plasma-derived therapies, rare diseases
Product categories: Innovative medicines, vaccines

M&A news: Takeda acquired Nimbus Lakshimi Inc. for USD 6bn in 2023.

Revenue by segment (2023) – in JPY

Pharmaceuticals	4,263.76 bn



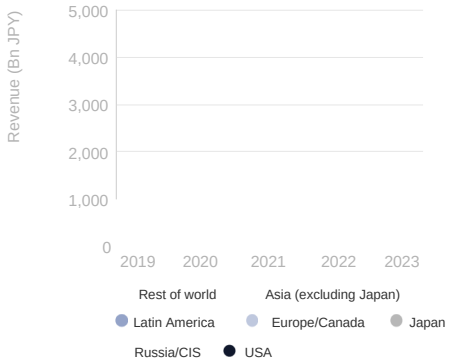
Total	4,263.76 bn

Sales in countries in scope

In scope, has sales offices
In scope, any sales
In scope, no sales
Not in scope

Takeda's products are sold in 33 out of 113 countries in scope of the Index. Takeda has sales offices in 19 countries and sells via suppliers and/or pooled procurement in an additional 14 countries.

Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE *for diseases in scope*

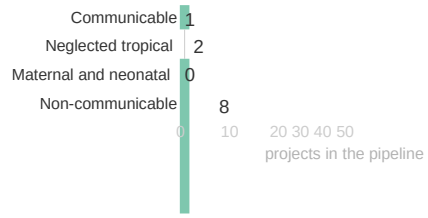
Takeda has 11 R&D projects in scope, 3 of which target priority diseases, focusing on Chagas disease and leishmaniasis (1), dengue (1) and malaria (1). The remaining 8 projects target other diseases in scope, including cancer (5). Of the 11 R&D projects, 3 are in late-stage development, with evidence of access planning for 100% (3/3) of these.

PORTFOLIO *as selected for analysis by the Index*

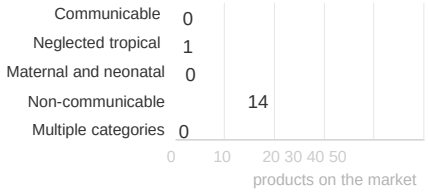
Takeda has 15 products in scope, including 14 medicines and 1 vaccine for the prevention of the neglected tropical disease, dengue fever. Four of its products are listed on the WHO EML and 11 medicines are on patent.

Takeda's medicines are all indicated for non-communicable diseases, namely cancer (6), diabetes (4) and cardiovascular diseases (3).

11 projects in the pipeline



15 products in the portfolio



Breakdown of projects

		Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Discovery									
Targets established R&D priorities	1	1	0	0	0	0	1	0	3
with access plan				0	0	0	1		1
Other projects in scope			6	0	1	0	1	0	8
with access plan				0	1	0	1		2

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Total
Medicines *on patent*	0	11		11
off patent	3	0		3
Vaccines	1	0		1
Contraceptives	0	0		0
Diagnostics		0		0
Other			0	0

Takeda Pharmaceutical Co, Ltd

GOVERNANCE OF ACCESS RANK 7 SCORE 4.16

7th place. Takeda performs above average in this Technical Area. The company has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as well as direct board-level responsibility for access. Takeda does not set individual-level targets for its sales agents; rather, targets are assessed collectively at a team level. It also has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies directly with the Board, namely the CEO of the Takeda Executive Team. Takeda incentivises its senior executives and in-country managers in its Growth and Emerging Markets units to act on access to medicine with financial and non-financial targets. The CEO has long-term access-related incentives.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Takeda publicly discloses its commitments to access to medicine, along with company-specific targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available, and updated regularly in its Annual Integrated Report.

rather, targets are assessed collectively at team level, and incentives are not solely based on sales volume. Takeda commits to ensuring ethical interactions with healthcare professionals in its code of conduct. It also declares that transfers of value to healthcare professionals (e.g., payments for ad-hoc consulting) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Takeda performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk

breaches in countries in scope were found in the period of analysis.

Takeda publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Takeda states that compulsory licensing is not a sustainable solution for addressing challenges in accessing medicines.

Fulfils some criteria with its process for measuring and reporting the patient reach of its affordability-based patient assistance programmes (PAPs). For this process, which covers some of its products and some countries in scope of the Index, Takeda publicly provides the underlying equation, metrics, assumptions and limitations. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

Shows comparatively strong commitment to responsible business practices. Takeda does not set individual-level targets for sales agents;

assessments and region or country risk-based assessments. Takeda also has an ethical decision-making framework for employees. No

RESEARCH & DEVELOPMENT

RANK 10 SCORE 2.63

10th place. Takeda performs above average in this Technical Area. It has an access planning framework and publicly commits to access planning from Phase II onwards, applying this to all late-stage pipeline candidates. It has a mixed pipeline, with projects targeting both priority and non-communicable diseases, although the number of priority projects has fallen. Some access plans are comprehensive, although often focused on a small number of countries, mainly UMICs. Takeda does not disclose disaggregated R&D investment data, but it performs strongly in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public com mitment addressing its systematic approach to access planning for LMICs.

includes multiple components, among others, a tech transfer manufacturing agreement, equitable pricing plans and WHO prequalification.

Small-sized pipeline, compared to peers, addressing other diseases in scope, with 100% (2/2) of late-stage projects covered by

Takeda does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

All 5 R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). For example, Takeda builds R&D capacity in Asia and Africa by educating, supporting and funding local researchers in their knowledge and securing follow-up funding for research gaps.

Small-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (1/1) of the late-stage candidates. Priority R&D pipe line of 3 projects, including 1 late-stage project that targets a priority gap. The company focuses on various priority areas, including Chagas dis ease, leishmaniasis and dengue. Takeda's 1 late-stage project targeting a priority product gap has evidence of an access plan in place and access plans. The company has 2 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer. Takeda provides evidence of access plans for both of its late-stage projects, including registration preparation, post-trial access and the inclusion of special populations in clinical trials.

Takeda Pharmaceutical Co, Ltd

PRODUCT DELIVERY

RANK 11 SCORE 3.17

11th place. Takeda performs above average in this Technical Area. The company has access strategies in place for its products; however, these are limited to upper-middle and lower-middle-income countries. It reports data on the outcomes of these strategies. The company did not engage in new intellectual property sharing agreements during the period of analysis. All its supply chain and health system strengthening initiatives meet all Good Practice Standards.

Takeda registers newer products* in 6 countries in scope on average. It registers 44% of products assessed in at least 1 of the 10 countries with the highest disease burden; only 1 product is registered in LICs. The company's brentuximab vedotin (Adcetris®), indicated for non-Hodgkin lymphoma, is most widely registered, totalling 19 countries in scope. The company reports engaging in mechanisms to facilitate registration, for example, the European Medicines Agency EU-M4all (former Article 58).

Takeda is not eligible for assessment of supra national access strategies because it has no products in scope that are supranationally procured.

Access strategies for its healthcare practitioner (HCP)-administered products in some countries, with outcomes tracked and reported. For the 3 products analysed, Takeda provides access strategy examples in UMICs and one example in an LMIC but not in any LICs. The strategies are comprehensive, and the company shows some efforts to consider different payers' ability to pay. For example, for 2 of its products Takeda has achieved or works towards public reimbursement in Thailand (UMIC) and the Philippines (LMIC). Health system strengthening initiatives are also reported as part of the strategies for these products. The company supplies its dengue vaccine (QDENGA®) through the public health system in Brazil (UMIC). The company also reported on several metrics that are monitored to track the strategy and has measurable goals for providing access in additional countries subject to approval. In addition, for the other strategies, Takeda provides patient reach data and some details on the approaches applied to measure the strategies' outcomes.

Provides evidence of access strategies for self-administered products in some countries, supported by information on outcomes. For 3 of the 4 products selected for analysis, Takeda provides access strategy examples in UMICs and for only one of them also an LMIC example. The company supplies the fourth product products the company is working towards national reimbursement in Thailand (UMIC); in the interim Takeda has offered an affordability-based patient assistance programme (PAP) to support patients' costs. For the same product, different PAPs are also implemented in the Philippines (LMIC), where the company offers a fixed-scheme co-payment support, or an affordability-based PAP based on the individual patient's ability to pay. Takeda shares plans to advance its strategies and reports on the patients reached, as well as the approaches used to track the strategies' outcomes.

Takeda publicly commits not to file for or enforce patents for all products in least developed countries and LICs.

Publicly discloses product patent status for countries in scope. Like most peers, Takeda publicly discloses patent information for small molecules in scope via the Pat-INFORMED data base, including information such as filing date, grant number, grant date and jurisdiction.

Takeda does not engage in non-exclusive voluntary licensing for products in scope.

Both manufacturing capacity building initiatives included for analysis meet all GPS. For example, Takeda is supporting Brazilian manufacturer Hemobras to build its infrastructure and biologics manufacturing capacity through a technology transfer initiative. Takeda is investing USD 250mn in the construction of a new manufacturing facility for the partner.

All 5 supply chain capacity building initiatives included for analysis meet all GPS. For example, through the Blueprint for Innovative Healthcare Access, Takeda and BIO Ventures for Global Health aim to improve cancer drug access in Nigeria by enhancing procurement processes, forecasting to stabilise supply and tracking shipments to the patient.

All 5 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Takeda is supporting IntraHealth International to

Takeda remains engaged in an existing IP-sharing agreement with a drug discovery - initiative. The company shares IP assets through the Corona Accelerated R&D in Europe, which aims to deliver new coronaviral products.

However, Takeda has not entered into any new agreements during the period of analysis.

Fulfils most criteria for ad hoc donations. Takeda has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in May 2023, Takeda responded to aid requests from Direct Relief, by donating medicines to Ukraine. The donation comprised 77,000 bottles of 11 products, including 1 product in scope, lanthanum carbonate (Fosrenol®). Takeda reports that it adheres to the most recent WHO Guidelines for Medicine Donations. However, it has not made a public commitment to doing so.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Takeda is transferring technology for full manufacturing of its dengue tetravalent vaccine (live, attenuated) (QDENGA®) to Biological E. Limited. Biological E. Limited will make the vaccine available in endemic countries, potentially through organisations such as Gavi, the Vaccine Alliance (Gavi) and the Pan American Health Organization (PAHO).

Takeda has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to national or local regulatory authorities within 7 days. The company provides evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation.

Takeda operates an inclusive business model that covers 6 countries in scope and offers 2 products. Launched in 2023, and evolving from a previous model, Takeda's Access to Medicine Units (ATMUs) operate in countries, such as Thailand and Vietnam alongside regular business units. ATMUs focus on expanding for patients and receive temporary relief on profitability targets, allowing for reinvestment of revenues. The model includes oncology products, brentuximab vedotin (Adcetris®) and brigatinib (Alunbrig®), and plans to expand the disease scope to include rare and neurological diseases.

included in the analysis – ponatinib (Iclusig®) – as a donation via the Max Foundation in all 3 country income classification examples. In the strategies analysed, Takeda demonstrates efforts in improving the availability and affordability of its products. For example, for one of its oncology

*Products that received their first marketing authorisation within the last 5 years.

improve maternal and child healthcare for rural populations in Mali, Niger and Senegal through improving quality education for nurses and mid wives. To date 3,073 students, faculty, and staff across the 3 countries developed new or enhanced healthcare skills and knowledge.

APPENDICES

APPENDIX I

Key parameters for evaluation

PIPELINE AND PORTFOLIO

Inclusion process for R&D pipeline and product portfolio The Index team reviewed both projects in companies' R&D pipelines and marketed products, prior to including them for

approved as a monotherapy for one form of leukaemia before the period of analysis, further projects for the development of this medicine as a monotherapy for another form of leukaemia, or in combination with another medicine that had also previously been approved for leukaemia,

analysis. This review ensured that projects and products were within the scope of the 2024 Index and met relevant inclusion criteria.

Furthermore, before scoring and analysis began, companies' R&D projects and marketed products were updated against public sources of information to ensure that the most up-to-date and accurate pipelines and portfolios were represented. Companies were given the opportunity to verify the content of pipelines and portfolios.

would be excluded.

2. If a medicine that had previously been approved for a specific cancer type is being developed for the same cancer

Inclusion criteria for R&D pipeline projects

Projects that target a disease, condition or pathogen within the disease scope of the Index (see Appendix II) and belong to a product type in scope (as detailed below) were included in the pipeline if they fell into one of the following categories: • Projects targeting a priority R&D product gap identified by Impact Global Health (formerly known as Policy

type, but in combination with a medicine that has not yet received an approval for treating this cancer type, the project was included. Where multiple projects were ongoing for a single cancer type and the medicine(s) had not yet been approved for this cancer type, the latest stage of development was included. Projects were pre-populated and clustered by multiple group indications if these indications were being examined together within the same clinical trial(s). For example, a Phase II trial of a medicine for patients with breast, lung and colorectal cancer was counted as one project for all three cancer types. However, if a new chemical or biological entity was being tested in a Phase II trial for breast cancer only and in a Phase II trial for colorectal cancer only, these projects were listed separately.

- Clinical-stage projects that do not target a priority R&D product gap identified by Impact Global Health and/or WHO but do target a disease, condition or pathogen within the scope of the Index.

Cures Research) and/or WHO, regardless of the stage of development.

Inclusion criteria for product portfolio

Approved products targeting a disease, condition or pathogen listed in the disease scope (see Appendix II) were included in the portfolio under several conditions:

- Collaborative projects in which companies continued to actively contribute resources and expertise, and had com mercialisation rights in countries in scope during the period of analysis.

The six lists that the Index used to determine priority R&D product gaps are:

- WHO Priority Pathogen List (2017)[1]
- WHO Preferred Product Characteristics (2010)[2]
- Medicines that are:
  - ▶ Patented; OR
  - ▶ Off-patent and listed on the 2023 WHO Model List of Essential Medicines (EML)[7] AND where it was deter mined that companies had significant ability to shape the market; OR
- WHO Prioritizing diseases for R&D in emergency contexts[3]• Impact Global Health G-FINDER emerging infectious dis

▶ Off-patent and not listed on the 2023 WHO EML, but listed as a first- or second-line treatment for a disease in scope by one of the five sets of guidelines (WHO, Centers for Disease Control (CDC), National Institute for Health and Care Excellence (NICE), National Comprehensive

eases (2024)[4]

Impact Global Health G-FINDER sexual & reproductive health (2024)[5]

Impact Global Health G-FINDER neglected diseases (2024)[6]

Cancer Network (NCCN), European Society for Medical • Oncology (ESMO)) used by the Index team AND where it was determined that companies had significant ability to • shape the market;

- To determine where companies had significant ability

Inclusion criteria for cancer projects in the R&D pipeline

1. For cancer projects, R&D projects were included only if they contained a chemical or biological entity that had not previously been approved for a given cancer type before the period of analysis. For example, if a medicine had been

to shape the market, the Index team used IQVIA MIDAS data. Market dominance was defined for products under the following conditions:

» Products with a mean and/or median number of manufacturers <4.0 in a set of ten representative

low- and middle-income countries (LMICs: Brazil, China, Egypt, India, Mexico, Morocco, Philippines,

Therapeutic vaccines

Covers vaccines intended to treat existing infections or diseases.

Preventive vaccines

South Africa, Tunisia and Vietnam), per IQVIA MIDAS data; OR

» Where a listed company has >70% of the market share in these countries by volume of sales, per IQVIA MIDAS data.

Covers vaccines intended to prevent infections.

- Diagnostics listed on the 2023 WHO Model List of Essential *Diagnostics*
  In Vitro Diagnostics.[8]
- All vaccines, vector control products and platform technol

Covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable and easier to use in the field).

ogies used for diseases in scope.

Determining patent status

Patent status was determined through a process of external research combined with verification from participating companies. The outcome of this process helped determine which products were included in companies' product portfolios, and consequently assessed as part of the Index (see 'Inclusion criteria for product portfolio').

This process was developed in consultation with experts from diverse constituencies. Patent status was first researched through the related regulatory authority websites (i.e., South Africa's CIPC Intellectual Property database[9], the US FDA Orange Book[10], Health Canada[11]) and/or patent databases (MedsPaL[12] and Pat-INFORMED[13]), and later verified with companies. The Index clarifies that, for the patent status in South Africa, if the information was not available, the Index looked at the status in the US and in some cases (e.g., for biologics) in Canada. However, this is not intended to be a presentation of patent rights worldwide, nor does it capture all patents that might apply to a product. It is therefore reasonable to assume that this Index may underreport where patents are in place. It should only be used as a proxy description and cannot be used as an indication of patent status outside of South Africa and/or the US and Canada. In some instances, the patent status of a particular product was identified as off-patent in South Africa, the US or Canada but on-patent in other jurisdictions.

Vector control products

Product types in scope

The product scope used in the 2024 Access to Medicine Index is deliberately broad in order to capture the wide-ranging product types available to support the prevention, diagnosis and treatment of relevant conditions and diseases in the 113 countries covered by the Index.

Includes pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for global public health use and specifically aimed at inhibiting and killing vectors that transmit diseases in scope of the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmitting diseases in scope of the Index are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Contraceptive methods & devices
This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

Platform technologies
Only platform technologies specifically directed at meeting the needs of people living in the countries covered by the Index are included. These comprise, for example, general diagnostic platforms, adjuvants, immunomodulators and delivery technologies and devices. Implants and platform technologies for reproductive health are also included in this category.
Platform technologies that have utility for accelerating the development of health products for 'Disease X', a term used by WHO to refer to currently unknown pathogens that could cause a serious international epidemic, are also included.

Determining countries with high disease burdens
• The Index considers in which of the countries in scope each company has registered its ten most newly approved products. The Index used data from the Institute for Health provided they meet inclusion criteria. Medicines used only for symptomatic relief are not included.

Medicines
All medicines (both patented and non-patented) that directly treat a target pathogen or disease process in scope are included,

Metrics and Evaluation's (IHME) 2019 Global Burden of Disease study (GBD)[14] to determine which countries in scope have the highest burden of disease. Countries in which companies have filed for registration were compared to the ten countries in scope with the highest burden of disease for the main indication of that product.

- For products with multiple indications, the total burden of all indications combined was used to determine which

Microbicides

Includes topical microbicides specifically intended to prevent HIV.

countries had the highest burden of disease.
• Since only one country in scope of the Index, Kosovo, was not in the IHME 2019 GBD database, this country was not considered in the analysis for indicators related to the GBD.

• Access strategies: Supranational products (PP3)
• Access strategy quality/outcomes: Healthcare practitioner-administered products (PP4a/b)
• Quality and geographic coverage of access-oriented licens ing (PPL4)
  • Global burden of disease was not considered for the follow ing indications:
    ▶ COVID-19 (no IHME GBD data, 2019)
    ▶ Contraceptive methods (no IHME GBD data, 2019)

SCORING

Companies were assessed and scored by the Index in three Technical Areas: Governance of Access, Research & Development and Product Delivery, with each area composed of several indicators. Analysis was carried out using a wide range of sources including data submitted by the companies themselves, independent reports and databases or documents from WHO, other multilateral organisations and

REVIEW PROCESS

Following clarification with companies, cross-check of company scores and consultation with experts, the Index team wrote the various sections of the Index report. The company

report cards were fact checked by companies and confidential information was requested to be lifted for publication. Global health experts provided reviews on each Technical Area analysed in the Index. Following internal review by the Foundation's management team, the entire Index was reviewed by the Chair of the Expert Review Committee (ERC), Professor Hans Hogerzeil.

non-governmental organisations. Public data sources, including information shared on company websites, in annual reports and through local health authorities, helped to triangulate data. The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process, beginning with scoring per company by the analyst during the first round of the data collection period, followed by re-scoring after companies have provided further clarification in areas identified by the analyst.

This was followed by verification by the analyst, including an extensive quantitative and qualitative check of each indicator for each company. The research manager(s) performed a quality assurance check on all scores to ensure consistency, with senior management performing a final spot-check. Each analyst then cross-checked their Technical Area

METHODOLOGY LIMITATIONS

Limitations exist in every study of this design. Significant limitations specific to this study are discussed here. These and other methodological limitations will be considered in the methodology review for the 2026 Access to Medicine Index.

Disease, product scopes and country comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scopes, as determined by the ERC during the methodology review process and as published in the Access to Medicine Index Methodology 2024. The limitations of this approach include:

- products to be assessed under an indicator or to avoid double negative marking of a company for the lack of a policy,

ranking, before the final ranking was cross-checked and veri fied by the data coordinator and research managers(s).

Neutral scoring protocol

Neutral scoring is used when a company does not have relevant

• Although the Foundation recognises that all products, diseases, countries, access and product initiatives are not the same, in most Technical Areas in this study they are generally treated equally. For example, in R&D, nearly all compounds are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy.

strategy, programme or initiative that has already negatively impacted the score, and the company cannot meet the additional expectations. For example, when a company has no priority R&D projects in their pipeline, it is assessed for scoring in the relevant R&D indicator (RD1a). In such cases, for the indicator on access plans for priority R&D projects (RD3a), the company receives a neutral score since it has no such projects in its pipeline. In that case, a proxy measure is identified for that indicator. The proxy measure includes the average score of the company across all indicators in the three Technical Areas.

In 2024, neutral scoring was applied with the following

- In access strategies, for indicators PP3, PP4a/b and PP5a/b, a maximum of five products were evaluated per company. These products were identified using criteria such as patent status (on- or off-patent), inclusion on the EML, clinical guidelines and consultation with global health stakeholders. Companies received an opportunity to verify and adjust as appropriate.
- For all four types of capacity building, PCB1, PCB2, PCB3 and RD6, companies could submit a maximum of five initiatives to be considered for analysis. This means that our analysis is not able to capture an overview of involvement in capacity building but instead an evaluation of the quality areas:

- Planning for access: Project-specific plans for prioritised diseases (RD3a)
- Access strategies: Long-term donation programmes (PP2b)

of selected examples.

Longitudinal comparability

Comparability between companies over successive Indexes is not always possible or appropriate, especially when the scoring criteria of an indicator have been refined. During the period of analysis, where trend analysis was useful, the Index team compared raw data from past Indexes with raw data from 2024.

Company comparability

The objective of the Index is to produce a standardised rela tive ranking of the 20 companies' access-to-medicine perfor mances. However, not all companies are the same. Some have large portfolios and pipelines. Some have a comparatively nar row disease focus. Some have a comparatively narrow scope of country operations. Others have generic pharmaceutical subsidiaries. Companies differ in size, geographical reach and capability for recording and reporting information. The Index uses various methods to correct for these variations between companies. In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process, and the analytical parameters for each indicator were clearly outlined during the data collection process. In addition, a clarification round was carried out, giving companies an opportunity to provide addi tional data where there were gaps, inconsistencies or where clarifications were necessary.

In several indicators that measure quantitative elements, in general, the Index makes adjustments for company size. In the case of some R&D indicators in this Index, the company's pipeline size was used as an additional differentiator to group companies together, so that both large and small companies' performances were scored relative to peers of similar size.

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APPENDIX II

Disease scope

DISEASES IN SCOPE OF THE 2024 ACCESS TO MEDICINE INDEX

Diseases are included based on their burden of disability-adjusted life years (DALYs) in countries in scope[1], WHO classifications and the relevance of pharmaceutical interventions. The disease scope for the 2024 Access to Medicine Index has decreased from 83 to 81 diseases, conditions and pathogens, due to the combination of hypertensive heart disease, ischaemic heart disease and stroke into the broader category of cardiovascular diseases.

TABLE 1 Diseases, conditions and pathogens (81) in scope of the 2024 Access to Medicine Index

Communicable Diseases (23 + 12 priority pathogens*)	Non-Communicable Diseases (16)	Neglected tropical diseases (20)	Reproductive, maternal and newborn health conditions (10)
Arenaviral haemorrhagic fevers	Alzheimer's disease	Buruli ulcer	Abortion and miscarriage
Bunyaviral diseases	Anxiety disorders	Chagas disease	Birth asphyxia and birth trauma
Coronaviral diseases	Asthma	Dengue and Chikungunya	Contraceptive methods
Diphtheria	Bipolar affective disorder	Dracunculiasis	Hypertensive disorders of pregnancy
Disease X**	Cancer†	Echinococcosis	Maternal haemorrhage
Emergent non-polio enteroviruses	Cardiovascular diseases	Food-borne trematodiases	Maternal sepsis
Enteric infections	Chronic obstructive pulmonary disease (COPD)	Human African trypanosomiasis	Neonatal sepsis and infections
Filoviral diseases	Depressive disorders	Leishmaniasis	Obstructed labour
Henipaviral diseases	Diabetes mellitus	Leprosy	Other neonatal conditions
HIV/AIDS	Endometriosis	Lymphatic filariasis	Preterm birth complications
Leptospirosis	Epilepsy	Mycetoma, chromoblastomycosis and other deep mycoses	
Lower respiratory infections	Kidney diseases	Onchocerciasis	
Malaria	Migraine	Rabies	
Measles	Schizophrenia	Scabies and other ectoparasites	
Meningitis	Sickle cell disease	Schistosomiasis	
Other prioritised antibacterial-resistant infections (12)*	Thalassemia	Snakebite envenoming	
Pertussis		Soil-transmitted helminthiasis	
Rheumatic fever		Taeniasis/cysticercosis	
Sexually transmitted infections (STIs)***		Trachoma	
Tetanus		Yaws and other endemic treponematosis	
Tuberculosis			
Viral hepatitis (B and C)			
Yellow fever			
Zika			

Blue text = Newly in scope for 2024 Access to Medicine Index

**Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious international epidemic.

***Excludes HIV/AIDS.

†Includes 19 cancer types. See p.212 for more details.

*These are collectively referred to as "Other prioritised antibacterial-resistant infections" in the 2024 Access to Medicine Index and categorised as one disease under communicable diseases:

- *Acinetobacter baumannii* (carbapenem-resistant)
- *Campylobacter spp.* (fluoroquinolone-resistant)
- *Enterobacteriaceae* (carbapenem-resistant, 3rd generation cephalosporin-resistant)
- *Enterococcus faecium* (vancomycin-resistant)
- *Haemophilus influenzae* (ampicillin-resistant)
- *Helicobacter pylori* (clarithromycin-resistant)
- *Neisseria gonorrhoeae* (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)
- *Pseudomonas aeruginosa* (carbapenem-resistant)
- *Salmonella spp.* (fluoroquinolone-resistant)
- *Shigella spp.* (fluoroquinolone-resistant)
- *Staphylococcus aureus* (methicillin-resistant, vancomycin-intermediate and vancomycin-resistant)
- *Streptococcus pneumoniae* (penicillin-non-susceptible)

Abbreviations: AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus; spp = species; WHO = World Health Organization

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CANCERS IN SCOPE OF THE 2024 ACCESS TO MEDICINE INDEX

Cancer remains in scope of the 2024 Access to Medicine Index, with the retainment of the 19 cancer types included in the 2022 Index. The latest data on cancer incidence did not show evidence that additional cancer types should be included. As with previous Indexes, products for the management of pain and supportive treatments (e.g., antiemetics) are not included.

TABLE 2 Cancer types (19) in scope of the 2024 Access to Medicine Index

Cancer types in scope (19)*
Bladder
Brain, nervous system
Breast
Cervical
Colorectal
Gallbladder
Head and neck**
Kaposi sarcoma
Leukaemia
Liver
Lung
Non-Hodgkin lymphoma
Oesophageal
Osteosarcoma
Ovarian
Prostate
Stomach
Thyroid
Uterine

*The 19 cancer types are collectively counted as one non-communicable disease.
**Includes all head and neck cancers in GLOBOCAN 2020: nasopharynx, lip, oral cavity, salivary glands, larynx, oropharynx and hypopharynx cancer.

APPENDIX III

Indicators and scoring guidelines

A GOVERNANCE OF ACCESS 15%		
Indicator		
GA1	Governance structures and incentives The company has a governance system that includes direct board-level responsibility and accountability for its access-to-medicine initiatives. To facilitate effective implementation of the strategy, senior management (i.e., CEO and/or senior executives) and in-country operational managers have access-to-medicine objectives and incentives to reward the effective delivery of initiatives that improve	5 The company has a clear access-to-medicine strategy with access to medicine in countries, and for diseases, in scope of the Index. 5 The company has a board member or board-level committee directly responsible for its access-to-medicine approach. Its

evidence of integration with the corporate strategy. The strategy is applied across the company's portfolio and pipeline, within the Index scope. As part of its access-to-medicine strategy, the company publicly and clearly discloses its commitments to access to medicine, alongside company-specific measurable goals, objectives and targets. The associated outcomes for all initiatives related to improving access to medicine are clearly reported (or the company plans to report outcomes when available). This is done regularly, and to facilitate accountability and transparency, is centrally available directly on its website.

CEO and/or senior executives have long-term access-related objectives and incentives. Its regional and/or in-country managers also have objectives and incentives to improve access in countries in scope of the Index.

4 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. Its CEO and/or senior executives have access-related objectives and incentives. Its regional and/or in-country managers also have objectives and incentives to improve access in countries in scope of the Index.

3 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. There is evidence of access-related incentives in place at a CEO/executive level or regional/in-country managers level in countries in scope of the Index.

2 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level.

0 The company has no board or executive level responsibility for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level in countries in scope of the Index.

4 The company has an access-to-medicine strategy that is integrated with its corporate strategy and applies to all or some of its portfolio and pipeline. The company publicly discloses its commitments to access to medicine, including at least one company-specific target, goal or objective. While not all of the goals may be measurable, the company demonstrates an effort towards specificity and measurability. The company reports on the associated outcomes, although the reporting may not be regular or fully centralised.

3 The company has an access-to-medicine strategy that is integrated with its corporate strategy and applies to all or some of its portfolio and pipeline. As part of its access-to-medicine strategy, the company publicly discloses its commitments to access to medicine, as well targets, goals, objectives and outcomes (or plans to report outcomes when available), but not for all initiatives in which it is involved. Reporting may not be centralised or updated regularly.

2 The company has an access-to-medicine strategy with a business rationale which applies to all or some of its portfolio and pipeline. As part of its access-to-medicine strategy, the company publicly discloses its commitments to access to medicine, as well as access to medicine targets, goals, objectives and outcomes (or plans to report outcomes when available),

GA2 Access-to-medicine strategy and outcomes

The company has an access-to-medicine strategy which it demonstrates is integrated within its corporate strategy and

but not for all initiatives in which it is involved. Reporting may not be centralised or updated regularly.

1 The company has made commitments to improve access to

extends across the company’s portfolio and pipeline, for diseases within scope of the Index. As part of the company's access-to-medicine strategy, it establishes and publicly shares progress on time-bound, measurable objectives, goals and targets related to improving access to medicine in countries within scope of the Index, as well as associated outcomes.*

medicine but does not have an access-to-medicine strategy, although it may be in the process of implementing one.

0 The company has neither an access-to-medicine strategy, nor commitments for improving access to medicine.

*Results achieved by a company’s access-related activities. These can be short term (such as an increased proportion of people with more knowledge about

GA4	Responsible business practices The company incentivises responsible business practices by taking steps to decouple bonuses for sales agents* from sales volume targets only, evidencing that sales targets are not set at the individual level and that sales target bonuses represent a minimal portion of overall compensation. The company has a clear public policy to ensure ethical interactions with healthcare professionals (HCPs) which has provisions specifying	1	The company does not decouple bonuses for sales agents the legitimate need for the interaction and limiting transfers of value** in countries in scope of the Index. Additionally, the company publicly discloses information about such transfers of value in countries in scope of the Index, where this is permit

from sales volume targets, i.e. incentives for sales agents are driven (almost) exclusively by sales volume targets. The company has a statement on payments to HCPs but does not provide evidence of a public policy to ensure ethical interactions with HCPs that align with the standards set by the Index. It discloses information regarding transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

0 The company does not decouple bonuses for sales agents from sales volume targets, i.e. incentives for sales agents are driven (almost) exclusively by sales volume targets. The com

ted by law. pany does not have a statement on payments to HCPs nor

5 The company demonstrates that they have no sales targets set at the individual level. Bonuses for sales agents are decoupled from sales volume targets only, and sales target bonuses represent a minimal proportion of overall compensation. It has a public policy to ensure ethical interactions with HCPs and voluntarily discloses information regarding its approach

does it provide evidence of a public policy to ensure ethical interactions with HCPs that align with the standards set by the Index. It only refers to adhering to voluntary disclosure codes on payments to HCPs. It discloses information regarding transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

to, or actual, transfers of value to HCPs in all countries in scope of the Index, and not only when required by law, regulation or trade association.

4 The company demonstrates that they have no sales targets set at the individual level. Bonuses for sales agents are decoupled from sales volume targets only, and sales target bonuses represent less than half of overall compensation. It has a

*Including sales representative employees and third parties.
**Transfers could include payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary benefits directed at HCPs. Companies should have a process in place to determine the legitimate need for HCP interactions and to ensure fair market value at both payment per interaction level and cumulative/overall payments per HCP

public policy to ensure ethical interactions with HCPs and dis	**GA5**	Ethics, risk and compliance
closes information regarding its approach to, or actual, transfers of value to HCPs in countries in scope of the Index, but		only when required by law, regulation or trade association.

The company has one or more policies in place to mitigate the risk of non-compliance in its operations in low- and middle-income countries (LMICs) – including by affiliated third parties –

OR

covering areas such as ethical marketing, anti-corruption and

The company demonstrates that they have some sales targets set at the individual level. Bonuses for sales agents are decoupled from sales volume targets only, and sales target bonuses represent less than half of overall compensation. It has a public policy to ensure ethical interactions with HCPs and

voluntarily discloses information regarding its approach to, or actual, transfers of value to HCPs in some countries in scope of the Index, and not only when required by law, regula

clinical trials. The company also has country- or region-specific procedures* in place to operationalise the policies, taking into account country- or region-specific risks. In addition, the company has a policy or framework in place to guide and promote ethical decision-making among employees.

5 The company demonstrates that it has robust controls in place to mitigate the risk of non-compliance in its operations in countries in scope of the Index, which include the following components:

tion or trade association.

3 The company demonstrates that they have some sales targets set at the individual level, and bonuses for sales agents are decoupled from sales volume targets only. It has a public policy to ensure ethical interactions with HCPs and discloses

(a) one or more policies on ethical marketing, anti-corruption and clinical trial standards;

(b) formal processes in place to ensure third-party compliance with ethical marketing, anti-corruption and clinical trial standards;

information regarding its approach to, or actual, transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

2 The company demonstrates that they have some sales targets set at the individual level, and bonuses for sales agents are decoupled from sales volume targets only. It has a public policy to ensure ethical interactions with HCPs, but the policy does not fully align with the standards set by the Index. It discloses information regarding its approach to, or actual, trans

(c) fraud-specific risk assessment;

(d) country or region risk-based assessment;

(e) policy or framework that guides and promotes ethical decision-making among employees.

4 The company has four of the above-mentioned elements in place that align with the standards set by the Index.

3 The company has at least three of the above-mentioned elements in place that align with the standards set by the Index.

fers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

2 The company has at least two of the above-mentioned elements in place that align with the standards set by the Index.

3 The company has a publicly available statement or policy on IP and access to medicine. The policy/statement discloses a degree/measure of support for, and is partially in line with, the Doha Declaration and/or the use of the provisions of TRIPS flexibilities.

1 The company has at least one of the above-mentioned elements in place that align with the standards set by the Index.

1 The company has a publicly available policy or statement on IP and access to medicine, but this is not supportive of, or in line with, the Doha Declaration and/or the use of provisions

0 The company has no policies or procedures in place which are designed to mitigate risk of non-compliance in its operations in LMICs and, has no framework to guide ethical decision making.

*The Index looks for procedures such as fraud-specific risk assessment, -country risk-based assessments and processes to ensure third-party compliance.

of the TRIPS flexibilities.

0 The company has no publicly available statement or policy on IP and access to medicine.

GA6 Incidence of breaches

The company has not been found to be the subject of negative legal rulings or settled legal cases for unethical marketing practices, corrupt practices, anti-competitive practices or misconduct in clinical trials in countries within scope of the Index during the past two years. In the event of such a ruling or settlement, there is

GA8 Measuring and reporting patient reach

The company has a process in place for measuring patient reach that:

publicly available evidence that the company has taken reme

a) is publicly available in terms of underlying methodology (equation/metrics/assumptions/limitations);
b) extends across the company's portfolio, for diseases within

dial actions (including cooperation with authorities), and steps scope of the Index;
designed to ensure the breach does not occur in future.

5 The company has not been the subject of any settlements for
criminal, civil or regulatory infractions in countries within the scope
of the Index during the past two years (pending cases, allegations and cases under appeal are not included).

2 The company has been the subject of at least one negative

c) covers all countries within scope of the Index, where the com pany's products are sold;
d) regularly reports resulting patient reach numbers publicly; e) incorporates clear goals and objectives to measure and improve* patient reach and associated health outcomes over time, and can demonstrate such improvements.

ruling or settlement in a country within the scope of the Index

over the period of analysis. There is publicly available evidence of the company taking either robust remedial actions and/or steps designed to ensure the breach does not reoccur. 0 The company has been the subject of at least one negative ruling or settlement in a country within the scope of the Index over the period of analysis. There is no evidence of the company taking robust remedial actions or steps designed to ensure the breach does not reoccur.

5 The company has a process in place for measuring patient reach which: is publicly available in terms of underlying methodology (equation/metrics/assumptions/limitations); extends across the company's portfolio, for diseases within scope of the Index; covers all countries within scope of the Index, where the company's products are sold; regularly reports resulting patient reach numbers publicly; incorporates clear goals and objectives to measure and improve* patient reach and associated health outcomes over time, and can demonstrate such improvements.

GA7 Trade policy: Intellectual property and access to medicine

The company employs an intellectual property (IP) strategy conducive to creating access to medicine. This is in accordance with the rights of national governments to deploy IP systems flexibly, as defined by the international framework on IP (i.e., the Doha Declaration on the TRIPS Agreement and Public Health). This is evidenced by the company having a publicly available IP policy or statement which discloses explicit support for, and is in line with, the principles embodied within the Doha Declaration on TRIPS

4-1 The company has a process in place for measuring patient reach that meets a number of the following criteria:

a) is publicly available in terms of underlying methodology (equation/metrics/assumptions/limitations);

b) extends across the company's portfolio, for diseases within scope of the Index;

c) covers all countries within scope of the Index, where the company's products are sold;

and Public Health. d) regularly reports resulting patient reach numbers publicly;

5 The company has a publicly available statement or policy on IP and access to medicine. The policy/statement discloses explicit support for, and is in line with, the Doha Declaration, with no reservations expressed on any of the provisions of

e) incorporates clear goals and objectives to measure and improve* patient reach and associated health outcomes over time, and can demonstrate such improvements.

0 The company does not provide evidence (publicly or directly reported to the Index) of having a process in place for meas TRIPS flexibilities.

4 The company has a publicly available statement or policy on uring patient reach.

IP and access to medicine. The policy/statement discloses explicit support for, and is in line with, the Doha Declaration, though reservations can be expressed on some of the provi sions of TRIPS flexibilities.

*Improvement in patient reach does not necessarily mean an increase in patients receiving a product (for example, where the goal of a product is elimination of a disease).

RESEARCH & DEVELOPMENT (R&D) 30%

Indicator		
RD1a	R&D pipeline: Prioritised diseases The company engages in the development of products that target priority product gaps identified by global health research organi-	4 The company has a structured process in place and commits sations.* This includes innovative and adaptive R&D and in-house

to develop access plans during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product and collaborative R&D.

5-1 The total size of each company's 'priority R&D' pipeline within the scope of the Index that targets priority product gaps identified by WHO and/or Impact Global Health, scaled across all companies and scored. To assess companies' focus and progress in addressing critical health needs, reductions in companies' R&D priority pipelines (compared to the previous Index) are considered within the analysis.

0 The company has no projects within the scope of the Index in its R&D pipeline that target priority product gaps identified by WHO and/or Impact Global Health.

*Currently, the Index categorises R&D priorities using lists from WHO and Impact Global Health (formerly Policy Cures Research).

types, disease targets and target populations. Access plans are initiated no later than Phase II of development.

3 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations.

2 The company has a structured process in place to develop access plans for a subset of its R&D projects targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations.

RD1b R&D Pipeline: Other diseases

1 The company has a general process in place to include

The company engages in the development of products for other diseases in scope of the Index beyond the R&D priorities identi

access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.

	fied by global health research organisations.* This includes innova tive and adaptive R&D.	0	The company has no processes in place in this area or applies access planning on an ad hoc basis.
5-1	The total size of each company's pipeline that does not target R&D priorities identified by WHO and/or Impact Global Health, scaled across all companies and scored. To assess the industry's focus and progress in addressing unmet healthcare needs for diseases in scope, reductions in companies' R&D pipelines (compared to the previous Index) are considered	**RD3a**	Planning for access: Project-specific plans for prioritised diseases

The company ensures that all R&D projects for diseases prioritised by WHO and Impact Global Health are supported by detailed commitments and strategies to improve access to

within the analysis.

products in countries within scope of the Index.

0 The company has no projects within the scope of the Index in its R&D pipeline that target other diseases in scope of the Index

beyond the R&D priorities identified by WHO and

5-1 Scaled across all companies. The extent to which a company engages in access planning for its late-stage R&D projects targeting diseases prioritised by WHO and Impact Global Health. This is determined by:

- the proportion of late-stage candidates with access plans in place;
- the quality of access plans;
- the extent of the geographic reach of access plans.

*Currently, the Index categorises R&D priorities using lists from WHO and Impact Global Health.

RD2 Planning for access: Framework

The company ensures it plans for equitable access for all products it develops successfully (both in-house and collaboratively) for people in LMICs, and demonstrates a systematic approach to access for all R&D projects, which is applied from Phase II of clinical development onward. The company makes public commitments addressing its systematic approach to access planning

0 The company provides no evidence of access plans for any late-stage R&D projects for diseases prioritised by WHO and Impact Global Health within the scope of the Index.

NS The company has no late-stage projects within the scope of the Index in its R&D pipeline that target priority product gaps identified by WHO and/or Impact Global Health, as assessed under RD1a.

5 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations. Access plans are initiated no later than Phase II of development. The company makes public commitments addressing its systematic approach to access planning for LMICs.

RD3b Planning for access: Project-specific plans for other diseases

The company ensures that all its R&D projects targeting other diseases in scope of the Index (beyond those identified as R&D priorities by WHO and Impact Global Health) are supported by

RD6 Capacity building in R&D

detailed plans to improve access to products in countries within

The company increases local capacity for health research (including clinical trial capacity) and product development by undertaking R&D capacity-building initiatives in partnership with local universities and/or public sector research organisations in LMICs.

scope of the Index. These initiatives address local R&D capacity needs, priorities

5-1 Scaled across all companies. The extent to which a company engages in access planning for its late-stage R&D projects

and/or skills gaps in countries in scope of the Index. The Index assesses whether these initiatives meet Good Practice Standards (GPS)*.

targeting other diseases in scope of the Index beyond those identified as R&D priorities by WHO and Impact Global Health (i.e. those included under indicator RD1b). This is determined

5 The company provides evidence of five R&D capacity building initiatives that meet inclusion criteria, of which at least three meet all GPS.

4 The company provides evidence of three R&D capacity building initiatives that meet all inclusion criteria and all GPS OR the company provides evidence of four R&D capacity building initiatives that meet inclusion criteria, of which at least

by:

- the proportion of late-stage candidates with access plans in place;
- the quality of access plans;
- the extent of the geographic reach of access plans.

0 The company provides no evidence of access plans for any late-stage R&D projects that target other diseases in scope of the Index beyond the R&D priorities identified by WHO and Impact Global Health (i.e. those included under indicator

		two meet all GPS OR the company provides evidence of five R&D capacity building initiatives that meet inclusion criteria, of which two meet all GPS.
	3 The company provides evidence of one to five R&D capacity RD1b).	building initiatives, of which one meets all GPS OR the com pany provides evidence of two or three R&D capacity building
RD4	Disclosure of resources dedicated to R&D The company publicly discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for	initiatives of which two meet all GPS.

2 The company provides evidence of at least two R&D capacity diseases within scope of the Index.

5 The company publicly discloses its R&D investments data, disaggregated at least at the level of disease, project *and* phase of development.

3 The company publicly discloses its R&D investments disaggregated to some degree: disease, product type or aggregated phase of development (e.g., clinical versus pre-clinical) and the company voluntarily discloses disaggregated R&D investment data to organisations that present anonymised aggregate data for global health purposes, such as Impact Global Health.

building initiatives that meet inclusion criteria, of which none meet all GPS.

1 The company provides evidence of one R&D capacity building initiative that meets inclusion criteria, but it does not meet all GPS.

2 The company publicly discloses its R&D investments disaggregated to some degree: disease, product type or aggregated phase of development (e.g., clinical versus pre-clinical).

0 The company does not provide any examples of R&D capacity building initiatives that meet all inclusion criteria.

*I.e., has good governance structures in place; initiative goals align with, or support, institutional goals; measures outcomes; and has long-term aims/aims for sustainability.

1 The company does not publicly disclose R&D investment data that has been disaggregated at any level.* However, it voluntarily discloses disaggregated R&D investment data to organisations that present anonymised aggregate data for global health purposes, such as Impact Global Health.

0 The company does not publicly disclose R&D investment data, disaggregated at any level,* and does not contribute data to global health organisations (e.g., Impact Global Health).

*Disaggregation by disease, product type or phase of development were considered for analysis. Other levels of disaggregation, such as business segments, IPR&D or acquisitions were not considered.

C PRODUCT DELIVERY 55%

Indicator

PR1 Registration performance

The company broadly files to register its most recently launched* products that target diseases in scope of the Index, in countries with the highest disease burden.** The company provides evidence of engaging with mechanisms to facilitate registration, such as WHO Collaborative Registration Procedure, where applicable. 5 The

PP2b Access strategies: Long-term donation programmes

company registers its products, in a majority of countries in scope of the Index and in a majority of countries with the highest disease burden** and engages in mechanisms to facili

The company engages in long-term, sustainable product donation programmes for neglected tropical diseases, where goals of elimination, eradication and control are possible and realistic.* It publicly commits to remaining engaged in these donation programmes as long as needed to support the achievement of such goals.

5 The company publicly commits to engage in donation programme(s) for a duration that supports the WHO goals for the control, elimination or eradication of neglected tropical

tate registration of its products in LMICs. diseases.

4-1 Scaled across companies. The number of countries in which the company registers its products*** and the proportion of these which have high disease burdens.** Whether a company engaged. engages in mechanisms to facilitate registration of its prodNS Companies without long-term donation programmes for ucts in LMICs. neglected tropical diseases receive a neutral score.

0 The company provides no evidence of filing to register any of its products in scope that target diseases in the Index scope in any countries in scope.

1 The company engages in donation programme(s) but makes no commitment regarding the duration that it will remain

*These goals are aligned with the WHO 2021-2030 Roadmap for Neglected Tropical Diseases.

*'Most recently launched' refers to the date that the product was first approved to be marketed anywhere globally. The Index analyses information for up to ten of the company's most recently launched products, depending on the size of the company's portfolio.
**The ten countries in scope with the highest DALY rate per disease.
***For analysis, the number of countries where the product is registered is weighted according to the length of time the product has been on the market.

PP2a Access strategies: Ad hoc donations

The company has public policies and supply processes* in place to ensure ad hoc donations** are carried out rapidly in response to expressed need. Efforts are made – in-house and/or via partner organisations – to monitor delivery of donations to ensure that they reach the patient.

PP3 Access strategies: Supranational products

The company applies access strategies to its supranationally procured products* and extends those strategies to countries in scope of the Index which do not qualify for the procurement agreements. This is evidenced by:

a) an access strategy to supply the product through a supranational procurement agreement;

5 The company has policies and supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company publicly commits to adhering to the most recent WHO guidelines on medicine donations. Efforts

b) an access strategy for a country outside of the procurement agreement that demonstrates how relevant payer(s)' ability to pay is considered, and how additional strategies improve the affordability and availability of the product for the different segments of the country's population across the full income pyramid. The company's strategy demonstrates goals aimed at improving patients' health outcomes and tracks the progress** of the access strategy to ensure that goals are achieved. This is evidenced by:

are made – in-house and/or via partner organisations – to moni

i) methods to define the total eligible patient population;***

tor delivery of donations to ensure that they reach the patient. 4 The company has policies and supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company either has no commitment, or commits to adhering to the most recent WHO guidelines on medicine donations, but these commitments are not public. Efforts are made – in-house and/or via partner organisations – to monitor delivery of donations to ensure that they reach the patient.

0 The company does not have policies or supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company does not commit, publicly or otherwise, to align with the WHO guidelines for medicine donations. No efforts are made – in-house and/or via partner organisations – to monitor delivery of donations to ensure that they reach the patient.

*These policies and processes should align with the latest WHO guidelines for medicine donations.
**A donation of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

ii) evidence of patient reach during the period of analysis;
iii) evidence of how the strategy has progressed,** and future plans for advancing the strategy.

*Products for which international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria, neglected tropical diseases, reproductive, maternal and newborn health conditions.
**An increase in the number of patients reached, or elimination/eradication targets achieved.
***Eligibility is defined as the patients that have been diagnosed or identified by a healthcare professional as suitable recipients of the product based on the licensed indication.

5 For all its supranationally procured products selected for anal ysis, the company meets all following criteria:

b) Evidence of an access strategy in a country that does not qualify for supranational procurement, where:

a) Evidence of an access strategy to supply the product through a supranational procurement agreement, including:

i) evidence of the access terms of the supranational agreement including pricing;

ii) evidence of the outcomes and impact of the agreement including the number of patients reached during

i) it applies the same pricing terms of the supranational agreement and/or provides details of a pricing strategy that considers the ability to pay of all relevant payers in the country;

ii) it applies additional strategies* to complement pricing strategies to increase reach among patients across the period of analysis. the income pyramid;

b) Evidence of an access strategy in a country that does not qualify for supranational procurement, where:

i) it applies the same pricing terms of the supranational agreement and/or provides details of a pricing strategy that considers the ability to pay of all relevant

iii) it reports the outcomes of the strategy and demonstrates that:

(a) it sets clear measurable access strategy goals

aiming to increase sustainable access across the income pyramid; (b) it provides evidence of the meth

payers in the country; ods used to calculate the strategy's targets and the

ii) it applies additional strategies* to complement pricing
strategies to increase reach among patients across

resulting numbers including the total eligible patient population and the target patient population; (c) it

the income pyramid; provides evidence of the methods used to measure

iii) it reports the outcomes of the strategy and demon

the outcomes of the strategy and the resulting num

strates that:

bers including patient reach; (d) it provides evidence

(a) it sets clear measurable access strategy goals aiming to increase sustainable access across the income pyramid; (b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population; (c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach; (d) it provides evidence

that the strategy has progressed, and future plans for advancing the strategy.

0 For its supranationally procured products selected for analysis, the company meets none of the above listed criteria.

NS Companies without products in scope that are supranationally procured receive a neutral score.

*For example, patient assistance programmes, donations, voluntary licensing, technology transfer, etc.

that the strategy has progressed, and future plans for advancing the strategy.

PP4a Access strategy quality: Healthcare practitioner-administered products

4-1 For its supranationally products selected for analysis, the extent to which the company meets the following criteria:

a) Evidence of an access strategy to supply the product through a supranational procurement agreement,

The company takes into consideration both the relevant payer(s)' ability to pay and the demographic* characteristics of a country to determine its access strategy, aiming to improve the affordability and availability of its healthcare practitioner-administered products** and increase reach among patients across the income pyramid.

including:

i) evidence of the access terms of the supranational agreement including pricing; This is evidenced by:

ii) evidence of the outcomes and impact of the agreement including the number of patients reached during

a) an access strategy that demonstrates how the relevant payer(s)' ability to pay for the different segments of the population is considered and any additional strategies*** to complement pricing strategies;

b) initiatives to strengthen health systems and build capacity to ensure the continuum of care for the product.

the period of analysis.

*The characteristics of a population such as age, sex, income level, education level, employment, etc.
**Products that often require either hospital administration or the attention of a skilled healthcare professional during administration.
***For example, patient assistance programmes, donations, voluntary licensing, technology transfer, etc

5 For all its healthcare practitioner-administered products selected for analysis, the company meets all the following criteria for all three country income classifications:
a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price; b) it applies additional strategies to complement pricing

5 For all its healthcare practitioner-administered products selected for analysis, the company meets all the following criteria in all three country income classifications:

a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid; b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient

strategies to increase reach among patients across the income pyramid;

c) it implements health system strengthening initiatives to facilitate the continuum of care for the product.

population;

c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;

4-1 For its healthcare practitioner-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income

d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

4-1 For its healthcare practitioner-administered products classifications: selected for analysis, the extent to which the company

a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price; b) it applies

meets the following criteria across the three country income classifications:

additional strategies to complement pricing strategies to increase reach among patients across the

a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid; b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the income pyramid; total eligible patient population and the target patient

c) it implements health system strengthening initiatives to population; facilitate the continuum of care for the product.

0 For its healthcare practitioner-administered products selected for analysis, the company meets none of the above

c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;

listed criteria. d) it provides evidence that the strategy has progressed, and

NS Companies without healthcare practitioner-administered products in scope receive a neutral score.

future plans for advancing the strategy.

0 For its healthcare practitioner-administered products selected for analysis, the company meets none of the above listed criteria.

NS Companies without healthcare practitioner-administered products in scope receive a neutral score.

PP4b Access strategy outcomes: Healthcare practitioner-administered products

The company demonstrates it has a process in place to monitor the performance of the access strategy for its healthcare practitioner-administered products aimed at reaching patients across the income pyramid. The company's strategy demonstrates goals aimed at improving patients' health outcomes and tracks the progress* of the access strategy to ensure that goals are achieved.

PP5a Access strategy quality: Self-administered products

The company takes into consideration both the relevant payer(s)' ability to pay and the demographic* characteristics of a country to determine its access strategy, aiming to improve the affordabil

This is evidenced by:

a) methods to define the total eligible patient population** and patient reach; This is evidenced by an access strategy that demonstrates how

b) evidence of patient reach during the period of analysis; c) evidence of how the strategy has progressed,* and future plans for advancing the strategy.

ity and availability of its self-administered products and increase reach among patients across the income pyramid.

*An increase in the number of patients reached, or elimination/eradication tar

all the relevant payer(s)' ability to pay for the different segments of the population is considered and any additional strategies** to complement pricing strategies.

*The characteristics of a population such as age, sex, income level, education level, employment, etc.

**Eligibility is defined as the patients that have been diagnosed or identified by a healthcare professional as suitable recipients of the product based on the licensed indication.

**For example, patient assistance programmes, donations, voluntary licensing, technology transfer, etc.

5 For all its self-administered products selected for analysis, the company meets all the following criteria for all three country

4-1 For its self-administered products selected for analysis, the extent to which the company meets the following criteria

income classifications: across the three country income classification:

a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price; b) it applies additional strategies to complement pricing

a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid; b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient strategies to increase reach among patients across the income pyramid.

4-1 For its self-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income classifications:

a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price;

population;

c) it provides evidence of the methods used to measure

the outcomes of the strategy and the resulting numbers including patient reach;

d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

0 For its self-administered products selected for analysis, the company meets none of the above listed criteria.

b) it applies additional strategies to complement pricing strategies to increase reach among patients across the income pyramid.

0 For its self-administered products selected for analysis, the company meets none of the above listed criteria.

PPL1 Patent filing and enforcement

The company publicly commits to not file for (or enforce) patents relating to diseases in scope in least developed countries (LDCs),

low-income countries (LICs), and in a subset of lower-middle-income countries (LMICs) and upper-middle-income countries (UMICs).

PP5b	Access strategy outcomes: Self-administered products	5 The company makes a public commitment not to patent, not The company demonstrates it has a process in place to monitor the performance of the access strategy for its self-administered products aimed at reaching patients across the income pyramid. The company's strategy demonstrates goals aimed at improving patients' health outcomes and tracks the progress* of the access strategy to ensure that goals are achieved.

to enforce, or to abandon existing patents relating to all products in the Index scope in all LDCs, LICs and a clearly named and publicly listed subset of LMICs and UMICs.

4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in all LDCs, LICs and a subset of LMICs

This is evidenced by:

a) methods to define the total eligible patient population** and patient reach; b) evidence of patient reach during the period of analysis; c) evidence of how the strategy has progressed,* and future plans for advancing the strategy.

and/or UMICs.

3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in all LDCs, LICs and a clearly named and publicly listed subset of LMICs and UMICs.

products in the Index scope in all LDCs, a subset of LICs, and LMICs OR in all LICs, a subset of LDCs and LMICs.

2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs and/or LICs.

1 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in scope of the Index and/or in a specific region or regions (e.g., some LDCs and/or LICs).

0 The company makes no commitment in this area.

*An increase in the number of patients reached or elimination/eradication targets achieved.

**Eligibility is defined as the patients that have been diagnosed or identified by a healthcare professional as suitable recipients of the product based on the licensed indication.

5 For all its self-administered products selected for analysis, the company meets all the following criteria in all three country income classifications:

a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid; b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient

PPL2 Patent status disclosure

The company publicly discloses the patent status of its products for diseases in scope of the Index, in countries within scope. 5 The company publicly discloses the patent status for all on-patent products within the Index scope. This informa

population;

tion is updated periodically, and the standard of transparency

c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting number, including patient reach;

achieved is analogous to or greater than that set out by the US Food and Drug Administration (FDA)'s Orange Book.*

d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

4 The company publicly discloses the patent status for a subset of the on-patent products, within the Index scope. This information is updated periodically, and the standard of transpar

5-1 Scaled across companies. The extent to which a company engages in access-oriented non-exclusive voluntary licensing and the quality of these licence(s) as determined by:

ency achieved is analogous to or greater than that set out by the US FDA's Orange Book OR companies that disclose patent status for all on-patent products and the standard of

- the extent to which the licensing agreement(s) includes

access-oriented clauses* to facilitate access and whether these terms are transparent and publicly disclosed.

transparency is less than that set out by the US FDA's Orange Book.

- the extent of the geographic reach of the licensing agreement(s).

3 The company publicly discloses the patent status for a subset of the on-patent products, within the Index scope. This infor

0 Companies without any VL for patented products within the Index scope, with relevant products in its portfolio to pursue a VL.

mation is updated periodically, but the standard of transparency achieved is less than that set out by the US FDA's Orange Book.

Companies without any VL for patented products within the Index scope, with no relevant products for pursuing a VL in the portfolio.

2 The company publicly discloses patent status for a subset of the on-patent products within the Index scope. There is no evidence that this information is updated periodically, and the standard of transparency achieved is less than that set out by the US FDA's Orange Book OR only off-patent products are disclosed.

0 The company makes no public disclosure in this area.

*1) Licence agreed prior to or shortly after approval of originator product, 2) ability to manufacture and source active pharmaceutical agreements without restriction, 3) ability to supply countries where no granted patents are infringed (including where compulsory licences are issued), 4) optional provision for technology transfer, 5) absence of no challenge clauses, 6) provision to facilitate rapid registration of product, 7) inclusion of quality assurance measures in line with WHO requirements.

*The FDA Orange Book includes product patent data, patent number and expiry date.

PPL3 IP Sharing

The company provides evidence of sharing its IP (such as mole cule libraries, patented compounds, processes and technologies) with research institutions and neglected disease drug discovery initiatives (such as World Intellectual Property Organization Re:Search, Medicines for Malaria Venture, Corona accelerated R&D in Europe) that are developing products for diseases and countries in scope of the Index.

PQ1 Ensuring continuous supply

The company has mechanisms in place to improve supply chain efficiency and takes informed action to ensure uninterrupted supply. The company uses the following mechanisms to make products available in sufficient quantities in a timely manner in LMICs:

a) the company has a system in place and works with relevant stakeholders (e.g., government agencies, distributors, hospitals, warehouses, wholesalers, or other relevant networks) to communicate about issues that may affect the supply chain. b) the company manages a buffer stock of relevant, finished products.

5-2 The company has previously made available its intellectual property through agreements with research institutions or drug discovery initiatives as described above and these agree

c) the company works with several active pharmaceutical ingredient (API) suppliers, holds API buffer stocks and/or produces

ments remain valid. In addition, the new agreements that in-house APIs.

each company has made during the period of analysis are
weighted, added together, ranked and scored accordingly.

d) the company works to enhance local supply capacities and strengthen supply chains.*

1 The company has previously made available its intellectual property through at least one agreement with research institutions or drug discovery initiatives as described above and these agreement(s) remain valid.

e) the company transfers technology (e.g., for API, vaccine adju

0 The company does not provide evidence of sharing its intel

vant and/or drug product) to manufacturers to improve manufacturing capacity and availability in LMICs* and/or manufactures relevant products in LMICs.

lectual property. 5 The company has elements (a) through (e) in place and pro

vides an example of implementing these activities to improve

PPL4	Quality and geographic coverage of access-oriented licensing The company engages in voluntary licensing (VL) agreements to	supply of a product addressing a disease in scope of the Index in a country in scope.

enable the generic supply of products in its portfolio. The com pany grants access-oriented, transparent, non-exclusive volun tary licences which include clauses that facilitate affordability and supply of quality products. The company includes a broad range of countries within the geographic scope of its licences, from a range of country income classifications.

4-1 The elements that the company does implement as well as examples are added, weighted and summed together and companies are scored relative to one another.

0 The company does not have elements (a) through (e) in place or does not disclose information about them.

*Analysis is based on submission in PCB1 and PCB2.

PQ2 Reporting substandard and falsified medical products

The company has a policy or procedure for reporting confirmed cases of substandard and falsified (SF) medical products in countries in scope of the Index to relevant stakeholders (national regulatory authorities and WHO Rapid Alert)* in a timely manner**. This prioritises the minimisation of harm to public health.

5 The company provides evidence of a policy or approach to report confirmed cases of SF medical products as soon as possible and within ten working days to WHO Rapid Alert and national regulatory authorities, when visual inspection (e.g., confirmation of

5 The company provides evidence of five manufacturing capac

mislabelling, confirmation of fake packaging) is sufficient to establish that the product packaging is falsified. In cases where laboratory analysis is required for confirmation of SF medical products, the policy should require reporting of cases of SF medical products to WHO Rapid Alert and/or national/local regulatory authorities as soon as possible and within ten working days from laboratory confirmation.

ity building initiatives that meet inclusion criteria, of which at least three meet all GPS.

4 The company provides evidence of three manufacturing capacity building initiatives that meet all inclusion criteria and all GPS OR the company provides evidence of four manufacturing capacity building initiatives that meet inclusion criteria, of which at least two meet all GPS OR the company provides evidence of five manufacturing capacity building initiatives that meet inclusion criteria, of which two meet all GPS.

3 The company provides evidence of one to five manufacturing capacity building initiatives, of which one meets all GPS OR the company provides evidence of two or three manufacturing capacity building initiatives of which two meet all GPS.

2 The company provides evidence of at least two manufacturing capacity building initiatives that meet inclusion criteria, of which none meet all GPS.

1 The company provides evidence of one manufacturing capacity building initiative that meets inclusion criteria, but it does not meet all GPS.

4 The company provides evidence of a policy or approach for reporting confirmed cases of SF medical products to WHO Rapid Alert and/or national/local regulatory authorities within ten working days of the confirmation in countries within scope of the Index but does not differentiate between cases

0 The company does not provide any examples of manufacturing capacity building initiatives which meet all inclusion
where only a visual inspection is sufficient and cases where criteria.
laboratory analysis is required for confirmation.

3 The company provides evidence of a policy or approach for
reporting SF medical product cases to WHO Rapid Alert and/

*I.e., guided by clear, measurable goals and/or objectives; measures outcomes; has long-term aims/aims for sustainability.

or national/local regulatory authorities, but it does not specify a reporting timeframe.

2 The company provides evidence/examples to the Index of consistent reporting of cases of SF medical products on a case-by-case basis, in countries within the scope of the Index,

PCB2 Capacity building in supply chain management

A company undertakes supply chain capacity building initiatives in countries within scope of the Index in partnership with local stakeholders (e.g., ministries of health and public procurement, logistics and distribution agencies) with the aim of improving the

to relevant authorities. affordability, accessibility and quality of products, including prod

0 The company does not provide evidence of a policy or approach to report confirmed cases of SF medical products or provide examples of reporting SF medical products.

*Reporting to national regulatory authorities should take place regardless of whether local regulations require it. Reporting to WHO Rapid Alert is encouraged in all cases, particularly when local regulatory systems are weak and/or compromised.

**The company provides evidence of a policy or approach to report confirmed cases of SF medical products as soon as possible and within ten working days to national regulatory authorities and WHO Rapid Alert, when visual inspection (confirmation of mislabelling, confirmation of fake packaging) is sufficient to establish that product packaging is falsified. In cases where laboratory analysis is required for confirmation, the policy should require reporting of cases as soon as possible (and within ten working days, once confirmation has taken place) to national regulatory authorities and WHO Rapid Alert.

ucts outside of its own portfolio. The Index assesses whether these initiatives meet Good Practice Standards (GPS).

5 The company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria, of which at least three meet all GPS.

4 The company provides evidence of three supply chain capacity building initiatives that meet all inclusion criteria and all GPS OR the company provides evidence of four supply chain capacity building initiatives that meet inclusion criteria, of which at least two meet all GPSs OR the company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria, of which two meet all GPS.

3 The company provides evidence of one to five supply chain capacity building initiatives, of which one meets all GPS OR

PCB1 Capacity building in manufacturing

A company undertakes manufacturing capacity building initiatives in partnership with third-party/unaffiliated local manufacturers or other external parties (e.g., universities) in LMICs. These initiatives address local manufacturing capacity needs, priorities and/ or skill gaps in countries in scope of the Index. The Index assesses

the company provides evidence of two or three supply chain capacity building initiatives of which two meet all GPS.

2 The company provides evidence of at least two supply chain capacity building initiatives that meet inclusion criteria, of which none meet all GPS.

whether these initiatives meet Good Practice Standards (GPS).*

1 The company provides evidence of one supply chain capacity building initiative that meets inclusion criteria, but it does not meet all GPS.

0	The company does not provide any examples of supply chain capacity building initiatives which meet all inclusion criteria.	

*I.e., guided by clear, measurable goals and/or objectives; measures outcomes; has long-term aims/aims for sustainability

3 The company develops and implements inclusive business model(s), but these address a less comprehensive range of access barriers of underserved or unserved populations, lack evidence of long-term plans for generating a sustainable source of revenue or lack evidence of long-term plans for scalability.

PCB3 Health system strengthening

With measures in place to mitigate or prevent conflicts of interest, a company works in partnerships – including with local stakeholders – to undertake health system strengthening initiatives that address local needs in countries in scope of the Index. Such initiatives work in a coordinated way with other parties, complementing the local health system, with outcomes clearly monitored. The Index assesses whether these initiatives meet Good Practice Standards (GPS).

5 The company provides evidence of five health system strengthening initiatives that meet inclusion criteria, of which at least three meet all GPS.

4 The company provides evidence of three health system

2 The company does not develop or implement inclusive business model(s) but engages in strategies or targeted initiatives that aim to specifically address the access needs of underserved or unserved populations.

0 There is no evidence of inclusive business model(s), strategies or targeted initiatives designed to address the access needs of underserved or unserved populations.

*This can include vulnerable populations that are at a higher risk of facing barriers to accessing medicines due to social, economic and/or health considerations.

strengthening initiatives that meet all inclusion criteria and all GPS OR the company provides evidence of four health sys tems strengthening initiatives that meet inclusion criteria, of which at least two meet all GPS OR the company provides evidence of five health system strengthening capacity build ing initiatives that meet inclusion criteria, of which two meet all GPS.

3 The company provides evidence of one to five health system strengthening initiatives, of which one meets all GPS OR the company provides evidence of two or three health systems strengthening initiatives of which two meet all GPS.

2 The company provides evidence of at least two health system strengthening initiatives that meet inclusion criteria, of which none meet all GPS.

1 The company provides evidence of one health system strengthening initiative that meets inclusion criteria, but it does not meet all GPS.

0 The company does not provide any examples of health system strengthening initiatives which meet all inclusion criteria.

*I.e., guided by clear, measurable goals and/or objectives; measures outcomes; publicly discloses outcomes; has long-term aims/achieves integration within the local health system.

PBM1 Inclusive business models

The company develops and implements inclusive business models that aim to provide its products to populations in LMICs that have been underserved or unserved, by existing business models.* These models work in partnership to address access issues and have long-term plans for scalability and to achieve a sustainable source of revenue in the long term. Outcomes of these models are measured over time.

5 The company develops and implements inclusive business model(s) with evidence of long-term aims for scalability. These models are comprehensive, addressing multiple access barriers for underserved or unserved populations. There is evidence that the company is aiming for a sustainable source of revenue through the model in the long-term.

APPENDIX IV

The 2024 Access to Medicine Index indicator weights

TABLE 1 The 2024 Access to Medicine Index indicator weights

Technical area	Indicator	Priority topic	Description	%
Governance of Access 15%	GA1	Governance and strategy	Governance structures and incentives	1.8
	GA2	Governance and strategy	Access-to-medicine strategy and outcomes	3
	GA4	Responsible business practices	Responsible business practices	1.8
	GA5	Responsible business practices	Ethics, risk and compliance	1.8
	GA6	Responsible business practices	Incidence of breaches	1.8
	GA7	Responsible business practices	Trade policy: Intellectual property and access to medicine	1.8
	GA8	Measuring and reporting patient reach	Measuring and reporting patient reach	3
Research & Development 30%	RD1a	Product development	R&D pipeline: Prioritised diseases	5.75
	RD1b	Product development	R&D Pipeline: Other diseases	4.5
	RD2	Access planning	Planning for access: Framework	2.25
	RD3a	Access planning	Planning for access: Project-specific plans for prioritised diseases	6
	RD3b	Access planning	Planning for access: Project-specific plans for other diseases	6
	RD4	Product development	Disclosure of resources dedicated to R&D	3
	RD6	Building R&D capacity	Capacity building in R&D	2.5
Product Delivery 55%	PR1	Registration	Registration performance	5
	PP2a	Product donations	Access strategies: Ad hoc donations	1
	PP2b	Product donations	Access strategies: Long-term donation programmes	3
	PP3	Equitable access strategies and outcomes	Access strategies: Supranational products	6.5
	PP4a	Equitable access strategies and outcomes	Access strategy quality: Healthcare practitioner-administered products	3.25
	PP4b	Equitable access strategies and outcomes	Access strategy outcomes: Healthcare practitioner-adminis-tered products	3.25
	PP5a	Equitable access strategies and outcomes	Access strategy quality: Self-administered products	3.25
	PP5b	Equitable access strategies and outcomes	Access strategy outcomes: Self-administered products	3.25
	PPL1	Intellectual property strategy	Patent filing and enforcement	1.5
	PPL2	Intellectual property strategy	Patent status disclosure	1.5
	PPL3	Intellectual property strategy	IP sharing	1.5
	PPL4	Licensing quality	Quality and geographic coverage of access-oriented licensing	4.5
	PQ1	Quality and supply	Ensuring continuous supply	4
	PQ2	Quality and supply	Reporting substandard and falsified medical products	2
	PCB1	Local manufacturing	Capacity building in manufacturing	2.5
	PCB2	Quality and supply	Capacity building in supply chain management	2.5
	PCB3	Health system strengthening	Health system strengthening	2.5
	PBM1	Inclusive business models	Inclusive business models	4

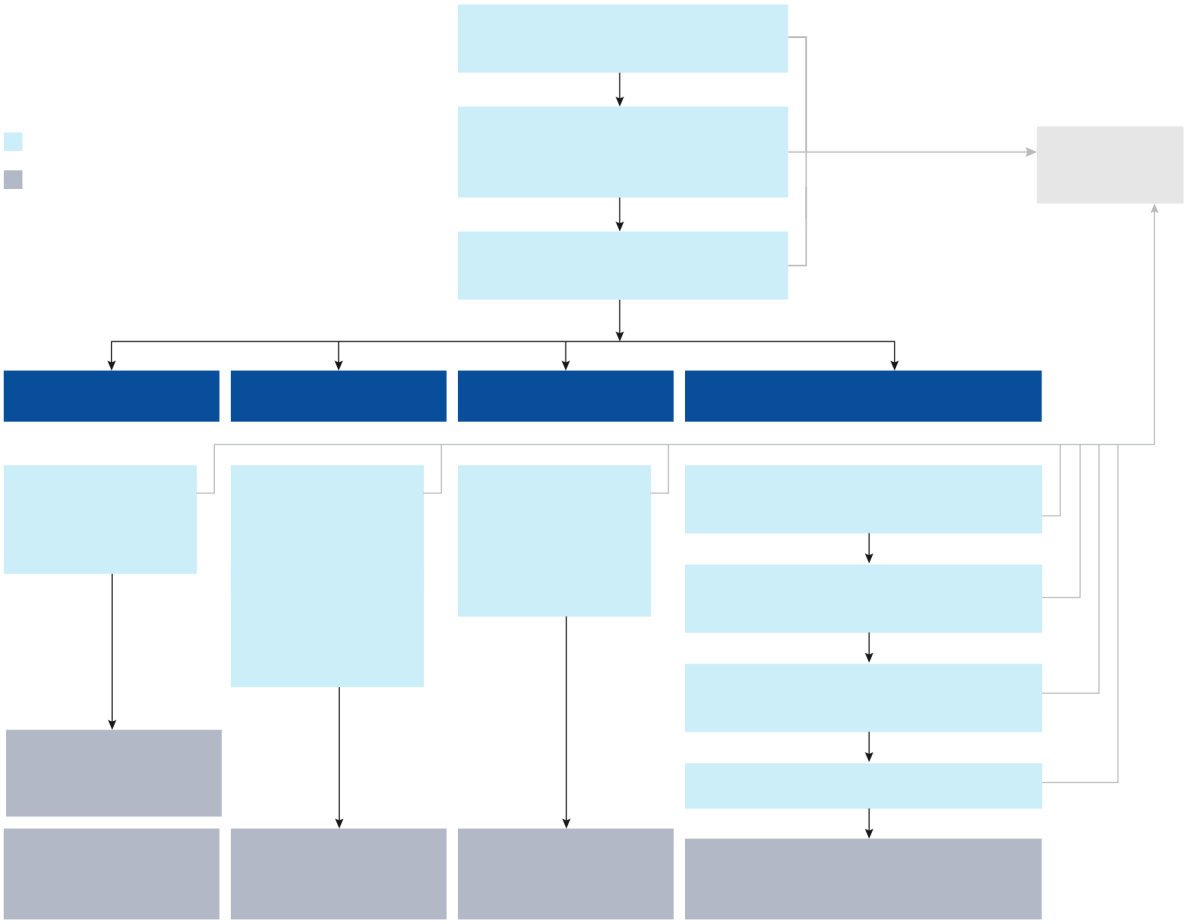
Abbreviations: IP = Intellectual property; R&D = Research & Development

APPENDIX V

The Good Practice Standards framework for capacity building

This framework has been developed to convey stakeholders' expectations for good practice in capacity building, with all company capacity building initiatives measured against this framework. There are three basic inclusion criteria that all initiatives must meet:

1. Be active during the period of analysis
2. Take place in a country/countries in scope of the Index
3. Address local needs

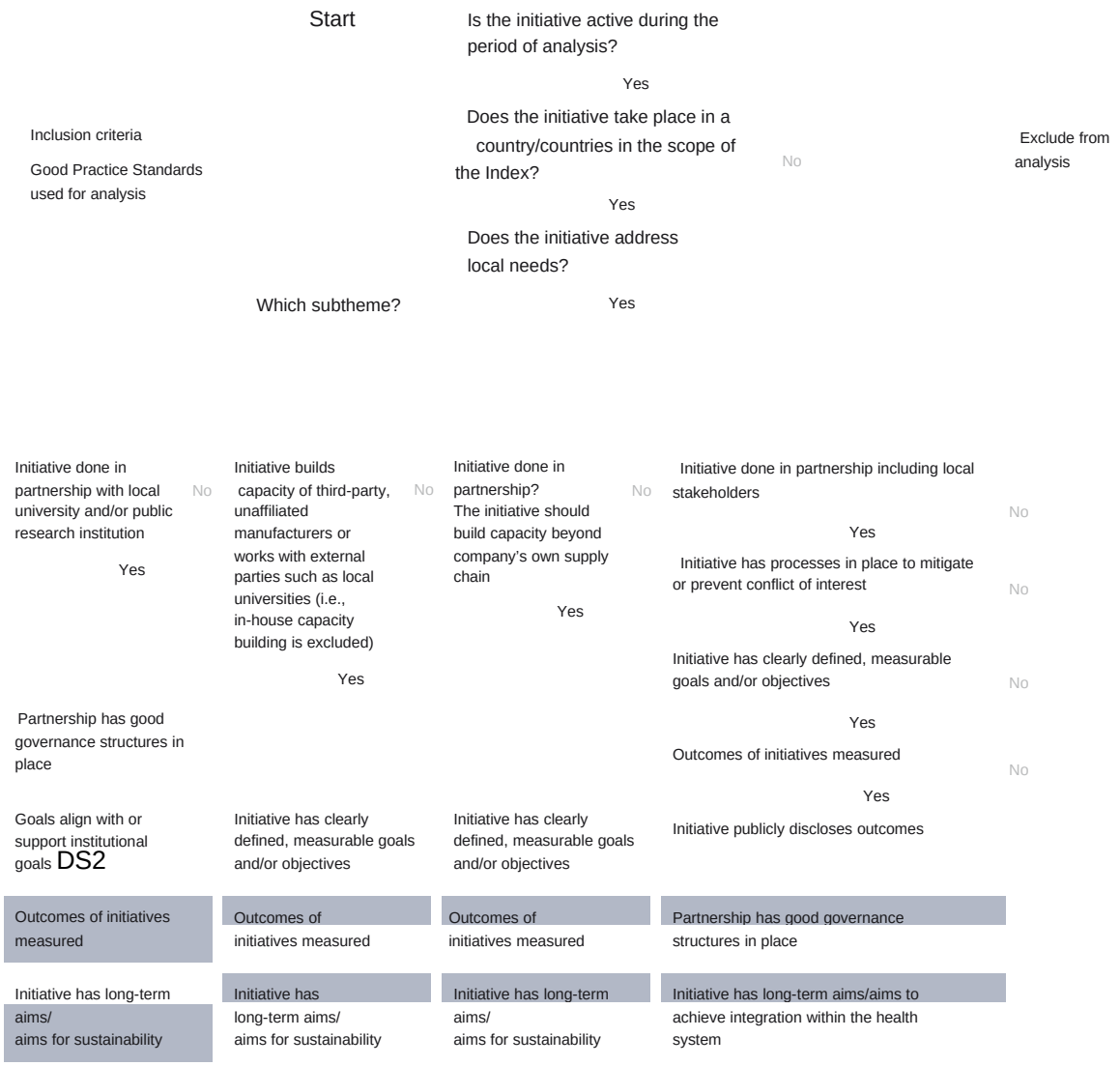


Beyond these general criteria, the chart is divided into four subthemes of capacity building, each with slightly different stakeholder expectations for inclusion criteria.

Initiatives that meet all inclusion criteria are assessed against the Foundation's Good Practice Standards (GPS). The GPS differ slightly per capacity building subtheme but all centre around four topics: governance, goals and objectives, outcomes and sustainability.

FIGURE 1 Good Practice Standards framework for capacity building

The flowchart provides a guide to the criteria by which company initiatives are included for analysis in the Index and the Good Practice Standards (GPS) by which they are analysed. The chart is broken down by subtheme of capacity building, each with slightly different expectations for analysis.



APPENDIX VI

Definitions

Terms defined below are tailored to the objectives and methodology of the Access to Medicine Index and should be understood within the context of this report.

Ad hoc donation

A donation of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of

Access plans

Plans to ensure that access needs in low- and middle-income countries are taken into consideration during the R&D stage.

medicines based on the explicit needs of a country. Donations

Access plans can be developed in-house or in collaboration.

made during emergency situations, such as conflicts and natural disasters, are also included here.

They can include commitments and strategies, as well as more concrete access provisions, such as specific measures developed in partnership with other organisations that can enforce accountability. Potential components of an access plan include registration commitments, equitable pricing strategies, sufficient supply commitments, and applying for World Health Organization prequalification. Access plans facilitate availability, affordability and supply for patients in countries within the scope of the Index.

Adaptive R&D

Access strategy (product specific)

The range of mechanisms a company can implement to - provide access to its product for a specific group of patients within a country. An access strategy can be composed of different elements, including pricing strategies and additional initiatives to improve the affordability and availability of the product. Access strategies with the biggest potential impact in terms of equitable access are those that aim to promote

R&D adaptations of existing/registered medicines, or other health products in scope that may address an unmet need in countries in scope of the Index. This can include adding new indications, new target patient populations (e.g., infants/ children, pregnant and lactating people), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., oral formulations).

Additional access initiatives
Initiatives, other than pricing, that improve the availability and affordability of products with the aim of increasing the number of patients reached. Such initiatives may include, but are not limited to, non-exclusive voluntary licensing, donations, private-public and private-private partnerships, patient assistance programmes, non-assert declarations, technology transfers and health system strengthening initiatives.

affordable access to medicine for all income groups of the population by considering the ability to pay of the payer, and by taking healthcare systems' needs and characteristics into	Affordability

This refers to the payer’s ability to pay for a product (whether or not they are the end user) – see ‘payers’ for definition.

account.

Affordability is one of the key dimensions for access to medi cine. The Index takes this into account when assessing pricing

Access-to-medicine strategy

A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (for example, a clear rationale, targets, objectives and expected outcomes). In low- and middle-income countries where the company operates, the strategy may apply to a defined set

strategies for relevant products. A product's affordability depends on different factors, including socioeconomic, demographic and healthcare system characteristics, which should be considered by pharmaceutical companies when setting the price of the products.

of diseases, products or therapeutic areas, or ideally to the whole pipeline and portfolio.

Budget impact

An estimated measure of the cost of treatment for a given therapy and a given number of patients in a specific population.

Active pharmaceutical ingredient (API)

The active pharmaceutical component of a medicine that causes its intended effects. Some medicines, such as combi

Buffer stock

nation therapies, have multiple active ingredients that target multiple disease pathways and/or symptoms. The inactive ingredients of a medicine are referred to as excipients.

A reserve or surplus quantity of essential materials, com ponents or finished products that a company maintains as a safeguard against potential disruptions in the supply chain.

Capacity building

The company forms partnerships with local stakeholders to develop and strengthen skills, resources or processes in

Equitable pricing strategy

LMICs (e.g., by training of staff or obtaining equipment and other necessary resources). The Index assesses capacity

A targeted pricing strategy which aims to improve access to medicine for those in need by considering the relevant payer’s ability to pay, and by taking healthcare systems’ needs and characteristics into account.

building across four subthemes: R&D, manufacturing, supply chains and health system strengthening.

Conflict of interest

When the commercial interests of a company are at odds with, or perceived to be at odds with, the interests of the

Ethical marketing

Promotional activities that are aimed at the general public,

patients, healthcare professionals/students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

partnership, the partner (i.e., local stakeholders) or the health and well-being of the population the partnership intends to help.

Country or region risk-based assessment
An assessment to help a pharmaceutical company to evaluate the risk of non-compliance with ethical marketing, anti-corruption and clinical trial standards in LMICs. This type of assessment examines the country-specific legal and regulatory environment, cultural and social factors, as well

Fair market value assessment
Assessment that defines the appropriateness of payments made to healthcare professionals (HCPs). These provide

as economic and political conditions that may influence the company's compliance risks.

Demographic factors
Characteristics of a population such as age, sex, income level, education level, employment, etc.

structure to ensure ethical interactions between the pharmaceutical industry and HCPs with whom companies engage.

Falsified medical products or medicines
Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Fraud-specific risk assessment
An assessment that identifies potential risks of fraud within a pharmaceutical company's operations in LMICs. This type of assessment considers the vulnerabilities and weaknesses within the company's operations, which could be exploited by employees, contractors or third-party service providers to commit fraud.

Disability-Adjusted Life Year (DALY)
A measure of disease burden that combines disease-associated mortality and morbidity. It is the sum of the number of years of life lost (YLLs) and years lived with disability (YLDs). DALYs allow the comparison of disease burden across different populations and health conditions across time. One DALY equals one lost year of healthy life.

Good governance structures

The structures put in place to establish clear roles, responsibilities and decision-making processes for access initiatives. These structures also include systems of communication whereby information about processes, decisions and outcomes of initiatives are regularly conveyed to the relevant stakeholders.

Drug product

The finished dosage form of a medicine obtained at the end of the manufacturing process, (e.g., the tablet, capsule or solution containing the API or APIs, generally, but not necessarily, in association with one or more other ingredients). Also referred to as a finished drug product, finished product or

Good manufacturing practice (GMP)

A system employed to ensure that products are consistently produced and controlled according to appropriate quality standards. Within pharmaceutical production this serves to

formulation.

minimise risks such as unexpected contamination, incorrect labelling or incorrect dosing of the active ingredient. GMP

End-to-end manufacturing
In the manufacturing of medicines, vaccines or other products in scope, this refers to a comprehensive production process in which a single manufacturer manages all stages, including purification and synthesis of active substances, formulation of the final dosage form, and packaging of the final product.

covers all aspects of pharmaceutical production (e.g., starting materials, premises, equipment, training and personal hygiene of staff) and includes processes that provide documented proof that correct procedures are consistently followed at each step of the manufacturing process. GMP guidelines are established and overseen by regulatory agencies in

Good Practice Standards (GPS)
A set of standards developed by the Foundation that are used to assess company capacity building initiatives that meet all inclusion criteria. Higher-performing companies have more capacity building initiatives that meet all GPS.

Healthcare practitioner-administered products
Products that typically require either hospital administration of the product or the continued attention of a skilled healthcare professional for administration, such as an intravenously administered oncology medicine.

Innovative R&D
The development of medicines, therapeutic and preventive vaccines, diagnostics, vector control products and micro-

Out-of-pocket-payment

bicides which have not previously been approved for use.

Long-term donation programmes
A donation of products for which a defined strategy exists as to the type, volume, duration and destination of donated products. These programmes are longer than five years, are based on country needs, and aim to control, eliminate or eradicate a disease. For analysis, the Index focuses on long-term donation programmes for neglected tropical diseases.

National regulatory authority

Payments made by people at the time of getting any type of service provided by any type of healthcare provider. They include cost-sharing (the part not covered by a third party
like an insurer) and informal payments, but they exclude insurance premiums. Out-of-pocket payments exclude any reimbursement by a third party, such as the government, a health insurance fund or a private insurance company. In the Index context, out-of-pocket payments relate to payments made for medicines or other health products in scope.

Patient assistance programmes
Programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

Patient reach
The number of people benefitting from access to a company's product(s), which can be demonstrated through, for example, annual sales volume divided by volume per patient or the estimated number of patients reached by a particular access strategy, initiative, or partnership. The Index evaluates a company's overall process for defining, measuring, and reporting on patient reach, as well product-specific examples of patient reach in the context of access strategies.

A national regulatory agency responsible for ensuring that products released for public distribution (normally phar maceuticals and biological products, such as vaccines and -

Payers

medical devices including test kits) are evaluated properly and meet international standards of quality, safety and efficacy.

Entities, including individuals, private health insurers, governments, and international organisations, which are responsible for funding and facilitating medical services. The entities vary based on the healthcare system's financial structure.

National reimbursement authority

Governmental bodies with the authority to control, approve and determine pricing and reimbursement of medicinal products in a country.

Period of analysis

Non-assert declarations

For the 2024 Index, the time period for which data will be analysed covers the company’s activities (which must have been ongoing) between 1 June 2022 and 31 May 2024, as this is the cycle of the Index.

A commitment by a rights holder not to enforce certain patents in a defined group of countries. This allows a generic version of a patent-protected product to be produced and/or commercialised in those countries.

Post-trial access

Non-exclusive voluntary licences

The continued provision of an investigational product or comparator to clinical trial participants following the end of the clinical trial in which they participated when continued treatment is beneficial.

Licences which enable – on a non-exclusive basis, and accord	Priority R&D

ing to the terms of the licence agreed – the manufacture and supply of generic versions of patented medicines by other manufacturers.

R&D that addresses product gaps resulting from a lack of effective or suitable products to treat, prevent or detect certain diseases, conditions and pathogens in countries

Second brand
A marketing strategy whereby a drug is sold under two dif ferent brand names. The second brand is a more affordable version of the original brand and is introduced to target new markets and/or different income groups within the patient population. Companies use different terminologies to refer to a 'second brand' strategy (e.g., emerging market brand, impact brand). 'Second brand' is an umbrella term throughout the Index for all companies to describe this approach.

Self-administered products
Products which patients can typically take or administer themselves for regular usage without needing a skilled healthcare worker. These products may or may not be priori tised by governments or by the global health community (e.g., treatments for non-communicable diseases such as diabetes, stroke and heart disease).

Substandard medicines OR Substandard medical products
Also called ‘out of specification’, these are authorised medical products that fail to meet either their quality standards or specifications, or both.

Supranationally procured products
Products for which international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist. These include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria, neglected tropical diseases and reproductive health.

Technology transfer
A pharmaceutical company transfers knowledge, tools and/or technology necessary for producing a specific product (e.g., medicine, vaccine) to a manufacturer. Technology transfer can improve the supply and availability of products, while also building manufacturing capacity that can be applied to other manufacturing processes.

Vulnerable populations
People at greater risk of facing barriers to accessing medi cines due to social, economic and/or health considerations.

The World Health Organization (WHO) Collaborative Registration Procedure (CRP)
A procedure launched by the WHO that aims to expedite registration of prequalified finished pharmaceutical products. It accelerates registration through improved information shar ing between the WHO prequalification system and national regulatory authorities. By leveraging assessment and inspec tion outputs already produced by WHO prequalification, and thereby eliminating duplicative regulatory work, it speeds up in-country registration of quality-assured products and contributes to their wider availability.

Report Design
Mark Bakker, Scribble Design

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