Access to Medicine Index 2024

METHODOLOGY

access to medicine FOUNDATION

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ACCESS TO MEDICINE FOUNDATION

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 middle-income countries.

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Ensuring progress in expanding access benefits more people

The publication of our Access to Medicine Index in November 2022 came at a critical juncture. With the world slowly emerging from the worst of the COVID-19 pandemic, companies could take stock and utilise learnings from this global health crisis to improve and maximise their access-to-medicine efforts going forward. Such efforts are vital to ensuring that medical progress benefits everyone – no matter where they live.

Encouragingly, the 2022 Index showed how companies are increasingly engaging in strategies to expand access to their products in low- and middle-income countries (LMICs). The Index identified positive examples of equitable pricing models, manufacturing capacity building, and voluntary licensing – with more companies newly engaged in such agreements and technology transfers. Companies are also rethinking their business models in LMICs and are starting to make bold, global commitments to expanding access, including promises to offer entire portfolios of products at not-for-profit prices in LMICs. However, the real impact of these early-stage efforts remains to be seen. This Methodology Report, which outlines the framework that will be used to evaluate companies in the 2024 Access to Medicine Index, will serve as a valuable tool for evaluating how well companies live up to these commitments.

While the industry has taken an increasingly systematic approach towards expanding access, progress remains uneven across LMICs, leaving many people, especially marginalised populations, without the healthcare they deserve. Among a few key enhancements identified through extensive stakeholder dialogue, the ratified framework will now place a greater emphasis on monitoring whether more patients are receiving essential healthcare products. To begin with, the Index will explore the varying approaches taken by companies to define, measure and report on the number of people that have been able to access their products. With this approach, the 2024 Index Methodology marks the first step in a long-term plan to help companies and other global health stakeholders identify gaps in access, address disparities, and promote accountability for improving health equity and access to medicine in LMICs.

While the COVID-19 pandemic is now behind many of us, the glaring inequities it exposed must come to an end. In many ways, the findings of this upcoming Index will be important in establishing whether companies have seized opportunities to improve and accelerate progress.

We have seen that by taking action, the industry and their partners can save lives. To close the equity gap we need to reach more people who need access today.

Jayasree K. Iyer
Chief Executive Officer
Access to Medicine Foundation

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FIGURE LIST

Executive Summary

Every two years, the Access to Medicine Foundation publishes the Access to Medicine Index, which evaluates and compares 20 of the world's largest research-based pharmaceutical companies according to their efforts to improve access to their products in low- and middle-income countries (LMICs).

This report sets out the 2024 Index Methodology, clearly defining the scopes and analytical framework – including priority topics and indicators – that will be used in the 2024 Access to Medicine Index.

TABLE 1 **The 20 companies in scope of the 2024 Access to Medicine Index**

Company Name	HQ
AbbVie Inc	USA
Astellas Pharma Inc	JPN
AstraZeneca plc	GBR
Bayer AG	DEU
Boehringer Ingelheim GmbH	DEU
Bristol Meyers Squibb Co	USA
Daiichi Sankyo Co, Ltd	JPN
Eisai Co, Ltd	JPN
Eli Lilly & Co	USA
Gilead Sciences Inc	USA
GSK plc	GBR
Johnson & Johnson	USA
Merck & Co, Inc (MSD)	USA
Merck KGaA (Merck)	DEU
Novartis AG	CHE
Novo Nordisk A/S	DNK
Pfizer Inc	USA
Roche Holding AG	CHE
Sanofi	FRA
Takeda Pharmaceutical Co, Ltd	JPN

How the Index drives change

The Index evaluates pharmaceutical companies in areas where they have the greatest potential and responsibility to make change, identifying best practice, tracking progress, and highlighting where critical action is needed to expand access to medicine. By ranking companies every two years, the Index shows which companies are leading the way and spurs them to be competitive and collaborate with local partners on priority access-to-medicine topics.

While the Index directly evaluates the actions of 20 companies, it also serves as a valuable self-assessment tool and provides a set of best practices that can empower a diverse range of entities in expanding access to medicine. The carefully constructed Index Methodology can, for example, be utilised by other innovative research-based firms and biotechnology companies to benchmark their actions. By analysing what is working where, and why, the Index also provides clear blueprints for expanding best practice.

Key to the Foundation's changemaking work is linking opportunities with the best practices identified through our research. By actively engaging with all stakeholders, the Foundation facilitates the wider application of best practices and the development of new approaches to long-standing access challenges. Beyond the Index Report, the Foundation engages in learning and evaluation sessions with companies to improve access to medicine. Investor briefings and topic-specific roundtables also form an integral part of our ongoing commitment to guide and incentivise companies on improving access to medicine for people living in LMICs.

Building stakeholder consensus

With over 15 years of methodological development, the Index framework and indicators have evolved through ongoing practical experience and extensive dialogue and consensus building between stakeholders. Through this process, the Foundation ensures the analytical framework, and its metrics, are aligned with societal expectations as to how pharmaceutical companies can make their products available, accessible, affordable, and of good quality to people living in LMICs.

For the 2024 Index, the Foundation interviewed over 100 global health stakeholders, including pharmaceutical companies, to refine the Methodology and reach consensus on enhancing and/or updating metrics.

Enhanced focus on patient reach

The previous Index aimed to encourage companies to widen the scale and scope of access, including increasing the number of products in their portfolios and targeting a wider range of LMICs to reach more patients. In line with this approach,

and based on stakeholder consensus, the 2024 Index will now also place greater emphasis on the concept of 'patient reach', which refers to the number of people that have managed to access a company's products. The aim is to evaluate and guide companies to more transparently define, measure, and report on their impact in reaching patients living in LMICs. Not only will this enable the assessment of successful strategies, but it can help companies to identify gaps in access, address disparities, and better allocate resources to improve health equity and the lives of underserved populations.

With this strengthened approach, the Foundation aims to promote accountability within the industry, and to encourage the development and improvement of inclusive business models aimed at LMICs. Additionally, assessing patient reach can help stakeholders – including governments, non-governmental organisations, and investors – make informed decisions regarding partnerships, policies and investments.

As set out below, this increased focus on patient reach is reflected in many of the enhancements and updates to the 2024 Index Methodology, particularly in the Governance of Access Technical Area.

What the Index will measure

Following analysis of company pipelines, portfolios, market capitalisations and revenue, the 2024 Index will assess the same 20 pharmaceutical companies as in the 2022 Index (see Table 1 on p. 5).

As summarised in Figure 1, companies will be analysed based on a fixed set of diseases and product types across a specific geographic scope, with some changes made since the 2022 Index.

FIGURE 1 **Scopes of the 2024 Access to Medicine Index**

COMPANY SCOPE	GEOGRAPHIC SCOPE	DISEASE SCOPE	PRODUCT TYPE SCOPE
20 research-based pharmaceutical companies Companies are selected based on their market capitalisation and revenue, and the relevance of their product portfolios and pipelines for the diseases and countries in scope of the Index.	**113 low- and middle-income countries (LMICs)** Company actions are measured in countries where better access to medicine is most urgently needed. All countries that were included in the 2022 Index will continue to be part of the scope. Five countries have been added since the 2022 Index: • Jamaica • Jordan • Lebanon • Marshall Islands • Saint Lucia	**81 diseases, conditions and pathogens** The diseases, conditions and pathogens in scope disproportionately impact people living in LMICs: • 23 communicable diseases • 16 non-communicable diseases • 20 neglected tropical diseases • 10 maternal and newborn health conditions • 12 priority pathogens	**8 product types** This scope 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 countries covered by the Index: • Medicines • Microbicides • Preventative vaccines • Therapeutic vaccines • Vector control products • Platform technologies • Diagnostics • Contraceptive methods and devices

How the Index will measure

The Methodology for the 2024 Index is based on a robust analytical framework that corresponds to the core role pharmaceutical companies can play to improve access to medicine. As in the previous Index, this role centres on the creation of equitable delivery of health products while ensuring responsible practice and appropriate management of access.

For the 2024 Index, the period for which data will be analysed covers company activities between 1 June 2022 and 31 May 2024.

3 Technical Areas

Stakeholders have again confirmed three Technical Areas in which pharmaceutical companies have responsibility and ability to influence access to medicine in LMICs. The Technical Areas are divided into 15 priority topics (see Figure 2 on p. 8). Each Technical Area is weighted differently, as indicated in brackets below.

1. **Governance of Access (15%)**: Assesses company strategies, goals and incentive structures related to access to medicine. It also looks at how companies apply processes to minimise the risk and occurrence of non-compliant and/or corrupt behaviour, and the remedial actions companies take when such breaches occur. Additionally, this Technical Area will newly assess how companies measure and report on patient reach.
2. **Research & Development (30%)**: Assesses in-house and collaborative research and development (R&D) activity aimed at developing or adapting products for diseases, conditions and pathogens in scope of the Index, and in response to the needs of people living in LMICs. It also examines whether companies plan sufficiently during the development of their products to make sure those that progress through the pipeline become swiftly accessible in LMICs.
3. **Product Delivery (55%)**: Assesses how companies improve access to their products through a variety of mechanisms, including registration, pricing strategies, responsible intellectual property management, inclusive business models and product donations. It also examines how companies design and measure outcomes of their access strategies and tailor their tools to boost access. Further, it captures how companies leverage their expertise and resources to address significant local barriers to access. Such barriers might include gaps in local healthcare infrastructure, poorly functioning supply chains, weak quality assurance systems and/or gaps in skills.

32 indicators

The 2024 Index will assess companies using an analytical framework consisting of 32 indicators of company performance (one more than in 2022) to provide a holistic view of companies' efforts to increase access to medicine in LMICs.

Several indicators have been either added, modified or merged to continue to tailor the analytical framework closely to evolving stakeholder expectations of company behaviour, or to improve elements of data collection and analysis.

All indicators that will be used in the 2024 Index, including descriptions and rationales for changes, are listed in this report, with a summary of key changes set out on page 8.

KEY CHANGES IN THE 2024 INDEX

GOVERNANCE OF ACCESS

This Technical Area has been significantly updated for the 2024 Index with a merging of overlapping indicators, and updates to the remaining indicators to better capture the most important elements of Governance of Access. Notably, a new priority topic on measuring and reporting patient reach has been introduced, which will look at the success of companies' strategies in ensuring their essential healthcare products reach patients living in LMICs. This includes a standalone patient reach indicator, which will evaluate how companies define, measure and report on patient reach.

RESEARCH AND DEVELOPMENT

This Technical Area has been updated to capture access plans for all R&D projects in Phase II or beyond targeting diseases in scope of the Index, in addition to projects that are deemed priority R&D. The Technical Area also newly includes a requirement that a company publicly discloses its overarching R&D access planning commitments for patients living in LMICs on its website or in its reporting.

PRODUCT DELIVERY

The main shift in this Technical Area is a complementary and expanded focus on how companies are improving the number of patients reached in LMICs for specific products. This has a bearing on access strategy indicators. Registration and ensuring continuous supply indicators have been updated to capture additional information on collaborative registration procedures and local manufacturing, respectively. To focus and streamline analysis, other modifications to indicators were made, including merging indicators and the addition of inclusion criteria, or clarifying language where needed.

FIGURE 2 **Analytical framework for the 2024 Access to Medicine Index**
The 2024 Access to Medicine Index will analyse company behaviour using an analytical framework of 32 indicators organised in three Technical Areas that are divided into 15 priority topics.

3 Technical Areas	15 Priority Topics	32 Indicators
GOVERNANCE OF ACCESS	Responsible business practices	●●●●
	Governance and strategy	●●
	Measuring and reporting patient reach	●
RESEARCH & DEVELOPMENT	Access planning	●●●
	Product development	●●●
	Building R&D capacity	●
PRODUCT DELIVERY	Equitable access strategies and outcomes	●●●●●
	Intellectual property strategy	●●●
	Quality and supply	●●●
	Product donations	●●
	Health system strengthening	●
	Inclusive business models	●
	Licencing quality	●
	Local manufacturing	●
	Registration	●

The 2024 Access to Medicine Index Methodology

The Access to Medicine Index is the product of a two-year cycle, which starts with a review of the previous Index Methodology aimed at ensuring the Index remains a rigorous tool for assessing companies' activities and is an effective guide for incentivising change.

In the following sections, the report outlines the 2024 Access to Medicine Index Methodology, including the review process and the analytical framework on which the 2024 Index will be based.

REVIEWING THE INDEX METHODOLGY

The 2024 Index Methodology Review started with a series of internal checks on indicators, data sets and analytical approaches. This was followed by an external review to confirm the consensus view among stakeholders on where companies should take action to make their products available, accessible, affordable, and of good quality to people living in low- and middle-income countries (LMICs).

ANALYTICAL FRAMEWORK

- **What the Index measures**
  This section sets outs the rationale for the analytical scopes of the 2024 Access to Medicine Index, and how they have been defined.
- **How the Index measures**
  This section explains how company actions will be measured across three Technical Areas and 15 priority topics in the 2024 Access to Medicine Index.

The analysis of company performance comprises 32 indicators grouped into three Technical Areas:

1. Governance of Access
2. Research and Development
3. Product Delivery

REVIEWING THE METHODOLOGY

How the Foundation defines actions companies can take to expand access

The publication of each Access to Medicine Index is the culmination of a two-year process known as the 'Index cycle', which starts with an extensive review of the Index Methodology. Through this review, the Foundation ensures the Index captures the priority areas that research-based pharmaceutical companies can focus on to make their products available, accessible, affordable, and of good quality to people living in low- and middle-income countries (LMICs).

The 2024 Methodology review commenced in 2023, with the Index team carrying out a targeted internal review of the analytical framework, scopes, and indicators used in the 2022 Index. This was followed by an external review to reaffirm the consensus view among stakeholders on the appropriate role of pharmaceutical companies in improving access to medicine in LMICs. The resulting consensus has been translated into a refined set of metrics for assessing how far the world's largest pharmaceutical companies are going in fulfilling their roles and meeting society's expectations.

Primary principles of the 2024 Methodology review

1. Ensure that the framework and indicator set clearly reflect the core role of large research-based pharmaceutical companies in access to medicine, are responsive to the emerging access needs in LMICs, and incentivise change.
2. Enable the identification of best practice in all aspects of access to medicine in order to facilitate broader uptake.
3. Ensure all metrics are robust and can be used to fairly compare a range of companies against each other.
4. Preserve the capacity of the Index to track pharmaceutical company activity on access to medicine over time.
5. Ensure the usefulness of the Index's findings and analyses for governments, companies, investors, non-governmental organisations (NGOs) and other key stakeholders in improving access to medicine.

How the Foundation develops and updates metrics

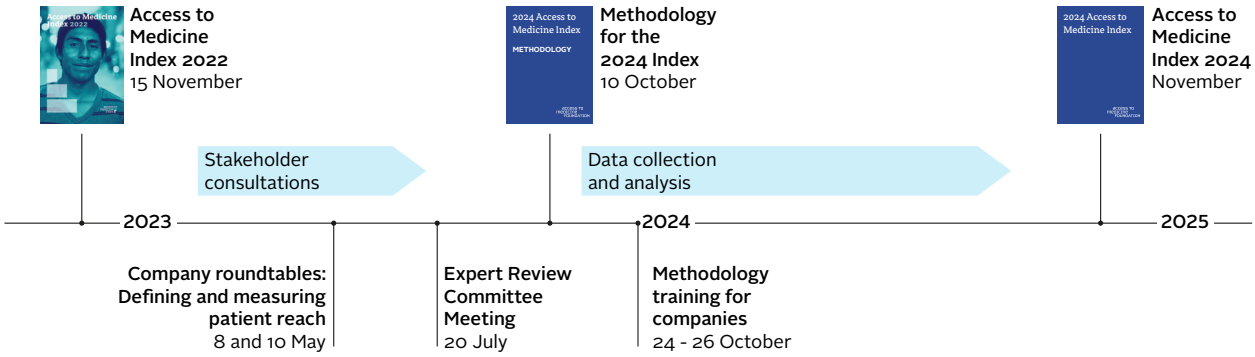
The Foundation uses strict standards for deciding when to merge or remove a metric within the analytical framework. These include the consensus view on the relevance of the measured behaviour, and the clarity and degree of consensus regarding the industry's role. As part of the Foundation's internal review of the Methodology, each of the indicators in the 2022 Access to Medicine Index was quantitively and qualitatively analysed for robustness, response quality, the potential for longitudinal analysis and the ability to drive change among companies. Further details of the review process are laid out below:

- **Distribution analyses:** Assessing the distribution of scores per indicator to check the spread of company behaviour in the 2022 Index. This indicates whether expectations of companies are fair (e.g., a cluster of high scores could indicate an area where expectations for company performance should be raised) and the extent of room for improvement. Outcomes inform refinements to indicators and scoring guidelines.

- **Response rate analyses:** Assessing company response rates and the quality of data provided for each data request in the 2022 Index. This establishes whether questions are clear and whether companies can feasibly gather data for each question.
- **Correlation analyses:** Indicator-level assessments of score correlations, which help diagnose less relevant indicators and can reveal or confirm positive or negative relationships between related areas of company behaviour.
- **Qualitative indicator review:** A battery of qualitative assessments of each indicator including clarity of the expectations and role for companies, continuing relevance to access to medicine, potential for longitudinal comparisons and the 'change-making' potential of each indicator.

These tests were used to detect and eliminate the risk of redundant measures, to pinpoint opportunities for enhancing data and to identify where scoring guidelines could be tightened. During the indicator review, topics were identified for discussion during external consultations with experts and stakeholders.

FIGURE 3 **Methodology review for the 2024 Access to Medicine Index**



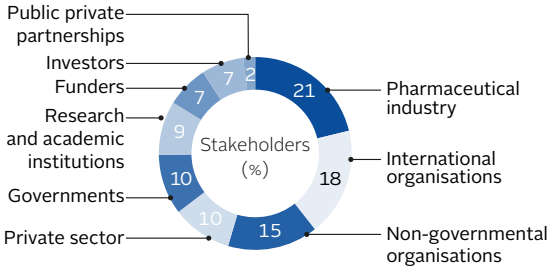
Stakeholder outreach for the 2024 Access to Medicine Index

A key step in the Index Methodology review process is building stakeholder consensus on what is expected from companies in advancing access to medicine. As in previous years, consultations were carried out with global health experts to ensure a diverse range of viewpoints and technical expertise were incorporated. For the 2024 Index Methodology, this included consultations with over 100 stakeholders from varying sectors, including all 20 pharmaceutical companies evaluated in the 2022 Index (see Figure 4 on p.12).

Importantly, in May 2023 the Foundation also held two roundtables on the topic of 'patient reach'. These sessions facilitated discussions with pharmaceutical companies about how they define and quantify patient reach. In combination with insights from experts on the topic, company feedback has been used to inform the modification and creation of indicators for the 2024 Index to measure patient reach, while fairly assessing company performance.

The Foundation continues to strive for diversity in consensus building with respect to factors like gender and ensuring the inclusion of individuals with relevant expertise and/or first-hand experience with access to medicine issues in LMICs. In the 2024 Index Methodology consultations, stakeholders representing LMICs increased, and gender parity was achieved.

FIGURE 4: **Stakeholders consulted during the 2024 Index Methodology review**



Expert Review Committee

The endpoint for the Methodology review is the meeting of the Expert Review Committee (ERC), who provide strategic guidance in ensuring the Methodology reflects expectations of pharmaceutical companies. The ERC is an independent body and comprises a diverse range of international experts on access to medicine – including from the World Health Organization (WHO), governments, the pharmaceutical industry, NGOs, academia, and investors. The ERC met in July 2023 to review proposals for the scope, structure, and analytical approach of the 2024 Index. This involved making recommendations where the consensus view was unclear or where uncertainty existed in areas of measurement, before endorsing the final Methodology.

Expert Review Committee for the 2024 Index

- Chair of the Committee: Hans Hogerzeil, Emeritus Professor of Global Health at the University of Groningen (Netherlands) and co-chair of the Lancet Commission on Essential Medicines Policies
- Mojisola Christianah Adeyeye, Director General at the National Agency for Food and Drug Administration and Control (NAFDAC) and Professor Emeritus at Roosevelt University (Chicago, USA)
- Malick Anne, Bureau Chief of non-communicable diseases (NCDs) at Senegal's Ministry of Health and Social Action
- Michela Gregory, Director, Responsible Investing & Environmental, Social and Governance (ESG) Services, at NEI Investments
- Fumie Griego*, Deputy Director General and Chief Operating Officer at the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Regina Mariam Namata Kamoga, Executive Director of the Community Health and Information Network (CHAIN) in Uganda and Founding Director of the World Patient Alliance
- Caroline S. Mbindyo, CEO of Amref Health Innovations for Amref Health Africa
- Hema Srinivasan, Chief Access Officer at MedAccess
- Fatima Suleman, Professor in the School of Health Sciences, University of KwaZulu-Natal (South Africa) and Director of Collaborating Centre for Pharmaceutical Policy and Evidence Based Practice at WHO
- Klara Tisocki, Team Lead (Pricing and Affordability) and Regional Advisor, Essential Medicines (South East Asia Regional Office) at WHO
- Prashant Yadav, Senior Fellow at the Center for Global Development and Affiliate Professor of Technology and Operations at Institut Européen d'Administration des Affaires (INSEAD)

*Designation at the time of the Expert Review Committee meeting. At the time of publishing the 2024 Index Methodology, this member had left her respective organisation.

What the Index measures

The Access to Medicine Index assesses pharmaceutical companies' policies and behaviour regarding specific diseases and product types across a specific geographic scope. The following pages set out the rationale for these analytical scopes and how they have been defined.

In this section:

COMPANY SCOPE
20 companies

DISEASE SCOPE
81 diseases, conditions and pathogens
- 23 communicable diseases
- 16 non-communicable diseases
- 20 neglected tropical diseases
- 10 maternal and newborn health conditions
- 12 priority pathogens

GEOGRAPHIC SCOPE
113 low- and middle-income countries

PRODUCT TYPE SCOPE
Medicines, microbicides, preventive vaccines, therapeutic vaccines, vector control products, platform technologies, diagnostics, contraceptive methods and devices.

WHAT WE MEASURE

Company Scope

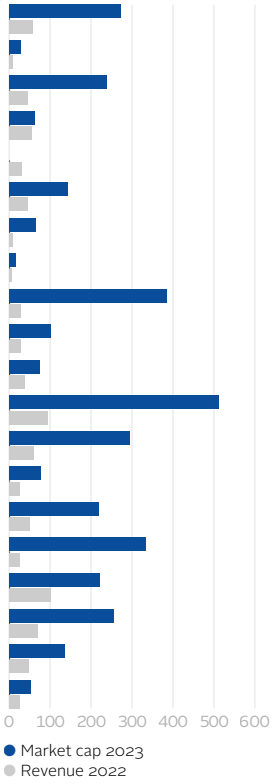
The Access to Medicine Index assesses 20 of the world's largest research-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their pipelines, portfolios, resources, and global reach, these companies have clear opportunities and a responsibility to address access.

Companies are selected for inclusion based on their market capitalisation and revenue, and the relevance of their product portfolios and pipelines for the diseases and countries in scope of the Index. The largest research-based companies in the world were identified through a company market capitalisation and revenue analysis, which also took mergers, acquisitions, and divestments into account. Their pipelines and portfolios were then mapped against diseases in scope of the Index and the research and development (R&D) needs of people living in countries in scope. Companies that qualified for analysis based on size could be disqualified for having fewer relevant products and R&D projects than companies of similar size. Following this review, the 2024 Index will evaluate the same 20 companies as in 2022, facilitating trend analysis.

Companies that exclusively produce generic medicines are not eligible for inclusion as they have a distinctly different role to play in improving access to medicine. These companies are assessed in the Access to Medicine Foundation's Generic and Biosimilar Medicines Programme.

FIGURE 5 **Companies in scope of the 2024 Access to Medicine Index**

Company	Stock exchange	Country	Ticker	Revenue 2022* (USD bn)**	Market cap*** 2023 (USD bn)**
AbbVie Inc	NYSE	USA	ABBV	58.054	271.166
Astellas Pharma Inc	TSE	JPN	4503	9.457	27.449
AstraZeneca plc	LSE	GBR	AZN	44.351	239.227
Bayer AG	XFRA	DEU	BAYN	55.773	62.073
Boehringer Ingelheim	Privately held	DEU	N/A	30.133	N/A
Bristol Myers Squibb	NYSC	USA	BMY	46.159	143.698
Daiichi Sankyo Co, Ltd	TSE	JPN	4568	7.624	64.893
Eisai Co, Ltd	TSE	JPN	ESALY	5.518	16.665
Eli Lilly & Co	NYSE	USA	LLY	28.541	385.224
Gilead Sciences	NASDAQ	USA	GILD	27.281	101.612
GSK plc	LSE	GBR	GSK	36.724	73.763
Johnson & Johnson	NYSE	USA	JNJ	94.943	510.406
Merck & Co, Inc (MSD)	NYSE	USA	MRK	59.283	295.235
Merck KGaA (Merck)	XFRA	DEU	MRK	24.438	77.040
Novartis AG†	SWX	CHE	NOVN	50.545	218.128
Novo Nordisk A/S	Nasdaq Copenhagen	DNK	NOVO-B	26.095	332.395
Pfizer Inc	NYSE	USA	PFE	100.330	221.317
Roche Holding AG	SIX	CHE	ROG.SW	70.723	255.783
Sanofi	EPA	FRA	SAN	47.263	134.604
Takeda Pharmaceutical Co, Ltd	TSE	JPN	TAK	26.040	52.147



*All revenues are taken from companies' 2022 annual reports. For the Japan-headquartered companies, this represents revenue from April 2021 to March 2022. For remaining companies, this represents revenue from January 2022 to December 2022.

**Exchange rates on 2 May 2023 from oanda.com
***Market cap on 2 May 2023 from finance.yahoo.com

†Novartis will spin off Sandoz, its generic pharmaceutical and biosimilar division, on or around October 4 2023, just prior to the publication of this Methodology.

WHAT WE MEASURE

Disease scope

The Access to Medicine Index evaluates pharmaceutical companies' actions in addressing access to medicine for diseases, conditions and pathogens that the global health community considers most critical to address in low- and middle-income countries (LMICs). This scope is defined by consulting epidemiological data and independent priority lists. In the development of each new Index Methodology, this analysis is conducted, and its results are ratified by the Expert Review Committee. Following this review, the disease scope for the 2024 Access to Medicine Index has been set at 81 diseases, conditions and pathogens.

Defining the disease scope

Some diseases are in scope of the Index because they impose a high global disease burden despite the existence of effective treatments, or because they affect poorer populations disproportionately. To identify such diseases, the Foundation used a screening protocol (see Figure 6 on p. 16). This is based on factors such as: the prioritisation of the disease by organisations such as Policy Cures Research and the World Health Organization (WHO) for improving access to medicine; global and/or country-level disease burdens; and the relevance of pharmaceutical intervention.

The 2024 Index disease scope has been updated according to the most recent Global Burden of Disease Study (GBD 2019),[1] which also provides country-level data on disability-adjusted life years (DALYs). This measure is commonly used to measure the burden of disease in a population. The WHO defines one DALY as "one lost year of 'healthy' life" to account for the gap between a given population's ideal health situation, and the actual situation.

- **All cardiovascular diseases are now included.** All diseases, conditions and pathogens that were included in the 2022 Access to Medicine Index scope will remain in scope for the 2024 Index. However, stroke, ischaemic heart disease and hypertensive heart diseases have been grouped into the umbrella category of cardiovascular diseases, reducing the total number of diseases, conditions and pathogens in the disease scope from 83 to 81.
- **Previous iterations of the Index have focused on diseases that mostly affect people in LMICs.** The Index considers this to be a strong indicator that a low level of incentive to invest in pharmaceutical research and development (R&D) will limit the availability of suitable treatment options. In 2024, the Index will retain its focus on these diseases and (where data is available) will specifically include diseases in which more than 95% of the global DALY burden is faced by countries in scope of the Index.[1]
- **Three diseases that exclusively affect women and girls (linked to biological sex) remain in scope for the 2024 Index.** According to a review of data from GBD 2019 and from the Global Cancer Observatory (GLOBOCAN 2020), endometriosis, ovarian and uterine cancers have comparably higher incidence rates and/or DALY burdens than other sex-linked diseases.[1,2] Their inclusion in the disease scope increases the capacity of the Index to assess the unmet needs of women and girls with sex-linked diseases living in LMICs.

DISEASE SCOPE

23 communicable diseases

This category includes the 10 communicable diseases with the highest DALY burdens in countries in scope of the Index, as well as diseases for which product gaps have been identified as priority R&D targets, such as emergent non-polio enteroviruses and 'Disease X', a WHO term to denote a currently unknown pathogen that could cause a serious international epidemic (as seen for COVID-19).

16 non-communicable diseases

This category includes the 10 non-communicable diseases with the highest DALY burdens in countries in scope of the Index. It also includes cancer types with a high or disproportionate incidence in LMICs.[2] For the 2024 Access to Medicine Index, hypertensive heart disease, ischaemic heart disease and stroke are combined into cardiovascular diseases. Sickle cell disease and thalassemia remain in scope due to a disproportionate disease burden in countries in scope of the Index. Bipolar affective disorder, epilepsy and schizophrenia are retained based on continuing stakeholder consensus on the critical need for access to treatment.

20 neglected tropical diseases

As in 2022, the 2024 Index includes all WHO-classified neglected tropical diseases.[3] Yaws now includes other endemic treponematoses (bejel and pinta).

10 reproductive, maternal and newborn health conditions

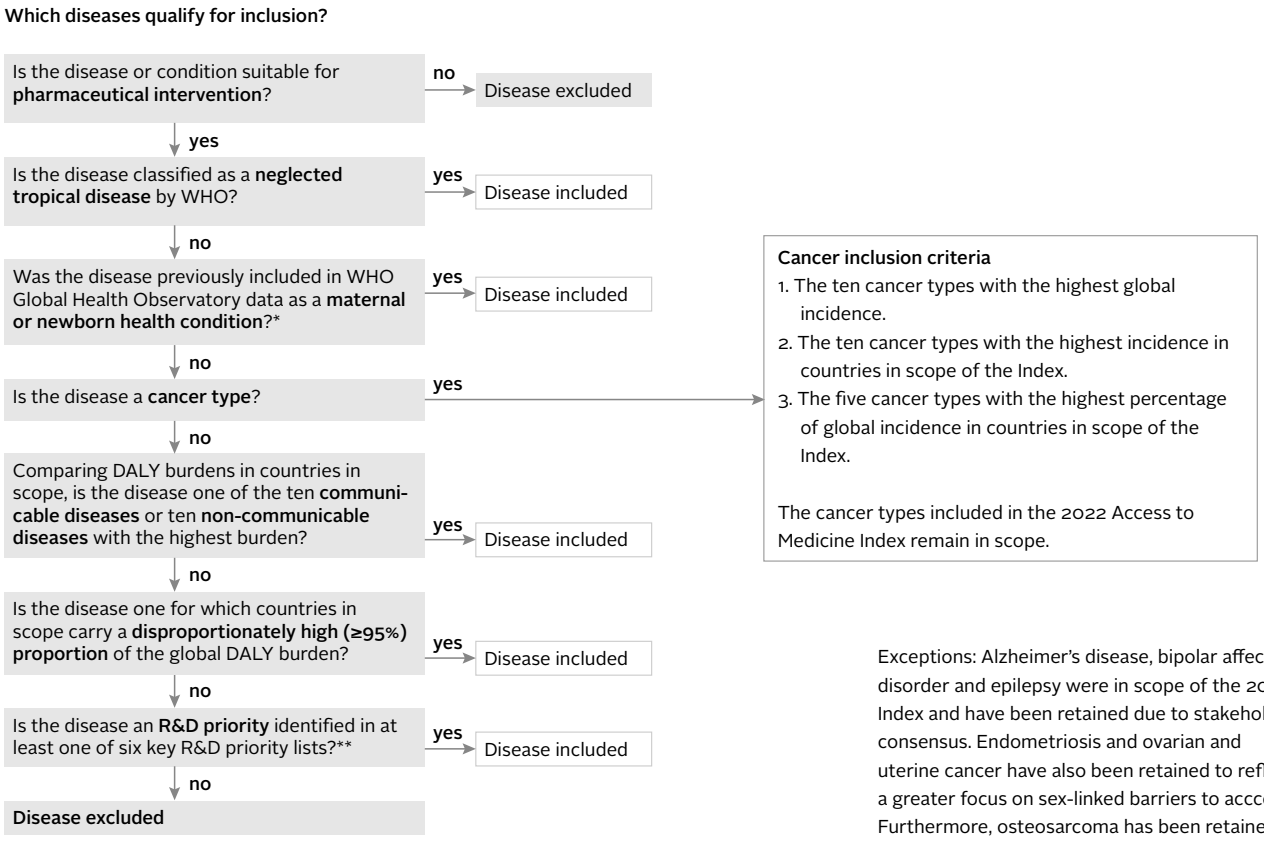
To recognise the importance of reproductive, maternal and child health, the Index has since 2014 included contraceptives and nine maternal and newborn health conditions.

12 priority pathogens

As in 2022, the Index covers the 12 pathogens included in the WHO's definitive priority pathogens list (2017). These are deemed a priority for efforts to curb antimicrobial resistance through the development of new and effective antibacterial agents.[4]

FIGURE 6 **Defining the disease scope**

The Access to Medicine Index analyses company practice in relation to a defined set of diseases, conditions and pathogens. These are identified as priorities for improving access to medicine using the following protocol.



Exceptions: Alzheimer's disease, bipolar affective disorder and epilepsy were in scope of the 2022 Index and have been retained due to stakeholder consensus. Endometriosis and ovarian and uterine cancer have also been retained to reflect a greater focus on sex-linked barriers to acccess. Furthermore, osteosarcoma has been retained as it is the most common primary malignant bone tumour in children and young adults.

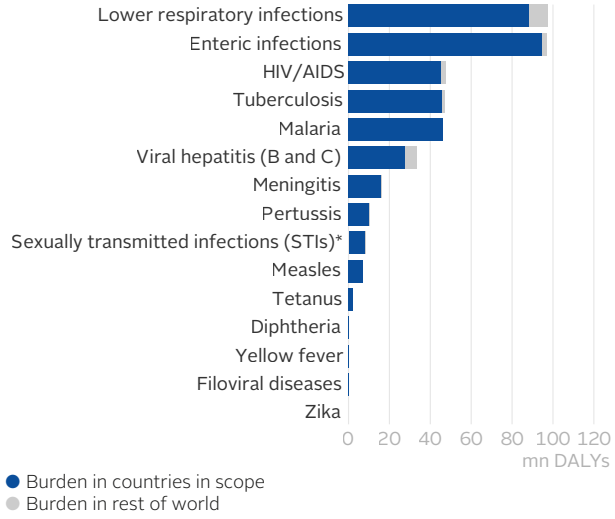
*As listed in the WHO methods and data sources for global burden of disease estimates 2000-2019

**Policy Cures Research G-FINDER neglected diseases, sexual and reproductive health, and emerging infectious diseases; WHO Prioritizing diseases for research and development in emergency contexts, WHO Target Product Profiles and WHO Priority Pathogen List.[5-10]

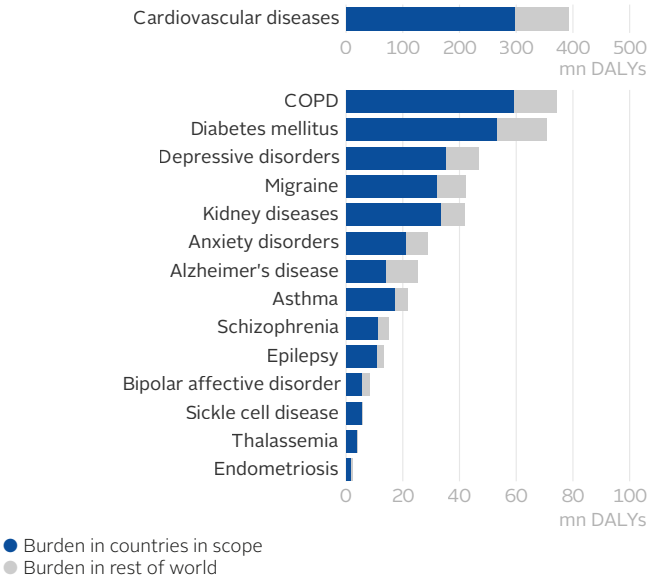
FIGURE 7 **Low- and middle-income countries have a disproportionate share of global disease burdens**

These four charts give an indication of how the diseases and conditions in scope disproportionately affect people living in low- and middle-income countries, who account for nearly 80% of the world's population. Behind these numbers are millions of people who cannot rely on access to affordable, quality medicine.

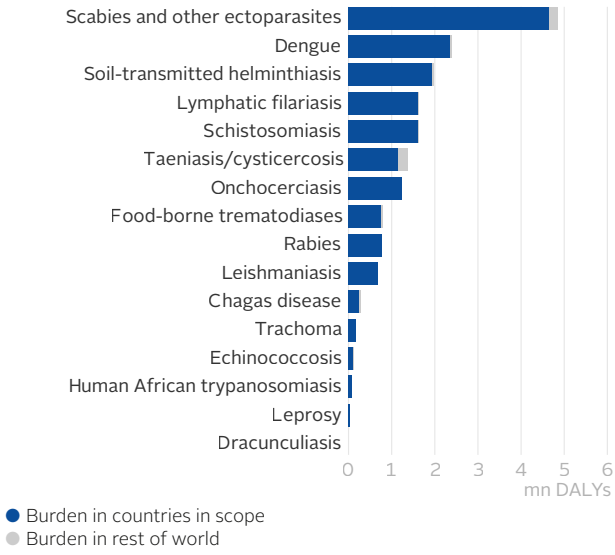
Communicable diseases



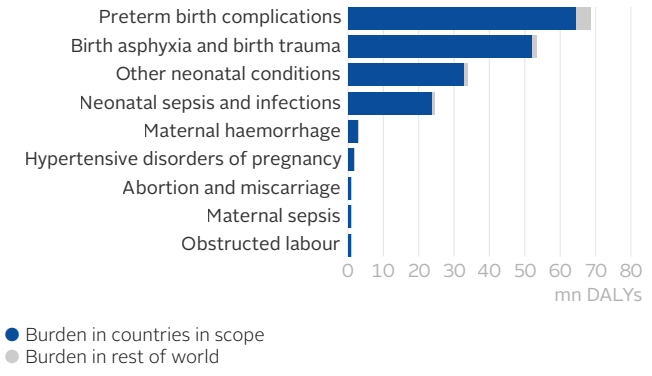
Non-communicable diseases**



Neglected tropical diseases



Maternal and newborn health conditions



*Excludes HIV/AIDS

**The incidence for cancer types in scope is found in Appendix IA on p. 40.

FIGURE 8 **List of diseases, conditions and pathogens included in the 2024 Access to Medicine Index**

	Top 10 DALY burden in countries in scope of the Index	≥95% disease burden in countries in scope of the Index	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Communicable diseases					
Arenaviral haemorrhagic fevers				●	
Bunyaviral diseases				●	
Coronaviral diseases				●	
Diphteria		●			
Disease X***				●	
Emergent non-polio enteroviruses				●	
Enteric infections	●	●		●	
Filoviral diseases		●		●	
Henipaviral diseases				●	
HIV/AIDS	●	●		●	
Leptospirosis				●	
Lower respiratory infections	●			●	
Malaria	●	●		●	
Measles	●	●			
Meningitis	●	●		●	
Pertussis	●	●			
Rheumatic fever				●	
Sexually transmitted infections (STIs)†	●	●		●	
Tetanus		●			
Tuberculosis	●	●		●	
Viral hepatitis (B and C)	●	●		●	
Yellow fever		●			
Zika				●	
Non-communicable diseases					
Alzheimer's disease	●				●
Anxiety disorders	●				
Asthma	●				
Bipolar affective disorder					●
Cancer‡	●			●	●
Cardiovascular diseases	●				
Chronic obstructive pulmonary disease (COPD)	●				
Depressive disorders	●				
Diabetes mellitus	●				
Endometriosis					●
Epilepsy					●
Kidney diseases	●				
Migraine	●				
Schizophrenia					●
Sickle cell disease		●			
Thalassemia		●			●

	Top 10 DALY burden in countries in scope of the Index	≥95% disease burden in countries in scope of the Index	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Neglected tropical diseases					
Buruli ulcer			●	●	
Chagas disease			●	●	
Dengue and chikungunya		●	●	●	
Dracunculiasis		●	●		
Echinococcosis			●		
Food-borne trematodiases		●	●		
Human African trypanosomiasis		●	●	●	
Leishmaniasis		●	●	●	
Leprosy		●	●	●	
Lymphatic filariasis		●	●	●	
Mycetoma, chromoblastomycosis and other deep mycoses			●	●	
Onchocerciasis		●	●	●	
Rabies		●	●		
Scabies and other ectoparasites		●	●	●	
Schistosomiasis		●	●	●	
Snakebite envenoming		●	●	●	
Soil-transmitted helminthiasis		●	●	●	
Taeniasis/cysticercosis			●	●	
Trachoma		●	●	●	
Yaws and other endemic treponematoses		●	●		
Reproductive, maternal and newborn health conditions					
Abortion and miscarriage		●	●		
Birth asphyxia and birth trauma		●	●		
Contraceptive methods			●	●	
Hypertensive disorders of pregnancy		●	●	●	
Maternal haemorrhage		●	●	●	
Maternal sepsis		●	●		
Neonatal sepsis and infections		●	●	●	
Obstructed labour		●	●		
Other neonatal conditions		●	●		
Preterm birth complications			●		

Priority pathogens§

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)

Blue text = Newly in scope for 2024 Access to Medicine Index

*Diseases, conditions and pathogens indicated as R&D priorities on identified lists published by Policy Cures Research and WHO. [5-10]
**These diseases have been retained or added due to specific access barriers, amongst other reasons, as identified in stakeholder engagement.
***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 Appendix IB on p. 43 for more details.
§These will be collectively referred to as 'Other prioritised antibacterial-resistant infections' in the 2024 Access to Medicine Index and categorised as one disease under communicable diseases.

WHAT WE MEASURE

Geographic scope

The Access to Medicine Index measures the actions of pharmaceutical companies in places where there is an urgent need for better access to medicine. Four criteria have been used to select countries for the geographic scope of the 2024 Index: (1) inclusion in the 2022 Index, (2) countries' level of income (gross national income per capita), (3) level of human development and (4) scale and scope of inequality. Each country was assessed based on data from the World Bank, the United Nations Development Programme (UNDP) and the United Nations Economic and Social Council (ECOSOC).

The geographic scope of the 2024 Index covers 113 countries. Five new countries have been added since the 2022 Index (Jamaica, Jordan, Lebanon, Marshall Islands and Saint Lucia). All countries included in the 2022 Index have also been included in this Index to enable the longitudinal tracking of efforts made by the pharmaceutical companies in these countries. Countries included in the 2022 Index that no longer qualify for inclusion under the below criteria (e.g., higher income level) were maintained in the 2024 Index. These countries will remain in scope for six years to facilitate longitudinal analysis and to prevent frequent switching out of countries.

DEFINING THE GEOGRAPHIC SCOPE

Step 1: Include all countries that were monitored in the previous Access to Medicine Index.

Step 2: Include countries classified as low-income or lower-middle-income countries, according to the most recent World Bank income group classification (FY2024).[11]

Step 3: Include all countries defined as having low or medium human development, according to the most recent UNDP Human Development Report (2021).[12]

Step 4: Include all high-development countries with a low inequality-adjusted human development index, according to the most recent UNDP Human Development Report (2021).[12] This enables the Index to track higher-income countries with significant levels of inequality.

Step 5: Include all Least Developed Countries (LDCs) as defined by the most recent ECOSOC list (2021).[13]

FIGURE 9 **113 countries are included in the 2024 Access to Medicine Index**

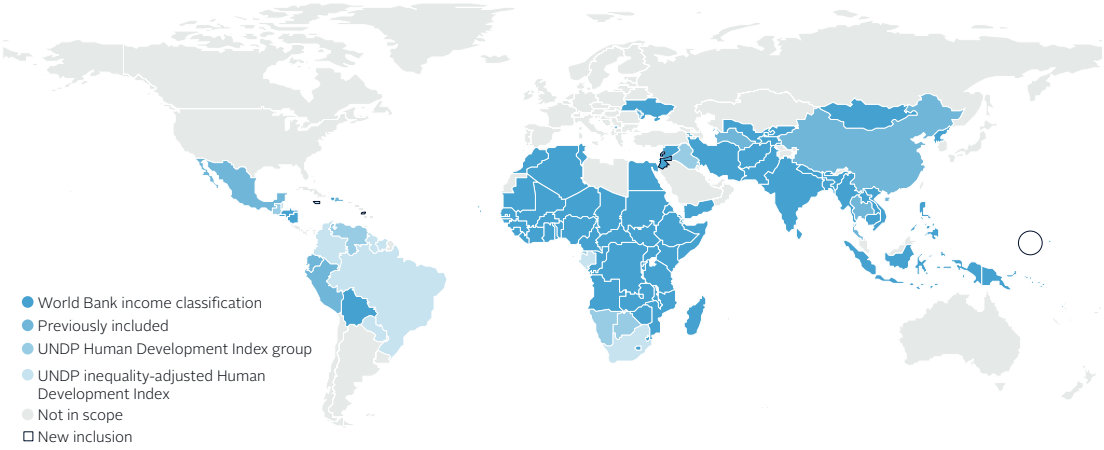


TABLE 2 **List of countries included in the 2024 Access to Medicine Index**

East Asia & Pacific	
Cambodia	LMIC
China	UMIC
Indonesia	UMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Lao PDR	LMIC
Marshall Islands	UMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Thailand	UMIC
Timor-Leste	LMIC
Tonga	UMIC
Tuvalu	UMIC
Vanuatu	LMIC
Vietnam	LMIC
Europe & Central Asia	
Armenia	UMIC
Kosovo	UMIC
Kyrgyzstan	LMIC
Moldova	UMIC
Tajikistan	LMIC
Turkmenistan	UMIC
Ukraine	LMIC
Uzbekistan	LMIC
Latin America & Caribbean	
Belize	UMIC
Bolivia	LMIC
Brazil	UMIC
Colombia	UMIC
Dominican Republic	UMIC
Ecuador	UMIC
El Salvador	UMIC
Guatemala	UMIC
Guyana*	HIC
Haiti	LMIC
Honduras	LMIC
Jamaica	UMIC
Mexico	UMIC
Nicaragua	LMIC
Paraguay	UMIC
Peru	UMIC
Saint Lucia	UMIC
Suriname	UMIC
Venezuela	Unclassified
Middle East & North Africa	
Algeria	LMIC
Djibouti	LMIC
Egypt	LMIC
Iran	LMIC
Iraq	UMIC
Jordan	LMIC
Lebanon	LMIC
Morocco	LMIC
Palestine, State of/West Bank Gaza	UMIC
Syrian Arab Republic	LIC
Tunisia	LMIC
Yemen, Rep.	LIC
South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	UMIC
Nepal	LMIC
Pakistan	LMIC
Sri Lanka	LMIC
Sub-Saharan Africa	
Angola	LMIC
Benin	LMIC
Botswana	UMIC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LMIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	UMIC
Eritrea	LIC
Eswatini	LMIC
Ethiopia	LIC
Gabon	UMIC
Gambia	LIC
Ghana	LMIC
Guinea	LMIC
Guinea-Bissau	LIC
Kenya	LMIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	UMIC
Niger	LIC
Nigeria	LMIC
Rwanda	LIC
São Tomé and Príncipe	LMIC
Senegal	LMIC
Sierra Leone	LIC
Somalia	LIC
South Africa	UMIC
South Sudan	LIC
Sudan	LIC
Tanzania	LMIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LMIC

LIC	Low-income country
LMIC	Lower-middle-income country
UMIC	Upper-middle-income country**
HIC	High-income country**

World Bank Income classifications (FY2024)

*Per the 2024 Index Methodology, Guyana is included despite recently receiving HIC classification. It will be retained for six years, after which it will be excluded from the country scope if it does not meet other inclusion criteria.

**All UMICs and HICs in a low or medium UNDP Human Development Index group or with a low inequality-adjusted Human Development Index were included.

WHAT WE MEASURE

Product 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 countries in scope of the Index. In 2024, as in the four previous iterations, the Index continues to include the same eight product types in scope, as described below.

- **Medicines**

All medicines (both patented and non-patented) that directly treat a target pathogen or disease process in scope are included, provided they meet inclusion criteria. Medicines used only for symptomatic relief are not included

- **Microbicides**

These include topical microbicides specifically intended to prevent HIV.

- **Therapeutic vaccines**

This covers vaccines intended to treat existing infections or diseases.

- **Preventive vaccines**

This covers vaccines intended to prevent infections.

- **Diagnostics**

This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable, easier to use in the field).

- **Vector control products**

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides that are intended for global public health use and specifically aim to inhibit and kill 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 and devices**

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used for 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 that are 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.

How the Index measures

The 2024 Access to Medicine Index assesses company behaviour using an analytical framework of 32 indicators organised in three Technical Areas. The following pages set out what each Technical Area measures and the rationale for each indicator.

In this section:

GOVERNANCE OF ACCESS 15%

Overview of the Technical Area

To improve access to medicine both tangibly and sustainably, pharmaceutical companies must implement clear access strategies that focus on the long term. By enforcing rigorous standards of behaviour across their operations (including with third-party contractors), companies can mitigate the risk of practices that cause harm and undermine their efforts to improve access to medicine.

The Governance of Access Technical Area looks at how companies align their corporate strategies with their access-to-medicine strategies, how they manage to achieve their access-to-medicine goals and objectives, and how they incentivise managers to deliver on access-to-medicine initiatives. It also looks at how companies apply processes to minimise the risk and occurence of non-compliant and/or corrupt behaviour, and the remedial actions companies take when such breaches occur. Additionally, the Governance of Access Technical Area now looks at how companies measure and report on patient reach.

Changes to the Methodology for the 2024 Index

- In the Methodology for the 2024 Index there are seven indicators, which is the same number as in the 2022 Index Methodology. However, significant updates have been made throughout the Technical Area; six out of seven indicators have materially changed (including one merger and one new indicator).
- Two indicators from the 2022 Index Methodology have been merged into a single indicator, although what the indicator assesses has not changed. The merged indicator is 'GA2: Access-to-medicine strategy and outcomes'.
- Indicator 'GA4: Responsible business practices' has been updated to ask for company policies on interactions with healthcare professionals (HCPs) to include reference to legitimate need for the interaction, as well as clarifying the wording around expectations for publicly disclosing information on transfers of value to HCPs.
- The wording of indicator 'GA5: Ethics, risk and compliance' has been updated to improve company understanding of the information required and to look at ethical decision-making policies/frameworks.
- In the indicator 'GA6: Incidence of breaches', additional analysis has been added to take into account publicly available evidence of remedial actions in the wake of a breach.
- 'GA7: Trade policy: Intellectual property and access to medicine' has been updated to focus on company intellectual property policies/statements, instead of the actions of the trade associations the companies belong to.
- A new indicator looking at the processes companies use to measure and report on patient reach has been added to the 2024 Index Methodology. This indicator is 'GA8: Measuring and reporting patient reach'.

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Governance and strategy

Indicator(s)

GA1, GA2

To ensure that they implement access strategies successfully, pharmaceutical companies must establish structures for governance and management. By assigning responsibility and offering incentives at the highest level, companies can increase the likelihood of prioritising, maintaining and achieving access-related objectives. Companies are expected to develop and implement a clear strategy with measurable goals to improve access to medicine. Such a strategy should not remain isolated from the main business of the company; it should seek to align with commercial concerns. Companies should publicly share their progress towards access-to-medicine goals.

2024 Indicator code	2024 Indicator text	Changes in 2024	Indicator rationale
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 access to medicine in countries, and for diseases, in scope of the Index.	**Retained**, with non-material editorial changes to indicator text.	Assigning responsibility for access to medicine in low- and middle-income countries (LMICs) at the highest level of a company increases the chance that access-related objectives are given attention, remain on track and are achieved. Access-related objectives and incentives encourage the CEO, senior management and in-country/regional managers to perform towards achieving access goals. Top-level responsibility is likely to trickle down into the rest of the company, ensuring the prioritisation of access.

GOVERNANCE OF ACCESS

2024 Indicator code	2024 Indicator text	Changes in 2024	Indicator rationale
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 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*. *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 diseases, symptoms or treatments) and/or medium to long term (such as number of patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; and/or availability of medicines at outlets). Outcomes can also relate to a country's health system (such as the number of healthcare professionals trained).	**Merged** with Indicator GA3.	An access-to-medicine strategy integrated in the overall corporate strategy indicates that a company considers access to medicine in LMICs to be relevant for its long-term growth, which makes access to medicine more sustainable. The strategy should cover all products in the company's portfolio and all projects, particularly those deemed to be of significant public health importance. Public reporting of access-to-medicine outcomes informs external stakeholders of companies' activities and progress, and enables accountability.
GA3	**Public disclosure of access-to-medicine outcomes** N/A	**Merged** with Indicator GA2 and removed as standalone indicator.	N/A

Responsible business practices

Indicator(s)

GA4, GA5, GA6, GA7

Corrupt behaviour and unethical marketing can have direct consequences for access to medicine, such as the misdirection of national health budgets and promotion of the irrational use of medicines. Pharmaceutical companies can limit misconduct by enforcing stringent ethics, risk and compliance processes across their operations, and with third parties, by modifying how they incentivise sales agents and by disclosing publicly how they engage with healthcare professionals (HCPs). They should also implement policies to ensure they interact ethically with HCPs, for example by setting limits on transfers of value (e.g., with fair market value assessments). The Index expects companies to have in place controls to mitigate the risk of non-compliance for their operations in LMICs. Companies should also be able to regulate the activities of contracted third parties. To assess the effectiveness of controls, the Index checks for negative rulings and/or settlements with regards to unethical marketing, corruption, anti-competitive practices, and clinical trial misconduct in LMICs. In accordance with their public standing, companies are expected to have intellectual property policies that are conducive to the international consensus on public health.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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 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 permitted by law. *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.	**Modified**, with material changes to indicator text.	Looking at responsible business practices provides insights on where and how companies may influence access in countries in scope of the Index, and ensures greater transparency and accountability. Decoupling sales agents' financial rewards from the volume of medicine they sell removes the incentive to engage in non-compliant behaviour (mis-sell, oversell, or other undue influence) in order for the sales agent to obtain their compensation. This is not only important to curb antimicrobial resistance, but also to prevent diversion of scarce resources from health budgets and ensure appropriate access to medicine. Public disclosure of transfers of value provide accountability regarding the interactions between companies and healthcare professionals, with the aim of, for example, curbing inappropriate incentives that can lead to irrational prescribing and divert resources from already burdened healthcare systems. It is also important for the appropriate use of company resources and managing external risks.

GOVERNANCE OF ACCESS

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
GA5	**Ethics, risk and compliance** 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 – covering areas such as ethical marketing, anti-corruption and 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. *The Index looks for procedures such as fraud-specific risk assessment, country or region risk-based assessments and processes to ensure third-party compliance.	**Modified**, with material changes to indicator text.	Corruption can inhibit access to medicine, so it is essential for companies to implement good ethics, risk and compliance policies and procedures to reduce this risk. Such policies and procedures aim to prevent non-compliant activities, which can negatively affect access by undermining confidence in the pharmaceutical sector, diverting scarce resources from health budgets, impacting prices and limiting the availability of medicines in the public sector.
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 publicly available evidence that the company has taken remedial actions (including cooperation with authorities) and steps designed to ensure the breach does not occur in future.	**Modified**, with material changes to indicator text.	Breaches of codes/regulations/laws can undermine confidence in the pharmaceutical sector, divert scarce resources from health budgets, impact prices and limit the availability of medicines in the public sector. Such civil, criminal and regulatory infractions provide information about the quality of a company's compliance systems and responses to unethical or illegal behaviour. Though cases of breaches may not be identified by such regulatory or law enforcement entities in LMICs and not exposed publicly, they do occur. Therefore, the Index assesses whether companies have been the subject of breaches in countries in scope of the Index involving unethical marketing practices, corrupt practices, anti-competitive practices, or misconduct in clinical trials. Remedial actions following a breach, as well as actions designed to ensure breaches do not reoccur, are important to demonstrate companies are accepting responsibility for the breach and are working to guarantee adherence to good business practices.
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 and Public Health.	**Modified**, with material changes to indicator text.	Where a company applies an IP strategy which does not operate in accordance with the international consensus on IP standards (through, for example, exerting pressure on governments not to incorporate provisions from the Doha Declaration on the TRIPS flexibilities within national legislation), there can be a knock-on negative impact to access to medicine in those countries. The Index looks at a company's public IP policy, and the extent to which that policy aligns with the principles embodied within the Doha Declaration on TRIPS and Public Health.

GOVERNANCE OF ACCESS

Measuring and reporting patient reach

Indicator(s)

GA8

Measuring and reporting patient reach numbers helps to identify gaps in access to medicine to allow for better allocation of resources. Companies are expected to publicly publish a methodology explaining how they calculate patient reach, as well as patient reach numbers, outcomes and improvements.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
GA8	**Measuring and reporting patient reach** The company has a process in place for measuring patient reach that: 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; 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. *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 or eradication of a disease).	**New indicator.**	Implementing policies and processes to define, measure, and report on the numbers of patients reached by a company's products promotes transparency, accountability, and corporate social responsibility. By measuring and reporting on patient reach, companies and their partners can identify gaps in access, address disparities, and better allocate resources to improve health equity and the lives of underserved populations.

RESEARCH AND DEVELOPMENT 30%

Overview of the Technical Area

Large research-based pharmaceutical companies play a significant role not only in developing new medicines and other lifesaving products needed in low- and middle-income countries (LMICs), but also in bringing them to market. Planning during drug development to improve access is needed to make such new products rapidly available to people who need them, wherever they live.

This Technical Area analyses in-house and collaborative research and development (R&D) activity that aims to develop or adapt products for diseases, conditions and pathogens in scope of the Index, and in response to the needs of people living in LMICs. It also examines whether companies plan sufficiently during the development of their products to make sure those that are successful become swiftly accessible in LMICs, and the extent to which they engage in R&D capacity building.

Changes to the Methodology for the 2024 Index

- Seven indicators remain in the R&D Technical Area in the 2024 Index Methodology. Two out of seven indicators in this Technical Area have materially changed.
- Within the 2024 Index pipeline analysis, 'RD1b: Other R&D projects' has been reworded to reflect that the Index not only assesses R&D pipeline projects that are defined as addressing a 'public health need' (e.g., by targeting a new population), but all R&D projects that are addressing diseases or conditions in scope of the Index (that are not deemed priority R&D under RD1a).
- For the 2024 Index, the indicator 'RD3b: Access planning for other R&D projects' has been changed to now assess access plans for all other R&D pipeline projects, beyond those that address an R&D priority gap. Access plans for late-stage projects (from Phase II onwards) that are included under indicator RD1b will be assessed under this indicator.
- The scope of the 'RD2: Planning for access: Framework' indicator has been expanded to evaluate whether companies make a public commitment to access planning in LMICs for pipeline candidates from Phase II onwards (e.g., on their website).

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Product development	Indicator(s)
Pharmaceutical companies have the capacity and expertise to develop and adapt products to address unmet public health needs in LMICs, where products are suitable for those populations. Companies can do this either in-house or in partnership. The Index maps companies' R&D activity against defined and published R&D priorities outlining where new, effective products are needed urgently: for example, for pathogens flagged as a priority due to antimicrobial resistance, or for neglected tropical diseases.[5-10] Additionally, the Index tracks product development for other diseases in scope for which R&D priorities have not yet been independently assessed (such as non-communicable diseases), as these diseases cause a disproportionately high burden in LMICs. Companies are also expected to disaggregate and disclose the resources they dedicate to such R&D.	RD1a, RD1b, RD4

RESEARCH AND DEVELOPMENT

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
RD1a	**R&D pipeline: Prioritised diseases** The company engages in the development of products that target priority product gaps identified by global health research organisations.* This includes innovative and adaptive R&D and in-house and collaborative R&D. *Currently, the Index categorises R&D priorities using lists from WHO and Policy Cures Research.	**Retained**, with no changes to indicator text.	Large research-based companies have the capacity, through R&D, to help address public health needs in LMICs for identified priorities. They are well positioned to ensure that these products progress through the pipeline, even if there is little commercial incentive. Additionally, companies should ensure that new product developments specifically address access barriers in LMICs by: 1. Creating new formulations to improve stability, administration or adherence (e.g., heat-stable formulations, dispersible oral formulations, long-acting formulations, new fixed-dose combinations). 2. Inclusion of special populations as it pertains to clinical research (e.g., pregnant/lactating individuals, children (<12 years), the elderly and immunocompromised). 3. Significantly improving the administrative burden, or total healthcare costs of existing products (e.g., require fewer hospital/clinic visits, long acting injectables, self-administered formulations). 4. Carrying out clinical trials in countries in scope of the Index.
RD1b	**R&D pipeline: Other diseases** The company engages in the development of products for other diseases in scope of the Index beyond the R&D priorities identified by global health research organisations.* This includes innovative and adaptive R&D. *Currently, the Index categorises R&D priorities using lists from WHO and Policy Cures Research.	**Retained**, with non-material editorial changes to indicator text.	The company engages in R&D (both innovative and adaptive) for all other diseases in scope of the Index (for which global health stakeholders have not formally identified priority product gaps). Additionally, companies should ensure that new product developments specifically address access barriers in LMICs by: 1. Creating new formulations to improve stability, administration or adherence (e.g., heat-stable formulations, dispersible oral formulations, long-acting formulations, new fixed-dose combinations). 2. Inclusion of special populations as it pertains to clinical research (e.g., pregnant/lactating individuals, children (<12 years), the elderly and immunocompromised). 3. Significantly improving the administrative burden, or total healthcare costs of existing products (e.g., require fewer hospital/clinic visits, long acting injectables, self-administered formulations). 4. Carrying out clinical trials in countries in scope of the Index.
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 diseases within scope of the Index.	**Retained**, with non-material editorial changes to indicator text.	Public disclosure of R&D investments can be used to identify and prioritise areas of limited financial investment, where additional investment from the public and private sector are needed. This can help promote transparency of R&D funding across the value chain and build understanding about the capital needed to bring different types of products, from different therapeutic areas, to market.

RESEARCH AND DEVELOPMENT

Access planning

Indicator(s)

RD2, RD3a, RD3b

Planning for access helps pharmaceutical companies ensure they take public health needs into account during product development. Such planning can help those in LMICs to gain access to products more rapidly and affordably following their market entry. When companies establish a structured process to develop access plans, this can help such planning become standard practice. Companies are expected to develop plans for all pipeline projects from Phase II of clinical development onwards.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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 onwards. The company makes public commitments addressing its systematic approach to access planning for LMICs.	**Modified**, with material changes to indicator text.	By establishing a structured framework and approach to develop access plans for all product candidates (both in-house and collaborative R&D), a company increases the likelihood of developing long-term access plans as early in the process as possible. When a company publicly commits to a systematic approach to access planning during R&D, this can help to ensure accountability, and can reinforce existing efforts.
RD3a	**Planning for access: Project-specific plans for prioritised diseases** The company ensures that all R&D projects for diseases prioritised by WHO and Policy Cures Research are supported by detailed commitments and strategies to improve access to products in countries within scope of the Index.	**Retained**, with no changes to indicator text.	Advance access planning is particularly critical for R&D projects developed to address key product gaps relevant to patients in LMICs. Companies should ensure these products quickly reach the people who need them by planning for access during clinical development (starting from Phase II). To increase the impact on public health, the company's access plans should go beyond filing for registration and consider affordability and aspects such as supply and demand planning, partnering with an access-oriented organisation, equitable pricing, WHO prequalification, post-trial access, technology transfers, product donations, patent waivers and non-exclusive voluntary licensing. Also, where applicable, companies should ensure inclusion of special populations, such as pregnant and breastfeeding individuals, children, and the elderly, in clinical research.
RD3b	**Planning for access: Project-specific plans for other diseases** The company ensures that all its R&D projects targeting diseases in scope of the Index (beyond those identified as R&D priorities by WHO and Policy Cures Research) are supported by detailed plans to improve access to products in countries within scope of the Index.	**Modified**, with material changes to indicator text.	To ensure successful products can be made available swiftly and widely, R&D projects require advance access planning. Companies should ensure these products are quick to reach the people who need them by planning for access during clinical development (starting from Phase II). To strengthen the potential impact on public health, the company's access plans should go beyond filing for registration and consider affordability and aspects such as supply and demand planning, partnering with an access-oriented organisation, equitable pricing, WHO prequalification, post-trial access, technology transfers, product donations, patent waivers and non-exclusive voluntary licensing. Also, where applicable, companies should ensure inclusion of special populations, such as pregnant and breastfeeding individuals, children and the elderly, in clinical research.

RESEARCH AND DEVELOPMENT

Building R&D capacity

Indicator(s)

RD6

Pharmaceutical companies have the expertise and ability to support the continuing development of R&D sectors in LMICs. Companies can engage in relevant activities, such as increasing clinical trial capacity (beyond their own interests and/or pipelines) or setting up research networks, to build local R&D capacity and support the development of research skills. In turn, this can enable local researchers to address relevant health needs and priorities.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
RD6	**Capacity building in R&D** 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. These initiatives address local R&D capacity needs, priorities and/or skills gaps in countries in scope of the Index. The Index assesses whether these initiatives meet Good Practice Standards (GPS).* *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.	**Retained**, with non-material editorial changes to indicator text.	For the development of medicines that can treat local diseases, meet local needs, and correspond to disease patterns in countries in scope, it is important to support local R&D. Companies need to be incentivised to take action for building local R&D capacity that goes beyond their own interests and/or pipeline, as they have expertise in R&D that they can share locally.

PRODUCT DELIVERY 55%

Overview of the Technical Area

Choices that pharmaceutical companies make regarding the delivery of their products strongly influence countries' efforts to achieve Universal Health Coverage. As a first step, companies must register their products for sale where they are needed, so that they can be made swiftly available to populations in need. Companies can then deploy three main access strategies that have the greatest potential for impact on the supply and affordability of medicine: equitable access and pricing strategies, responsible intellectual property (IP) management and product donations.

This Technical Area assesses how companies improve access to their products through a variety of mechanisms, including registration, pricing strategies, responsible IP management, inclusive business models and product donations. It also examines how companies design and measure outcomes of their access strategies and tailor their tools to boost access. Further, it captures how companies leverage their expertise and resources to address significant local barriers to access. Such barriers might include gaps in local healthcare infrastructure, poorly functioning supply chains and/or weak quality assurance systems.

Changes to the Methodology for the 2024 Index

- In the 2024 Index Methodology there are 18 indicators in the Product Delivery Technical Area, compared to 17 in the 2022 Index Methodology. Ten indicators in this Technical Area have materially changed (with two new indicators and one merger).
- The main shift in this Technical Area is the increased focus on capturing patient reach in the three access strategy indicators ('PP3: Access strategies: Supranationally procured products,' 'PP4: Access strategies: Healthcare practitioner-administered products' and 'PP5: Access strategies: Self-administered products'). PP4 and PP5 have now each been split into part 'a' and 'b', signifying the relative importance of both the quality of the access strategy (part a) and outcomes of the strategy, including patient reach (part b). PP3 will remain as one indicator but has also been modified to include measurement of patient reach and outcomes.
- Analysis in 'PBM1: Inclusive business models' has been modified to expand the target population addressed and to focus analysis on models offering company products instead of building capacity of separate models.
- 'PQ1: Ensuring continuous supply' has been modified to collect additional data on company efforts to support manufacturing capacity in low- and middle-income countries (LMICs).
- Under 'PR1: Registration,' mechanisms to facilitate registration, will be newly considered for analysis.
- PP2a has been modified to include public commitments to adhere to international standards.
- 'PPL4: Access-oriented licensing' and 'PPL5: Licensing: Geographic scope' have been merged into a single indicator, 'PPL4: Quality and geographic coverage of access-oriented licensing.'

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Registration

Indicator(s)

PR1

Registration is a key first step for products to become available to populations in need. The Index continues to look at how widely pharmaceutical companies file to register their newest products in countries in scope and make them available for patients' use in these countries. Companies are expected to prioritise registration in countries with a high burden of disease, and to aim for registration in LMICs within 12 months of first global regulatory approval by, for example, the European Medicines Agency, Food and Drug Administration, or Japanese Pharmaceuticals and Medical Devices Agency. Where applicable, companies can engage in Collaborative Registration Procedures (CRP), among other mechanisms, to facilitate widespread registration in LMICs.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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. *'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.	**Modified**, with material changes to indicator text.	Filing to register products in LMICs is a critical step to enable more widespread access in these countries, especially in those with high disease burdens. Companies should engage with international organisations and regulators to facilitate international regulatory reliance. Participating in joint assessments and other procedures can also help build capacity of regulatory authorities in LMICs, thus facilitating and accelerating the registration of products.

PRODUCT DELIVERY

Equitable access strategies and outcomes

Indicator(s)

PP3, PP4a, PP4b, PP5a, PP5b

Equitable access means no one is left behind, with everyone in LMICs – including lower-income groups with limited ability to pay – able to benefit from products. Companies are expected to apply access strategies to key products across LMICs, maximising the availability of these products to those with less income. Such strategies include pricing, non-exclusive licensing, product donations and technology transfer. When setting pricing strategies, companies are expected to aim for affordability by integrating payers' ability to pay for a product into their pricing approach.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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; 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: i) methods to define the total eligible patient population***; 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, and reproductive health. **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. Note: Companies that do not market these products will not have this indicator applied to them.	**Modified**, with material changes to indicator text.	This indicator evaluates products for which companies engage with market-shaping and/or pooled procurement organisations, such as UNICEF; Gavi, the Vaccine Alliance; and the Global Fund to Fight AIDS, Tuberculosis and Malaria, to increase access. Importantly, it also assesses the extent to which companies consider access to products for countries which do not qualify for such support.

PRODUCT DELIVERY

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
PP4a	**Access strategy quality: Healthcare practitioner-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 affordability and availability of its healthcare practitioner-administered products** and increase reach among patients across the income pyramid. This is evidenced by: 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 characteristics of a population such as age, sex, income level, education level, employment, etc. **Products that often require either hospital administration of the product or the attention of a skilled healthcare professional during administration. ***For example, patient assistance programmes, donations, voluntary licensing, technology transfer etc. Note: Companies that do not market these products will not have this indicator applied to them.	**Modified**, with material changes to indicator text.	Companies have an important role in supporting governments to achieve universal health coverage by improving the reach of products across the income pyramid. Companies should carefully determine different payer(s)' ability to pay, taking socioeconomic into account. Products that need the oversight of a healthcare practitioner for administration are likely to be more complex and require more sophisticated health systems for administration and ongoing care. Companies may therefore choose to also partner with organisations to build capacity and/or strengthen health systems. Companies can choose to use a mix of strategies to maximise their product reach: intra-country segmentation, licensing and donations.
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 health 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. 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. *An increase in the number of patient 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. Note: Companies that do not market these products will not have this indicator applied to them.	**New indicator.**	To determine the success of their access strategies, companies should have goals in place to increase access to patients across the income pyramid. Successful strategies should be evidenced by an increase in patient numbers (or a decrease when eradication is the goal) both to date and along with future projections.

PRODUCT DELIVERY

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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 affordability and availability of its self-administered products and increase reach among patients across the income pyramid. This is evidenced by an access strategy that demonstrates how 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. **For example, patient assistance programmes, donations, voluntary licensing, technology transfer etc.	**Modified**, with material changes to indicator text.	Companies have an important role in supporting governments to achieve universal health coverage by improving the reach of products across the income pyramid. Companies should carefully determine different payer(s)' ability to pay, taking socioeconomic factors into account. Companies can choose to use a mix of strategies to maximise their product reach: intra-country segmentation, licensing and donations.
PP5b	**Access strategy outcomes: self-administered products** 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. 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. *An increase in the number of patient 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. Note: Companies which do not market these products will not have this indicator applied to them.	**New indicator.**	To determine the success of their access strategies companies should have goals in place to increase access to patients across the income pyramid. Successful strategies should be evidenced by an increase in patient numbers (or a decrease when eradication is the goal) both to date and along with future projections.

Intellectual property strategy

Indicator(s)

PPL1, PPL2, PPL3

Responsible, transparent management of intellectual property (IP) can stimulate R&D by third-party researchers. Companies that choose not to develop their IP assets further can license these out to external researchers on access-oriented terms. For LMICs, responsible IP management can also facilitate the affordable supply of medicines and other health products by supporting the entry of generic pharmaceutical manufacturers into new markets and the decision-making of international procurers. Companies are expected to publish patent statuses and implement patent filing/enforcement policies to mitigate the risk that patent protections will limit R&D and product availability and affordability.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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, low-income countries, and in a subset of lower-middle-income countries and upper-middle-income countries.	**Retained**, with non-material editorial changes to indicator text.	Clarity about where patents are to be filed, or will be enforced, gives greater certainty to international drug procurers and generic medicine manufacturers when planning the manufacture and/or supply of generic products.

PRODUCT DELIVERY

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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.	**Retained**, with non-material editorial changes to indicator text.	Transparency is part of the social contract that underlies the patent system. When transparency is standard, this supports procurement agencies to make important decisions about which products to supply. Companies should have a transparent approach for all relevant therapeutic areas and product types, including biologics. Companies should disclose detailed information on the status of their patents, including the nature of the patent, filing date, grant number, grant date and jurisdiction.
PPL3	**IP sharing** The company provides evidence of sharing its IP (such as molecule 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.	**Retained**, with non-material editorial changes to indicator text.	When a company shares its intellectual property on terms conducive to increasing access, this can accelerate R&D efforts and help to make new products available to populations in need in LMICs. Such potential for access is optimised when companies share their more valuable assets, such as those more likely to accelerate product entry into the market.

Licensing quality

Indicator(s)

PPL4

Non-exclusive voluntary licensing supports the market entry of alternative manufacturers of patented products, in turn supporting a more secure supply of products and enhancing affordability through increased competition. Pharmaceutical companies are expected to engage in quality non-exclusive licensing (acting to quickly license newly registered products, or those still in development, on terms that promote access) and to ensure they disclose these agreements publicly. Additionally, a broad range of countries should be included within the geographic scope of the licence to ensure widespread access for people living in LMICs.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
PPL4	**Quality and geographic coverage of access-oriented licensing** The company grants access-oriented, transparent, non-exclusive voluntary 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.* *Low-income countries, lower-middle income countries and upper-middle income countries in scope as defined by the World Bank country classification by income level.	**Merged** with Indicator PPL5.	Licences allow generic medicine manufacturers to enter markets where a large research-based pharmaceutical company might not be distributing a product already, resulting in access to generic versions of the patented medicine. Access-oriented terms provide generic medicine manufacturers with additional flexibility (in manufacturing and/or distribution processes, for example) supporting them to optimise affordability and supply. Quality of these terms is assessed according to the context of the licence (type of product, indication, etc). Including more countries in a licence will increase the potential for that licence to make an impact on public health. Often, the terms of voluntary licences exclude entire populations of middle-income countries. To increase access to medicine and its benefits for public health, voluntary licences should include those populations with proven need.
PPL5	**Licensing: Geographic scope** N/A	**Merged** with Indicator PPL4.	N/A

PRODUCT DELIVERY

Product donations

Indicator(s)

PP2a, PP2b

Product donations continue to play an important role in eliminating, eradicating and/or controlling some diseases that affect populations living in LMICs. For people living in poverty, donations may represent the only opportunity to access the medicines they need. Pharmaceutical companies supplying such products are expected to publicly commit to remaining engaged until established elimination, eradication and control goals are reached. Companies must also be able to respond rapidly to requests for ad hoc donations, taking steps to ensure that their products reach the end user.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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. *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.	**Modified**, with material changes to indicator text.	Ad hoc donations can fill critical resourcing gaps when health systems are under strain. When donations are made ad hoc in humanitarian situations (e.g., conflicts, natural disasters), they should be made rapidly in response to expressed need. Companies should also monitor donations to ensure that they reach the patient so that products are not damaged, sold, misused, or redirected.
PP2b	**Access strategies: Long-term donation programmes** 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 for as long as needed to support the achievement of such goals. *These goals are aligned with the World Health Organization's 2021-2030 Roadmap for Neglected Tropical Diseases	**Retained**, with non-material editorial changes to indicator text.	Long-term donation programmes can be a route to increased access to medicine for those with limited ability to pay. They play a specific role in elimination, eradication and control programmes where there is a limited ability to pay for products. Public disclosure of a commitment with no time limit indicates a company's intention to continue donating products for as long as needed to support the achievement of public health goals.

Inclusive business models

Indicator(s)

PBM1

To achieve Universal Health Coverage, companies must develop and implement inclusive business models that address access needs for their products, reaching the most vulnerable groups. These models specifically address the access needs of populations that may not be reached by existing business models due to social, economic or health factors. In addition to positive patient outcomes (e.g., increased affordability and awareness), these models can benefit a company through access to new markets, increased earnings and innovations that are transferrable to other contexts.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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. *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.	**Modified**, with material changes to indicator text.	Companies should develop and implement inclusive business models to address access issues for populations in LMICs that are overlooked by existing business models. Inclusive business models can bring benefits to patients and business alike, improving health outcomes, strengthening supply chains, increasing affordability and expanding markets.

PRODUCT DELIVERY

Quality and supply

Indicator(s)

PQ1, PQ2, PCB2

Inefficiencies and weaknesses in supply chains (whether in procurement processes, delivery logistics, storage or at other stages) can have a stark impact on the accessibility, availability and quality of medicines. To identify bottlenecks and improve capacity for good supply chain management in LMICs, pharmaceutical companies are expected to engage with relevant local partners. Substandard and falsified (SF) medicines represent a significant threat to public health. To mitigate this, companies are expected to report SF cases to national authorities and/or WHO Rapid Alert in a timely manner.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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. c) The company works with several active pharmaceutical ingredient (API) suppliers, holds API buffer stocks and/or produces in-house APIs. d) The company works to enhance local supply capacities and strengthen supply chains.* e) The company transfers technology (e.g., for API, vaccine adjuvant and/or drug product) to manufacturers to improve manufacturing capacity and availability in LMICs* and/or manufactures relevant products in LMICs. *Analysis is based on submission in PCB1 and PCB2.	**Modified**, with material changes to indicator text.	Ensuring continuous supply and preventing the risk of stockouts means patients who need essential medicines can continue to access high-quality products.
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. *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.	**Retained**, with non-material editorial changes to indicator text.	Reporting confirmed cases of SF medical products in a timely manner to the relevant authority is important from a public health point of view, allowing withdrawal from the market quickly. SF medical products can cause harm and death. Pharmaceutical companies have a responsibility to ensure access to quality products and to mitigate the risk of harm by sharing information with health authorities rapidly. The Index looks at specific policies or procedures in place that require a company to consistently report confirmed SF cases in a timely manner. Some stakeholders argue that it is good practice for companies to alert relevant authorities as soon as they suspect a case.

PRODUCT DELIVERY

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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 affordability, accessibility and quality of products, including products outside of its own portfolio. The Index assesses whether these initiatives meet Good Practice Standards (GPS).* *I.e., guided by clear, measurable goals and/or objectives; measures outcomes; has long-term aims/aims for sustainability.	**Retained**, with non-material editorial changes to indicator text.	An inefficient supply chain can significantly impact access to medicine. It can increase the risk of low-quality, substandard/falsified medicines and stockouts. Companies have a role in supporting strong, resilient supply chains which also benefit products beyond their own portfolios.

Local manufacturing

Indicator(s)

PCB1

Making medicines locally can help to reduce costs and improve supply, but quality must be guaranteed. When pharmaceutical companies work with third-party manufacturers in LMICs, they can take steps to ensure local staff have the skills and technology necessary to meet the requirements of Good Manufacturing Practices (GMP). By engaging more widely with other manufacturers and organisations such as universities, companies can bring broader value in terms of quality manufacturing to build local capacity beyond that needed for their own products and portfolios.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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 whether these initiatives meet Good Practice Standards (GPS).* *I.e., guided by clear, measurable goals and/or objectives; measures outcomes; has long-term aims/aims for sustainability.	**Retained**, with non-material editorial changes to indicator text.	Companies have a role in supporting local manufacturing outside of their own plants, contributing to the quality manufacturing of other products. Local manufacturing can bring medicines to market in LMICs more quickly, and can simplify supply chains.

Health system strengthening

Indicator(s)

PCB3

Robust health systems must be in place for products to be deployed, prescribed and administered safely and effectively. Such systems may include infrastructure, trained health professionals, diagnostic capacity, data management and the means to reduce stigma. Although health system strengthening is not a central responsibility of pharmaceutical companies, their expertise and capacity can be used to help support efforts made by other partners. Companies must manage conflicts of interest and monitor outcomes.

2024 Indicator code	2024 Indicator	Changes in 2024	Indicator rationale
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).* *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	**Retained**, with non-material editorial changes to indicator text.	While health systems are the primary responsibility of governments, companies can provide support. Well-functioning health systems promote better diagnosis, pharmacovigilance, disease surveillance and overall treatment. They are critical for sustainable access to medicine.

Appendices

APPENDIX IA

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, WHO classifications and the relevance of pharmaceutical interventions. The disease scope for the 2024 Index has decreased from 83 to 81 diseases, conditions and pathogens. There are two fewer diseases than in the 2022 Access to Medicine Index due to the combination of hypertensive heart disease, ischaemic heart disease and stroke into cardiovascular diseases. The reason for this change is that products for cardiovascular diseases (including statins, antihypertensives, antiarrhythmics and anticoagulants) will be included under a clearer rationale. DALY burden and mortality data was collected from the Institute for Health Metrics and Evaluation's 2019 Global Burden of Disease study (GBD 2019) and are presented as totals for countries in scope and disaggregated by sex where possible.[1] Incidence data for cancer types was collected from GLOBOCAN 2020.[2]

FIGURE 10 **Diseases, conditions and pathogens in scope of the 2024 Access to Medicine Index**

	Disease burden in DALYs (countries in scope)	% DALYs (female)	% DALYs (male)
NON-COMMUNICABLE DISEASES (16)			
Alzheimer's disease	14,121,433	60	40
Anxiety disorders	21,079,626	61	39
Asthma	17,228,459	50	50
Bipolar affective disorder	5,736,709	51	49
Cancer*	DALY not applicable	N/A	N/A
Cardiovascular diseases	297,986,563	43	57
Chronic obstructive pulmonary disease (COPD)	59,365,204	43	57
Depressive disorders	35,512,221	61	39
Diabetes mellitus	53,461,951	49	51
Endometriosis	1,820,882	100	0
Epilepsy	10,908,201	45	55
Kidney diseases	33,437,603	47	53
Migraine	32,094,478	62	38
Schizophrenia	11,268,674	46	54
Sickle cell disease	5,720,857	60	40
Thalassemia	3,811,736	63	37

	Total incidence (countries in scope)	% incidence (female)	% incidence (male)
CANCER TYPES IN SCOPE (19)*			
Bladder	207,694	24	76
Brain, nervous system	189,928	45	55
Breast	1,211,993	100	0
Cervical	496,792	100	0
Colorectal	955,869	44	56
Gallbladder	79,438	65	35
Head and neck	628,126	25	75
Kaposi sarcoma	27,740	33	67
Leukaemia	262,842	43	57
Liver	675,942	29	71
Lung	1,203,383	33	67
Non-Hodgkin lymphoma	268,963	43	57
Oesophageal	488,887	33	67
Osteosarcoma	Incidence not available in GLOBOCAN 2020	N/A	N/A
Ovarian	193,455	100	0
Prostate	492,398	0	100
Stomach	721,890	33	67
Thyroid	368,668	77	23
Uterine	182,174	100	0

*The 19 cancer types are collectively counted as one non-communicable disease.

	Disease burden in DALYs (countries in scope)	% DALYs (female)	% DALYs (male)
COMMUNICABLE DISEASES (23 + 12 PRIORITY PATHOGENS)**			
Arenaviral haemorrhagic fevers	DALY not available in GBD 2019	N/A	N/A
Bunyaviral diseases	DALY not available in GBD 2019	N/A	N/A
Coronaviral diseases	DALY not available in GBD 2019	N/A	N/A
Diphtheria	365,636	48	52
Disease X	N/A	N/A	N/A
Emergent non-polio enteroviruses	DALY not available in GBD 2019	N/A	N/A
Enteric infections	94,536,740	48	52
Filoviral diseases***	195,394	54	46
Henipaviral diseases	DALY not available in GBD 2019	N/A	N/A
HIV/AIDS	45,406,645	52	48
Leptospirosis	DALY not available in GBD 2019	N/A	N/A
Lower respiratory infections	88,276,785	48	52
Malaria	46,424,214	49	51
Measles	6,994,415	49	51
Meningitis	16,005,996	45	55
Other prioritised antibacterial-resistant infections**	DALY not available in GBD 2019	N/A	N/A
Pertussis	10,122,828	54	46
Rheumatic fever	DALY not available in GBD 2019	N/A	N/A
Sexually transmitted infections (STIs)	8,335,093	49	51
Tetanus	2,309,409	45	55
Tuberculosis	46,045,180	37	63
Viral hepatitis (B and C)	27,963,181	27	73
Yellow fever	287,110	28	72
Zika	263	45	55
NEGLECTED TROPICAL DISEASES (20)			
Buruli ulcer	DALY not available in GBD 2019	N/A	N/A
Chagas disease	245,559	41	59
Dengue and chikungunya†	2,349,463	47	53
Dracunculiasis	1	54	46
Echinococcosis	98,503	51	49
Food-borne trematodiases	747,283	39	61
Human African trypanosomiasis	82,612	48	52
Leishmaniasis	692,733	42	58
Leprosy	28,678	36	64
Lymphatic filariasis	1,613,541	19	81
Mycetoma, chromoblastomycosis and other deep mycoses	DALY not available in GBD 2019	N/A	N/A
Onchocerciasis	1,230,270	47	53
Rabies	780,126	30	70
Scabies and other ectoparasites	4,636,790	49	51
Schistosomiasis	1,614,937	52	48
Snakebite envenoming	DALY not available in GBD 2019	N/A	N/A
Soil-transmitted helminthiasis	1,946,535	58	42
Taeniasis/cysticercosis‡	1,151,503	54	46
Trachoma	180,125	52	48
Yaws and other endemic treponematoses	DALY not available in GBD 2019	N/A	N/A

**Collectively, these will be referred to as communicable diseases in the 2024 Access to Medicine Index as 'Other prioritised antibacterial-resistant infections'.

***Includes DALY burden for Ebola only.

†Includes DALY burden for dengue only.

‡Includes DALY burden for cysticercosis only.

	Disease burden in DALYs (countries in scope)	% DALYs (female)	% DALYs (male)
REPRODUCTIVE, MATERNAL AND NEWBORN HEALTH (10)			
Abortion and miscarriage	1,114,569	100	0
Birth asphyxia and birth trauma	51,991,484	42	58
Contraceptive methods	DALY not applicable	N/A	N/A
Hypertensive disorders of pregnancy	1,780,833	100	0
Maternal haemorrhage	3,040,655	100	0
Maternal sepsis	1,045,195	100	0
Neonatal sepsis and infections	23,883,067	45	55
Obstructed labour	986,019	100	0
Other neonatal conditions	33,024,628	45	55
Preterm birth complications	64,631,489	43	57

APPENDIX IB

Cancers in scope of the 2024 Access to Medicine Index

Cancer remains in scope for the 2024 Index. The 19 cancer types in scope for the 2022 Index have been retained. The latest data on cancer incidence does not show evidence that additional cancer types should be included.

As in the methodologies for the 2018, 2021 and 2022 Indexes, products for the management of pain and supportive treatments (e.g., antiemetics) are not included.

TABLE 3 **Cancer types in scope and basis for inclusion**

Cancer types in scope (19)	Ten cancer types with the highest global incidence rates	Ten cancer types with the highest incidence in countries in scope	Five cancer types where countries in scope account for highest % of global incidence	Included in 2022 Access to Medicine Index
Bladder				●
Brain, nervous system				●
Breast	2,261,419	1,211,993		●
Cervical	604,127	496,792	82%	●
Colorectal	1,931,590	955,869		●
Gallbladder			69%	●
Head and neck*	931,931	628,126		●
Kaposi sarcoma			81%	●
Leukaemia				●
Liver	905,677	675,942	75%	●
Lung	2,206,771	1,203,383		●
Non-Hodgkin lymphoma				●
Oesophageal	604,100	488,887	81%	●
Osteosarcoma				●
Ovarian				●
Prostate	1,414,259	492,398		●
Stomach	1,089,103	721,890		●
Thyroid	586,202	368,668		●
Uterine				●

*Includes all head and neck cancers in GLOBOCAN 2020: nasopharynx, lip, oral cavity, salivary glands, larynx, oropharynx and hypopharynx cancer.

APPENDIX II

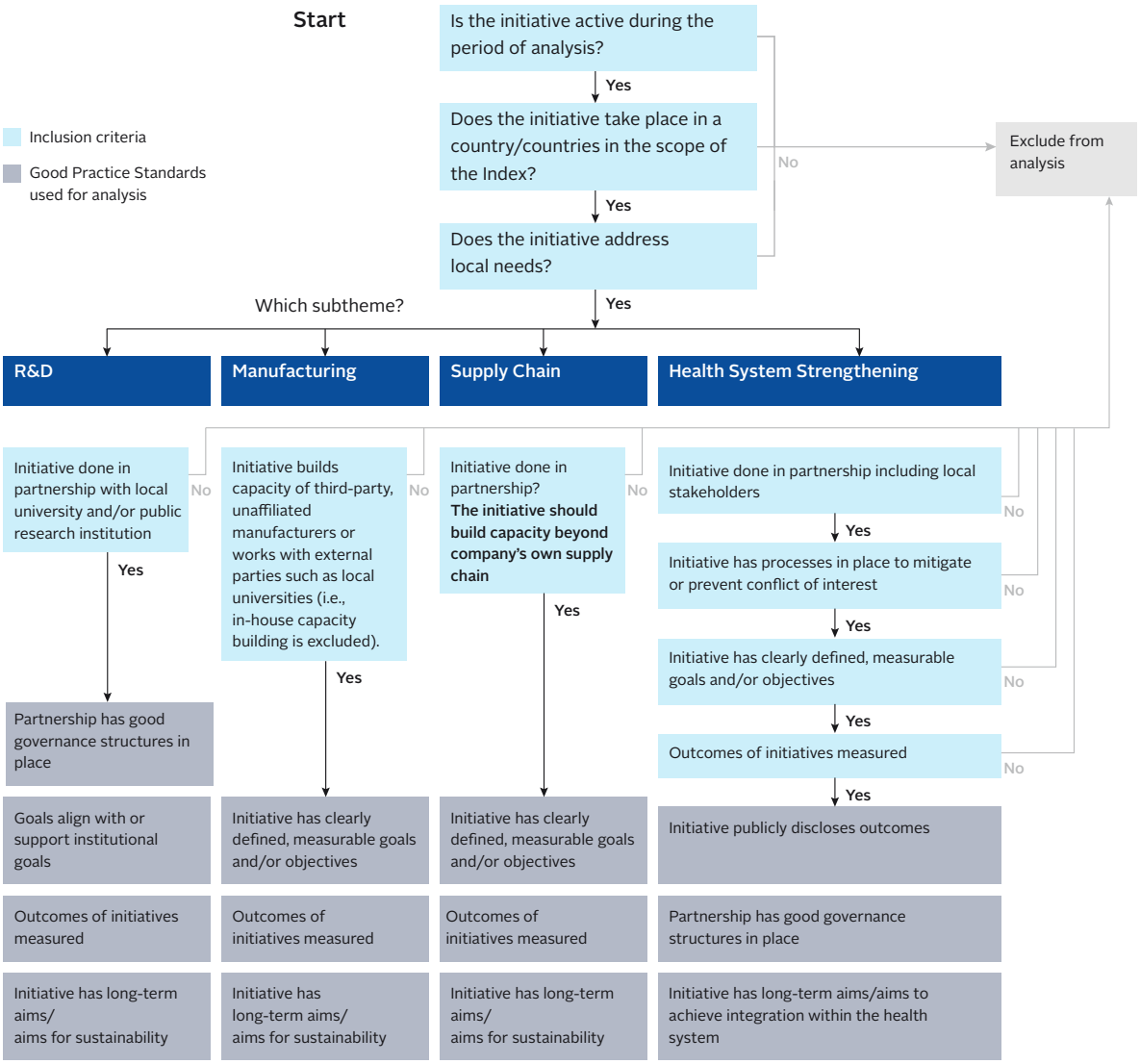
The Good Practice Standards framework for capacity building

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 and 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. Companies are assessed based on a maximum of five initiatives per subtheme, with higher-performing companies having more initiatives that meet all GPS.

FIGURE 11 **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 III

R&D priorities

TABLE 4 **Priority diseases, conditions and pathogens**

Disease	Specific disease target	Medicines	Vaccines (preventative)	Vaccines (therapeutic)	Diagnostics	Microbicides	Vector control products	Devices (for reproductive health only)	Policy Cures Research G-FINDER Neglected Diseases	Policy Cures Research G-FINDER Sexual & Reproductive Health	Policy Cures Research G-FINDER Emerging Infectious Diseases	WHO Prioritizing diseases for R&D in emergency contexts	WHO Prefered Product Characteristics	WHO Priority Pathogen List
Arenaviral haemorrhagic fevers (other than Lassa fever)		●	●	●	●		●				●			
Lassa fever		●	●	●	●		●				●	●		
Bunyaviral diseases	Crimean-Congo haemorrhagic fever (CCHF)	●	●	●	●		●				●	●		
	Rift Valley fever (RVF)	●	●	●	●		●				●	●		
	Severe fever with thrombocyto-penia syndrome (SFTS)	●	●	●	●		●				●			
	Bunyaviral diseases (other than CCHF, RVF or SFTS)	●	●	●	●		●				●			
Buruli ulcer		●	●		●				●					
Cancer	HPV-related cervical cancer	●	●	●	●	●		●		●				
Chagas disease		●	●	●	●		●		●					
Contraceptive methods		●	●	●				●		●				
Coronaviral diseases	Middle East respiratory syndrome coronavirus (MERS-CoV)	●	●	●	●		●				●	●		
	Severe acute respiratory syn-drome (SARS)	●	●	●	●		●				●	●		
	Coronavirus disease 2019 (COVID-19)	●	●	●	●		●				●	●		
	Highly pathogenic coronaviral diseases (other than MERS-CoV, SARS and COVID-19)	●	●	●	●		●				●			
Dengue and Chikungunya	Chikungunya	●	●	●	●		●				●			
	Dengue	●		●	●		●		●					
Enteric infections	Cholera	●	●	●	●				●					
	Cryptosporidiosis	●	●	●	●				●					
	Enterotoxigenic *E. coli* (ETEC) infections		●		●				●				●	
	Enteroaggregative *E. coli* (EAEC) infections		●		●				●					
	Giardiasis (lambliasis)				●				●					
	Rotaviral gastroenteritis		●						●					
	Shigellosis	●	●	●	●				●				●	
	Typhoid and paratyphoid fever (*S. typhi*, *S. paratyphi A*)	●	●	●	●				●					
	Non-typhoidal *S. enterica* (NTS)	●	●	●	●				●					
Emergent non-polio enteroviruses (including EV71, D68)		●	●	●	●						●			

Blue text = priority R&D product gap newly in scope for the 2024 Index.

● Gap identified
Definition: Product gap identified for the disease, condition or pathogen on one or more of the R&D priority lists.

● Specific gap
Definition: Specific R&D need or product gap identified, e.g., for a new route of administration to be developed or specific serotypes to be targeted.

● Included on priority R&D list.

Disease	Specific disease target	Medicines	Vaccines (preventative)	Vaccines (therapeutic)	Diagnostics	Microbicides	Vector control products	Devices (for reproductive health only)	Policy Cures Research G-FINDER Neglected Diseases	Policy Cures Research G-FINDER Sexual & Reproductive Health	Policy Cures Research G-FINDER Emerging Infectious Diseases	WHO Prioritizing diseases for R&D in emergency contexts	WHO Prefered Product Characteristics	WHO Priority Pathogen List
Filoviral diseases	Ebola virus disease (EVD)	○	○	○	○		○				●	●		
	Marburg virus disease (MVD)	○	○	○	○		○				●	●		
	Filoviral diseases (other than EVD or MVD)	○	○	○	○		○				●			
Henipaviral diseases	Nipah virus (NiV) infection	○	○	○	○		○				●	●		
	Henipaviral diseases (other than NiV infection)	○	○	○	○		○				●	●		
HIV/AIDS		◐	○	◐	○	○			●	●			●	
Human African trypanosomiasis		○	○	○	○		○		●					
Hypertensive disorders of pregnancy	Pre-eclampsia and eclampsia	◐		○	○					●				
Leishmaniasis		○	○	○	○				●					
Leprosy		○	○	○	○				●					
Leptospirosis					◐				●					
Lower respiratory infections	Pneumococcal disease (*S. pneumoniae*)		◐		○				●					
	Influenza		○										●	
	Respiratory syncytial virus (RSV) disease		◐										●	
Lymphatic filariasis (elephantiasis)		○			○		○		●					
Malaria	Malaria (*P. falciparum*)	○	○	○	○		○		●				●	
	Malaria (*P. vivax*)	○	○	○	○		○		●				●	
	Malaria (other strains than *P. falciparum* or *P. vivax*)	○	○	○	○		○		●					
Maternal haemorrhage	Postpartum haemorrhage	○						◐		●				
Meningitis	Meningitis (*N. meningitidis*)		◐		○				●					
	Meningitis (*C. neoformans*)	○		○					●					
Mycetoma, chromoblastomycosis and other deep mycoses	Mycetoma	○			○				●					
	Histoplasmosis	○			○				●					
Neonatal sepsis	Group B *Streptococcus*		◐										●	
River blindness (onchocerciasis)		○	○		○		○		●					
Rheumatic fever	Group A *Streptococcus*		○						●				●	
Scabies		○			○				●					
Schistosomiasis (bilharzia)		○	○	○	○		○		●					
Sexually transmitted infections (STIs)	Chlamydia		○	○	○	○				●				
	Gonorrhoea	◐	○	○	○	○				●			●	
	Herpes simplex virus type 2 (HSV-2) infection	○	○	○	○	○				●			●	
	Human T-cell lymphotropic virus type 1 (HTLV-1) infection	○	○	○	○	○				●				
	Syphilis	◐	○	○	◐	○				●				
	Sexually transmitted infections (other than chlamydia, gonorrhoea, syphilis or HSV-2 or HTLV-1 infections)	◐	◐	◐	◐	◐				●				

Blue text = priority R&D product gap newly in scope for the 2024 Index.

○ Gap identified
Definition: Product gap identified for the disease, condition or pathogen on one or more of the R&D priority lists.

◐ Specific gap
Definition: Specific R&D need or product gap identified, e.g., for a new route of administration to be developed or specific serotypes to be targeted.

● Included on priority R&D list.

Disease	Specific disease target	Medicines	Vaccines (preventative)	Vaccines (therapeutic)	Diagnostics	Microbicides	Vector control products	Devices (for reproductive health only)	Policy Cures Research G-FINDER Neglected Diseases	Policy Cures Research G-FINDER Sexual & Reproductive Health	Policy Cures Research G-FINDER Emerging Infectious Diseases	WHO Prioritizing diseases for R&D in emergency contexts	WHO Prefered Product Characteristics	WHO Priority Pathogen List
Soil transmitted helminthiasis	Hookworm infection (ancylostomiasis/necatoriasis)	○	○						●					
	Strongyloidiasis and other round-worm infections (excl. ascariasis)	○	○		○				●					
	Whipworm infection (trichuriasis)	○							●					
	Roundworm infection (ascariasis)	○							●					
Snakebite envenoming		◐		◐	◐				●					
Tapeworm infection (taeniasis/cysticercosis)		○			○		○		●					
Trachoma			○		○				●					
Tuberculosis		○	○	○	○				●				●	
Viral hepatitis (B and C)	Hepatitis B	◐		◐	○				●	●				
	Hepatitis C	◐	○		○				●					
Zika virus disease		○	○	○	○		○				●	●		
Disease X*												●		
Other prioritised antibacterial-resistant infections	*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)								●					●

Blue text = priority R&D product gap newly in scope for the 2024 Index.

○ Gap identified
Definition: Product gap identified for the disease, condition or pathogen on one or more of the R&D priority lists.

◐ Specific gap
Definition: Specific R&D need or product gap identified, e.g., for a new route of administration to be developed or specific serotypes to be targeted.

● Included on priority R&D list.

*Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious international epidemic. Priority R&D for this disease is restricted to platform technologies that enable cross-cutting R&D preparedness that is also relevant for an unknown Disease X.

APPENDIX IV

Ensuring the Methodology considers issues of sex and gender

To ensure access to medicine and health products, access plans and strategies also need to address barriers to access that lie beyond affordability, sustainable supply, and the strength of a health system. The lived experience of patients can have a significant impact on their ability to access essential healthcare, as well as the type of healthcare they need. For example, the socioeconomic status or age of a patient, or the prevalence of certain diseases where they live, need to be considered. Critically, many patients face barriers to access that are rooted in sex and gender.

Biological characteristics related to an individual's sex (e.g., hormones, anatomical differences, immune responses, genetics) as well as gender-related factors (e.g., societal expectations, stigma and differences in exposure to risk factors) can influence the likelihood of contracting a disease and how it presents itself.

Moreover, sex and gender often influence crucial elements of access – such as the safety and efficacy of medicines, the opportunity to access quality care in a safe environment, and access to information about treatment and prevention of disease – making it critical to consider these two factors when addressing barriers to access.

Governments, civil society groups, and non-governmental organisations (NGOs) play a key role in addressing how issues pertaining to sex and gender are considered in healthcare delivery. However, pharmaceutical companies are also a vital piece of the puzzle. From the way they conduct research, to the way they deliver products to the patient, efforts can be made by pharmaceutical companies to uncover and address access barriers related to sex and gender.

In evaluating pharmaceutical companies' actions to improve access to medicine, continual effort is made by the Foundation to explore how analysis and reporting can include gender - and sex- related issues more comprehensively. The approach for the 2024 Index Methodology is laid out below:

- For each review of the Index Methodology, the Foundation examines the sex-disaggregated epidemiological data to consider the inclusion of additional diseases or conditions that have a disproportionate burden on either sex. The latest analysis did not find any additional diseases or conditions that needed to be included based on our methodological approach. The current disease scope considers diseases for which the burden is disproportionately high (more than 70%) for either females or males, such as maternal health conditions and endometriosis. Assessment of the sex-linked cancer types (both globally and in countries in scope of the Index) previously led the Index to include uterine and ovarian cancer, as these have a significantly higher incidence than other sex-linked cancers such as testicular, vulval, penile and vaginal cancer.[2] Breast, cervical and prostate cancer types remain included in the disease scope on the basis of high incidence both globally and in countries in scope of the Index.
- The Index continues to assess companies' inclusive business models which address access issues for individuals who cannot access products through existing business models. These inclusive business models exemplify company efforts to embed vulnerable groups into the way they design, sell, and deliver products by considering social, economic and health factors that impede access. In considering these factors, inclusive business models can also address access barriers related to sex and gender.
- In R&D, pregnant and lactating populations have been historically excluded from clinical trials for non-obstetric conditions. Safety concerns as well as ethical and legal considerations are often cited as reasons for their exclusion.[14] As a result, the safety profiles and appropriate doses of many products are unknown for these populations. In line with the World Health Organization's call to action, the Index will, where applicable, assess the fair inclusion of those who are pregnant and lactating in clinical trials.[15]

APPENDIX V

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.

Access plans
Plans to ensure that access needs in low- and middle-income countries are taken into consideration during the R&D stage. Access plans can be developed in-house or in collaboration. 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 Programme.

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 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 account.

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 of diseases, products or therapeutic areas, or ideally to the whole pipeline and portfolio.

Active pharmaceutical ingredient (API)
The active pharmaceutical component of a medicine that causes its intended effects. Some medicines, such as combination therapies, have multiple active ingredients that target multiple disease pathways and/or symptoms. The inactive ingredients of a medicine are referred to as excipients.

Adaptive R&D
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 Programme. 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 the 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 transfer and health system strengthening initiatives.

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 medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

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. Affordability is one of the key dimensions for access to medicine. The Programme takes this into account when assessing pricing 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.

Budget impact
An estimated measure of the cost of treatment with a given therapy for a given number of patients in a specific population.

Buffer stock
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.

Capacity building
The company forms partnerships with local stakeholders to develop and strengthen skills, resources or processes in LMICs (e.g., by training of staff or obtaining equipment and other necessary resources). The Index assesses capacity 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 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- or region-specific legal and regulatory environment, cultural and social factors, as well 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.

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.

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(s), generally, but not necessarily, in association with one or more other ingredients). Also referred to as a finished drug product, finished product or formulation.

Equitable pricing strategy
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.

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.

Fair market value assessment
Assessment that defines the appropriateness of payments made to healthcare professionals (HCPs). These provide structure to ensure ethical interactions between the pharmaceutical industry and HCPs they engage with.

Falsified medical products
Medical products that deliberately/fraudulently misrepresent their identity, composition or source.[16]

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.

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.

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 minimise risks such as unexpected contamination, incorrect labelling or incorrect dosing of the active ingredient. GMP 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 individual countries or regions, as well as the World Health Organization.

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 microbicides 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 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
A national regulatory agency responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines and medical devices including test kits) are evaluated properly and meet international standards of quality, safety and efficacy.[17]

National reimbursement authority
Governmental bodies with the authority to control, approve and determine pricing and reimbursement of medicinal products in a country.

Non-assert declarations
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.[18]

Non-exclusive voluntary licences
Licences which enable – on a non-exclusive basis, and according to the terms of the licence agreed –the manufacture and supply of generic versions of patented medicines by other manufacturers.

Out-of-pocket payment
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.[19] In the Programme's 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 as product-specific examples of patient reach in the context of access strategies.

Payers
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.

Period of analysis
For the 2024 Index, the time period for which data will be analysed covers the company's activities between 1 June 2022 and 31 May 2024.

Post-trial access
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.

Priority R&D
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 within scope of the Programme. Product gaps may be medicines, vaccines, diagnostics, medical devices or vector control products. These product gaps are defined as being those listed in a series of six priority lists developed by the World Health Organization and Policy Cures Research, an independent R&D-focused policy group.

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 prioritised by governments or by the global health community (e.g., treatments for non-communicable diseases such as diabetes, stroke and heart disease).

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.[16]

Supranationally procured products
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 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 medicines 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 sharing between the WHO prequalification system and national regulatory authorities. By leveraging assessment and inspection 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.[20]

APPENDIX VI

References

1 Institute for Health Metrics and Evaluation. Global Burden of Disease (GBD) Results. 2019. Accessed June 7, 2023. https://vizhub.healthdata.org/gbd-results/.

2 Global Cancer Observatory. Cancer Today. 2020. Accessed June 7, 2023. https://gco.iarc.fr/today/online-analysis-table.

3 World Health Organization. Control of Neglected Tropical Diseases. Accessed June 7, 2021. https://www.who.int/data/gho/data/themes/neglected-tropical-diseases.

4 World Health Organization. Prioritization of Pathogens to Guide Discovery, Research and Development of New Antibiotics for Drug-Resistant Bacterial Infections, Including Tuberculosis. 2017. Accessed June 7, 2023. https://apps.who.int/iris/handle/10665/311820.

5 Policy Cures Research G-FINDER. Neglected Disease R&D Scope. 2023. Accessed August 24, 2023. https://gfinder.policycuresresearch.org/staticContent/pdf/G-FINDER_ND_R%26D_scope.pdf.

6 Policy Cures Research G-FINDER. Sexual and Reproductive Health R&D Scope. 2023. Accessed August 24, 2023. https://gfinder.policycures-research.org/staticContent/pdf/G-FINDER_ND_R%26D_scope.pdf.

7 Policy Cures Research G-FINDER. Emerging Infectious Disease R&D Scope. 2023. Accessed August 24, 2023. https://gfinder.policycures-research.org/staticContent/pdf/G-FINDER_EID_R%26D_scope.pdf.

8 World Health Organization. Prioritizing diseases for research and development in emergency contexts. Accessed August 30, 2023. https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts.

9 World Health Organization. WHO Preferred Product Characteristics (PPCs). Accessed August 30, 2023. https://www.who.int/teams/immunization-vaccines-and-biologicals/product-and-delivery-research/ppcs.

10 World Health Organization. WHO priority pathogens list for R&D of new antibiotics. Accessed August 30, 2023. https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed.

11 The World Bank. World Bank Country and Lending Groups. 2023. Accessed August 9, 2023. https://blogs.worldbank.org/opendata/new-world-bank-group-country-classifications-income-level-fy24.

12 United Nations Development Programme. Human Development Report 2021-2022. 2022. Accessed June 7, 2023. https://hdr.undp.org/content/human-development-report-2021-22.

13 United Nations Department of Economic and Social Affairs. LDCs at a Glance. 2021. Accessed June 7, 2023. https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html.

14 Smith DD, Pippen JL, Adesomo AA, Rood KM, Landon MB, Costantine MM. Exclusion of pregnant women from clinical trials during the coronavirus disease 2019 pandemic: A review of international registries. American Journal of Perinatology. 2020;37(08):792-799. doi:10.1055/s-0040-1712103.

15 Word Health Organization, International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT), International AIDS Society. Research for Informed: Accelerating the study of New Drugs for HIV in Pregnant and breastfeeding Women. 2021. Accessed June 7, 2023. https://www.impaactnetwork.org/sites/default/files/inline-files/PW_Call_to_Action_final.pdf.

16 World Health Organization. Substandard and falsified medical products. January 31, 2018. Accessed August 9, 2023. https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products.

17 World Health Organization. National Regulatory Agencies. Accessed August 9, 2023. https://www.who.int/southeastasia/activities/national-regulatory-agencies#:~:text=SEARO%20%2F%20IVD-,Overview,quality%20and%20safety%20and%20efficacy.

18 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). Voluntary licenses and non-assert declarations. July 28, 2010. Accessed September 06, 2023. https://www.ifpma.org/resource-centre/voluntary-licenses-and-non-assert-declarations/

19 World Bank. Databank - Metadata Glossary. Accessed June 24, 2023. https://databank.worldbank.org/metadataglossary/health-nutrition-and-population-statistics/series/SH.UHC.OOPC.25.TO#:~:text=Out%2Dof%2Dpocket%20payments%20are,by%20any%20type%20of%20provider.

20 Collaborative procedure for Accelerated Registration. World Health Organization. March 31, 2023. Accessed August 9, 2023. https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration.

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