# Access to Medicine Index 2021

## METHODOLOGY

access to medicine index

## ACKNOWLEDGEMENTS

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### ACCESS TO MEDICINE FOUNDATION
The Access to Medicine Foundation is an independent non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access.

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# Pharma's role for a decade of action

In the face of the current pandemic, the resilience of our healthcare systems is being put to the test, as is the agility and leadership of the pharmaceutical industry. The global need for sustainable access to medicine is being felt more urgently than ever, as we face the consequences of health systems that are hampered by a lack of access.

Through the UN, we have pledged a decade of action to achieve the Sustainable Development Goals (SDGs) by 2030, and to deliver on the promise of universal health coverage. The SDGs represent our shared commitment as a society to do better by the poorest and most vulnerable among us. We are currently seeing that pharmaceutical companies can be agile when it comes to responding to global health crises, particularly through rapid engagement in product development, and through stabilising the equitable supply of existing essential medicines and vaccines.

Achieving the SDGs and UHC by 2030 means matching the action to the scale of the challenge. In the past decade, pharmaceutical companies have made progress on access to medicine. Yet, their actions so far benefit only a limited proportion of the people in need. For many, the current pandemic poses additional challenges in an already precarious situation, particularly for people relying on overwhelmingly weak health systems. We have a shared responsibility to ensure they are not left behind.

During 2019, my team has built consensus around tangible and scalable priorities for pharmaceutical companies to focus on to support the achievement of the SDGs and UHC by 2030. This consensus is translated into this methodology for the next Access to Medicine Index. We have defined the priority actions for pharmaceutical companies, what good looks like and how to get there, in governance and compliance, in R&D and in product delivery. Especially in product delivery, we are planning ambitious analyses in search of good practices that can be mirrored by others.

The 2021 Access to Medicine Index will evaluate the work of 20 of the world's biggest pharmaceutical companies in addressing access to medicine in 106 of the most vulnerable countries, where access to essential or new products is often overlooked.

This ambitious methodology seeks to set a new direction for the decade to come, so we can demonstrate and achieve the goals we have set for ourselves as a global society, and fulfil the needs of the people waiting patiently for their rights to treatments and vaccines to be fulfilled.

Jayasree K. Iyer

Jayasree K. Iyer
Executive Director
Access to Medicine Foundation

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# About this report

The Access to Medicine Foundation has built broad consensus on what society expects of pharmaceutical companies by 2030 when it comes to access to medicine in low- and middle-income countries (LMICs). By translating these expectations into a set of 33 metrics, the next Access to Medicine Index will assess how 20 of the world's largest research-based pharmaceutical companies make medicines, vaccines, diagnostics and other health products more accessible in LMICs. The Index highlights best practices and shows where progress is being made, and where action is still required. It has been published every two years since 2008.

**THE 2021 ACCESS TO MEDICINE INDEX**

| | | |
|---|---|---|
| A | **GOVERNANCE OF ACCESS**<br>2 priority topics, 7 indicators | 20% |
| B | **RESEARCH & DEVELOPMENT**<br>3 priority topics, 8 indicators | 25% |
| C | **PRODUCT DELIVERY**<br>9 priority topics, 18 indicators | 55% |

## TIGHTER FRAMEWORK OF ANALYSIS

The UN has called for a decade of action in order to achieve the Sustainable Development Goals (SDGs) and universal health coverage (UHC) by 2030. Pharmaceutical companies have a unique capacity to develop the treatments needed by people in low- and middle-income countries (LMICs), and to improve products' availability across socioeconomic divides. Today, LMICs are home to 83% of all people.

### Ensuring access at scale moves into the mainstream

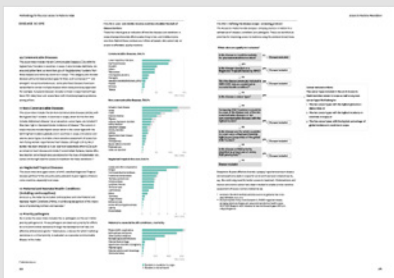
Each Access to Medicine Index is the result of a two-year process that begins with a review of the Index methodology. For 2020, the Foundation carried out a broader review than in previous cycles, engaging with more than 100 experts and organisations. It also took a longer horizon, defining the role for pharmaceutical companies through the coming decade. By 2030, the mainstream approach across the pharmaceutical industry will be to address access to medicine at scale, ensuring that healthcare products are delivered to the right people via initiatives tailored to local needs and health systems.

### 2021 Index: tighter framework, more sensitive to context

The 2021 Index has a new, tighter analytical framework with a sharper analytical application. In line with previous reviews, the emphasis has increased on R&D and product delivery strategies addressing affordability and supply. Indicators have been tailored to better compare like with like. As a result, the 2021 Index will make more sensitive comparisons of the access approaches being used by pharmaceutical companies in different markets and territories.

## IN THIS REPORT





# The 2021 Access to Medicine Index

## Methodology 2020

The Access to Medicine Index is the product of a two-year cycle known as the Index cycle, which starts with a review of the Index methodology. The aim of the review is to distill global priorities regarding access to medicine and define how society expects pharmaceutical companies to contribute. The emphasis is on defining ambitious, but achievable, actions for companies to take.

In this section:

**REVIEWING THE METHODOLOGY**
The 2019 Methodology Review started with a series of internal checks on indicators, data sets and analytical approaches. This was followed by an external review to identify the con-sensus view among stakeholders on where pharmaceutical companies should take action in the coming decade.

**STAKEHOLDER CONSENSUS**
The Access to Medicine Foundation has built broad consen-sus on what society expects of pharmaceutical companies by 2030 when it comes to access to medicine in low- and mid-dle-income countries in order to achieve the Sustainable Development Goals and universal health coverage.

**ANALYTICAL FRAMEWORK**
The 2021 Access to Medicine Index is based on a new ana-lytical framework of three Technical Areas, and 14 priority themes for corporate activity.

The framework for 2020 has a tighter structure, with 33 indi-cators grouped into three Technical Areas:
1. Governance of Access
2. Research & Development
3. Product Delivery

**REVIEWING THE METHODOLOGY**

# How the Index distills access-to-medicine priorities for pharmaceutical companies

Each Access to Medicine Index is the result of a two-year process known as the 'Index cycle', which begins with a targeted review of the Index methodology. The aim is to distill global priorities regarding access to medicine and to define how society expects pharmaceutical companies to contribute. The emphasis is on defining ambitious, but achievable, actions for companies to take.

For this latest review, the Foundation looked ahead to the 2030 deadline for achieving the Sustainable Development Goals and drew on the findings of its recent Ten-Year Analysis of pharmaceutical companies and global health. The Ten-Year Analysis concluded that pharmaceutical companies are gradually changing how they do business in low- and middle-income countries, but that the pace of change does not match the scale of the challenge. Activity is concentrated on a few diseases and being carried out by a few companies.

The 2019 Methodology Review started with a series of internal checks on indicators, data sets and analytical approaches. This was followed by an external review to identify the consensus view among stakeholders on how pharmaceutical companies should take action in the coming decade.

In 2019, the Foundation carried out a broader Methodology Review than in previous cycles, engaging with more than 100 experts and organisations. The resulting consensus was translated into a set of metrics for assessing how far the world's largest pharmaceutical companies are meeting society's expectations. The result is the methodology for the 2021 Access to Medicine Index.

### Primary principles

The primary principles of the 2019 Methodology Review:

1 Tighten the Index focus on the core access-to-medicine roles and responsibilities of large R&D-based pharmaceutical companies
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 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

### Strict standards for developing indicators

In 2019, the Foundation sought to tighten the focus of the Index in order to sharpen its analytical application. This led to the development of even stricter standards for deciding when to merge or remove a metric. These were linked to the relevance of the measured behaviour to access to medicine, clarity regarding the industry's role and the degree of consensus regarding how companies should behave.

Using these standards, the Foundation reviewed each of the indicators of the 2018 Access to Medicine Index for robustness, response quality and the potential for companies to improve access to medicine through a series of quantitative and qualitative analyses.

FIGURE 1 **2019 Methodology Review for the 2021 Access to Medicine Index**

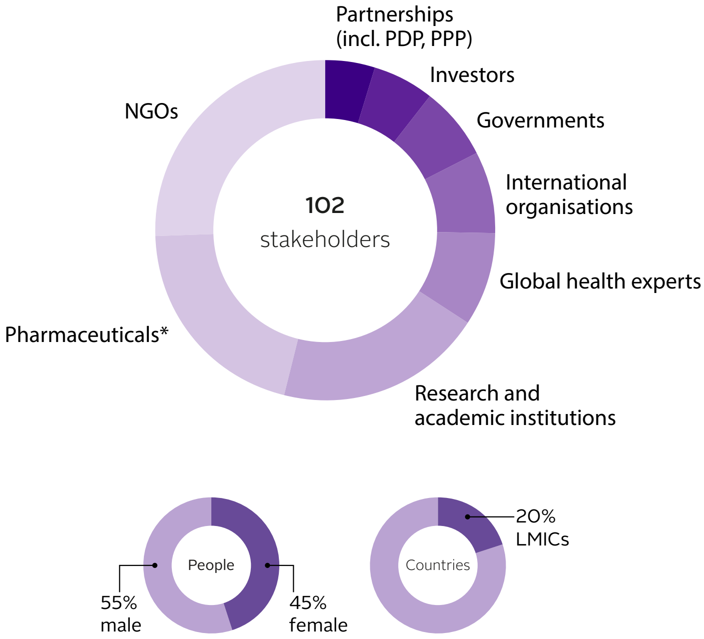

*At time of ERC meetings

FIGURE 2 **Stakeholder outreach for the 2021 Access to Medicine Index**

The Foundation has built stakeholder consensus on what we can expect from pharmaceutical companies on access to medicine since 2008. Over time, the depth of consensus has grown. For 2020, the Foundation took a longer horizon than in previous cycles, focusing on the role for pharmaceutical companies in the coming decade.

Experts were identified through a literature review and recommendations, to ensure a diverse range of alternative viewpoints and technical expertise were incorporated. The Foundation also engaged with companies evaluated in the 2018 Index.

Topics were prioritised through internal analyses of data and indicators, independent reviews of the Index research during the 2016-2018 period of analysis and a review of developments in access-to-medicine theory and practice.




* Pharmaceutical industry, including companies and associations

## INTERNAL INDICATOR ANALYSES

- **Distribution analyses**. Assessing the distribution of scores per indicator to check the spread of company behaviour in the 2018 Index. This indicates whether expectations of companies are fair (large clusters of low scores may indicate expectations may be too high) and the extent of room for improvement. Outcomes inform refinements to indicators and scoring guidelines.
- **Response rate analyses:** Assessing company response rates and quality regarding each data request in the 2018 Index. This confirms whether questions are clear and whether companies can feasibly gather data per 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 the next phase of stakeholder dialogue.

## EXPERT REVIEW COMMITTEE

Throughout each Methodology Review, strategic guidance is provided by the Expert Review Committee (ERC), an independent body including experts from WHO, governments, the industry, non-governmental organisations (NGOs), academia and investors. The ERC met to review proposals for the scope, structure and analytical approach of the 2021 Index, making recommendations where the consensus view is unclear or where uncertainty exists in areas of measurement, before endorsing the final methodology.

**Expert Review Committee in 2020**

| | |
|---|---|
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| Emily Bleimund | U.S. Department of Health and Human Services |
| Githinji Gitahi | Amref Health Africa |
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| Dennis Ross-Degnan | Harvard Medical School |
| Alan Staple | The Clinton Health Access Initiative |
| Yo Takatsuki | AXA Investment Managers |
| Prashant Yadav | INSEAD and Center for Global Development |

STAKEHOLDER CONSENSUS

# The path for pharma companies to ramp up access by 2030

## 2020

### WHERE IS THE PHARMA INDUSTRY NOW ON ACCESS TO MEDICINE?

**Use of access tactics has expanded, yet many key products are still not covered.**
In 2019, a Ten-Year Analysis carried out by the Access to Medicine Foundation showed that pharmaceutical companies have made progress when it comes to access to medicine. Yet, the pace of change is slow. R&D for key diseases has increased, while for other diseases, such as maternal and neonatal health conditions, R&D lags behind. The use of access tactics such as equitable pricing and voluntary licensing has grown, yet many key products are still not covered.

**Companies' actions target specific, prioritised diseases.**
The big picture shows that pharmaceutical companies' access-to-medicine initiatives tend to focus on specific diseases or countries. Such initiatives are more likely to target infectious diseases, particularly HIV/AIDS, malaria and TB. Initiatives for non-communicable diseases (NCDs), such as heart disease, cancer and diabetes, are now beginning to gain traction. This balance reflects how society more broadly has responded to global health needs – by mobilising around specific diseases.

## CHANGE IN THREE PHASES

Achieving the SDGs and UHC by 2030 means addressing access to medicine at scale: delivering products to all people in need, wherever they live. Success depends on pharma companies moving to systematically address access at all levels of the health system: from the levels of the patient and healthcare professional; through infrastructure challenges for hospitals and clinics; to the level of regulatory systems.

**1**
**Match products to populations**
Map who needs each product, where they live and the barriers they face to equitable access.

## TOOL FOR DRIVING CHANGE

ANALYTICAL FRAMEWORK FOR THE 2021 ACCESS TO MEDICINE INDEX

| 3 TECHNICAL AREAS | 14 PRIORITY TOPICS | Indicators per topic |
|---|---|---|
| A GOVERNANCE OF ACCESS 20% | Responsible business practices | 4 |
| | Governance and strategy | 3 |
| B RESEARCH & DEVELOPMENT 25% | Access planning | 4 |
| | Product development | 3 |
| | Building R&D capacity | 1 |
| C PRODUCT DELIVERY 55% | Equitable access strategies | 4 |
| | Intellectual property strategy | 3 |
| | Quality and supply | 3 |
| | Licensing quality | 2 |
| | Product donations | 2 |
| | Registration | 1 |
| | Inclusive business models | 1 |
| | Local manufacturing | 1 |
| | Health systems strengthening | 1 |

The UN has called for a decade of action in order to achieve the Sustainable Development Goals (SDGs) and universal health coverage (UHC) by 2030.[1] This means access to medicine must continue to expand, particularly for people living in low- and middle-income countries (LMICs), who account for 83% of people alive today. Progress is being made, yet the UN has warned that many people are being left behind.[2] The Access to Medicine Foundation has built broad consensus on what society expects of pharmaceutical companies by 2030 when it comes to access to medicine in LMICs, translating these expectations into a set of 33 metrics for the next Access to Medicine Index. Achieving further progress on access to medicine depends on many actors, including governments, civil society and the private sector. Pharmaceutical companies have a unique capacity to develop the treatments needed by people in low- and middle-income countries and to improve products' availability across socioeconomic divides. To achieve the SDGs and UHC by 2030, the mainstream approach across the pharmaceutical industry must continue to move: toward addressing access to medicine at scale.

**2**
**Learn from what works; expand best practice to reach change at scale**
Adapt and scale up best practices to suit different country contexts, diseases, modes of administration and levels of funder and government engagement demand.

**3**
**Implementation and monitoring**
Review the success of the approach in meeting identified health needs, checking to ensure no one is being left behind.

The Access to Medicine Index is a tool for driving change in the pharmaceutical industry. By ranking companies every two years, it spurs them to compete and collaborate on priority access-to-medicine topics. It shows which companies are leading the way, as better performers rise in the ranking.

**WHAT THE INDEX MEASURES**

1 Governance of Access: access strategies, compliance controls
2 Research & Development: pipelines and access planning
3 Product Delivery: including registration, pricing, licensing, donations

**20 companies**
20 R&D-based pharmaceutical companies with the most relevant products for people living in LMICs

**106 countries**
106 low- and middle-income countries with high burdens of disease and/or high inequality

**82 diseases**
82 diseases, conditions and pathogens, including high-burden communicable diseases, non-communicable diseases, neglected tropical diseases, maternal & neonatal health conditions and priority pathogens

# 2030

## WHAT ARE WE WORKING TOWARD?

**Governance of access by 2030**
1 Access-to-medicine is fully integrated into commercial strategy, including oversight, incentives and accountability from HQ to in-country operations.
2 Results of access initiatives are monitored and shared publicly.
3 Business is conducted in an ethical and responsible manner.

**Research & Development by 2030**
4 Pharmaceutical R&D responds to the needs of people in low- and middle-income countries.
5 Companies' access plans for registration, supply and affordability are systematically developed during R&D, from at least Phase II of clinical development.

**Product Delivery by 2030**
6 Access is prioritised for products viewed as essential to public health, particularly where there are few manufacturers.
7 New products are quickly and widely registered in low-and middle-income countries.
8 LMICs can rely on a steady and sufficient supply of quality products.
9 Payers and patients can afford the health products they need, including people at the base of the income pyramid.
10 Alternative manufacturers are enabled to supply quality products, competing on price, to countries where patent-holding companies do not plan to supply directly.
11 Health systems are supported through partnerships including local stakeholders and in line with local needs.

1. United Nations. Decade of Action - United Nations Sustainable Development. https://www.un.org/sustainabledevelopment/decade-of-action/. Published 2020. Accessed March 17, 2020.
2. Universal health coverage (UHC). https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-%28uhc%29. Accessed March 19, 2020.

ANALYTICAL FRAMEWORK

# A new, tighter analytical framework for 2021

The 2021 Access to Medicine Index is based on a new analytical framework of three Technical Areas, and 14 priority themes for corporate activity. Per area, companies' policies and practices are measured by indicators that correspond to pharmaceutical companies' core role for improving access to medicine. This role centres on the development and equitable delivery of health products, while ensuring appropriate management of access and responsible business practice. The indicators have been developed through an extensive stakeholder dialogue, informed by ten years of methodology development. The result is a set of ambitious yet achievable expectations of pharmaceutical company behaviour.

### Tighter analytical focus in 2021

The new analytical framework for 2021 has a tighter structure, with 33 indicators grouped into three Technical Areas:

1 Governance of Access
2 Research & Development
3 Product Delivery

For the 2021 Index, the analytical criteria per indicator have been tailored to better compare like with like, for example, to compare companies' approaches in similar country contexts and/or where similar external market incentives such as pooled procurement mechanisms are in place. As a result, the 2021 Index will make more sensitive comparisons of the access approaches being used by pharmaceutical companies in different markets and territories.

### Three Technical Areas

The three Technical Areas have been confirmed by stakeholders as the core areas where pharmaceutical companies have the responsibility and ability to influence access to medicine in low- and middle-income countries (LMICs). Each area is assigned a weight according to its importance for improving access to medicine.

For 2021, the Index framework is further divided into 14 priority topics, in place of the 'strategic pillars' used in past iterations. In its first ten years, the strategic pillars enabled the Index to capture different stages of company action to improve access to medicine, from commitment to performance and innovation, supported by transparency. By moving from strategic pillars to priority topics, the Index further emphasises and clarifies the precise areas of performance and action for pharmaceutical companies to focus on.

### 33 indicators

There are 33 indicators in the Framework in 2020, down from 68 in 2018. The Index framework is now streamlined around the identification and confirmation of best practices and practices that are proven to be successful, scalable and accepted by governments and other stakeholders. This focus reflects the emphasis placed by the global health community on access programmes that can achieve scale and sustainability.

Some indicators are new in 2020, and others have been refined, either to tailor the metric more closely to stakeholders' expectations of company behaviour or to improve data capture, comparison between companies and other analyses. Other indicators have been removed or merged, depending on either the relevance of the measured behaviour to access to medicine or the level of importance regarding the industry's role. Indicators are listed from page 30 onwards.

#### KEY CHANGES IN 2020

- The Index newly assesses whether companies' access-to-medicine strategies cover all their therapeutic areas.
- The Index newly looks at whether access-related governance structures include monitoring and incentives for country-level managers, as well as for senior leadership.
- The Index now focuses on the actions companies can take to minimise risk at the country level, for example, country-by-country risk assessments.
- The Index now asks whether companies monitor the risk of non-compliance at the country-level, for example to ensure adherence with standards and laws for ethical marketing, corruption and clinical trials.
- The Index will assess the rigour and strength of access plans for late-stage R&D projects in ensuring widespread, rapid access following market approval.
- The Index will newly assess the speed of registration filings in low- and middle-income countries (LMICs).
- The Index will assess how companies tailor access strategies to key products using three categorisations: supranationally procured products such as vaccines; healthcare practitioner-administered products; and self-administered products.
- For key products, the Index will assess the geographic coverage of the following access strategies: equitable pricing strategies, voluntary licensing, non-assert declarations and donation programmes.

FIGURE 3 **Analytical Framework for the 2020 Access to Medicine Index**
The 2020 Access to Medicine Index analyses company behaviour using a framework of 33 indicators organised in three Technical Areas. In line with previous Index methodology reviews, the emphasis has increased on R&D and product delivery strategies such as pricing and licensing. The new framework enables more sensitive comparisons of the access approaches being used by pharmaceutical companies in different markets and territories.

**ANALYTICAL FRAMEWORK FOR THE 2021 ACCESS TO MEDICINE INDEX**

| 3 TECHNICAL AREAS | 14 PRIORITY TOPICS | Indicators per topic |
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| A GOVERNANCE OF ACCESS 20% | Responsible business practices | 4 |
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| | Product development | 3 |
| | Building R&D capacity | 1 |
| C PRODUCT DELIVERY 55% | Equitable access strategies | 4 |
| | Intellectual property strategy | 3 |
| | Quality and supply | 3 |
| | Licensing quality | 2 |
| | Product donations | 2 |
| | Registration | 1 |
| | Inclusive business models | 1 |
| | Local manufacturing | 1 |
| | Health systems strengthening | 1 |

## GOVERNANCE OF ACCESS 20%

Implementing a clear, long-term access strategy is crucial to tangibly improving access to medicine for the long term. Further, by enforcing rigorous standards of behaviour across their operations, including third-party contractors, pharmaceutical companies can mitigate the risk of practices that cause harm and undermine efforts to improve access. This Technical Area looks at how pharmaceutical companies govern, plan and manage the achievement of access-to-medicine objectives, while ensuring they apply processes that minimise the risk of non-compliant or corrupt behaviour occurring. It looks at access-to-medicine strategies, including whether they are aligned with corporate strategies, and how progress towards access to medicine objectives is measured and incentivised.

**Key changes in 2020**

- This Technical Area now covers (a) access-to-medicine governance and strategy, as well as (b) activities related to compliance and ethical marketing. These two areas were previously analysed separately.
- The Index newly assesses whether companies' access-to-medicine strategies cover all its therapeutic areas, which is expected to lead to a wider range of access initiatives.
- The Index looks at whether access-related governance structures include monitoring and incentives for all relevant staff, from the CEO to country-level managers.
- The Index now asks whether companies monitor the risk of non-compliance at the country-level to ensure, for example, adherence with standards and laws for ethical marketing, corruption and clinical trials.

### PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

| Governance & strategy | Indicator(s) |
|---|---|
| To ensure that access strategies are successfully implemented, structures for governance and management need to be established. Assigning responsibility and incentives at the highest level of the company increases the likelihood that access-related objectives are prioritised, kept on track and achieved.<br>Pharmaceutical companies are expected to develop and implement a clear, long-term strategy for improving access to medicine. Such a strategy should not remain isolated from the main business of the company and should seek to align with commercial concerns. Progress towards strategic goals should be publicly shared. Consideration for access to medicine should not be limited to few areas, but instead be incorporated systematically into all R&D projects and all commercialisation/market access strategies, specifically in relation to low- and middle-income countries. | GA1, GA2, GA3 |

| Responsible business practices | |
|---|---|
| Corrupt behaviour and unethical marketing can have direct consequences on access to medicine, including misdirecting national health budgets and promoting the irrational use of medicines. Pharmaceutical companies can limit misconduct by enforcing stringent compliance processes across their operations and with third parties, by modifying how they incentivise sales agents and by publicly disclosing how they engage with healthcare professionals.<br>Pharmaceutical companies are expected to have controls in place to mitigate the risk of non-compliance within its operations in low- and middle-income countries (LMICs). These controls are expected to include monitoring and auditing processes, and be able to regulate the activities of contracted third parties. To assess the effectiveness of these controls, the Index checks for negative rulings and/or settlements with regards to unethical marketing, corruption, anti-competitive behaviour (IP-related or non-IP related) and clinical trial misconduct in low- and middle-income countries. Companies are expected to publicly align with the international consensus on public health and intellectual property. | GA4, GA5, GA6, GA7 |

For indicators and their full rationales, see p.30-31.

## RESEARCH & DEVELOPMENT 25%

Large research-based pharmaceutical companies are well positioned to develop new medicines and other life-saving products and to bring them to market. New products should be made rapidly available to people who need them, wherever they live, which requires advance planning. This Technical Area analyses in-house and collaborative R&D activity that aims to develop or adapt products targeting the diseases, conditions and pathogens within the Index scope, and in response to the needs of people living in low- and middle-income countries (LMICs). It also examines whether companies put plans in place during development to ensure successful products are rapidly made accessible in LMICs.

**Key changes in 2020**

- The 2021 Index will emphasise R&D that addresses specific product gaps identified by Policy Cures Research and the World Health Organization and R&D that does not address defined priorities but does address unmet need in LMICs.
- The R&D Technical Area will newly assess the rigour and strength of access plans for late-stage projects deemed most relevant to LMICs, as well as the proportion of companies' projects that are covered by access plans to ensure widespread, rapid access following market approval. Previously, only the proportion of the late-stage pipeline covered by access plans was assessed.

### PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

| Product development | Indicator(s) |
|---|---|
| Pharmaceutical companies have the capacity and expertise to – either in partnership or in-house – develop and adapt products that address unmet public health needs and are suitable for people living in low- and middle-income countries. The Index will map companies' R&D activity against defined and published R&D priorities where new, effective products are urgently needed, for example for pathogens flagged as an R&D priority due to antimicrobial resistance, or for neglected tropical diseases. These R&D priorities also include 'Disease X', a term used by WHO to refer to currently unknown pathogens that could cause a serious international epidemic, as occurred in the case of COVID-19. With regards to diseases where R&D priorities have not yet been independently assessed, such as non-communicable diseases, the Index will examine whether companies' projects take account of the unique needs of people living in LMICs. Companies are also expected to disaggregate and disclose the resources dedicated to such R&D. | RD1a, RD1b, RD4 |
| **Planning for access** | |
| Planning for access helps ensure public health needs are taken into consideration during product development. Such planning can help people in need of those products to gain access more rapidly and at affordable prices following market entry. The establishment of a structured process to develop access plans can help ensure access plans become a standard process. Pharmaceutical companies are expected to have plans in place for pipeline projects from (at least) Phase II clinical trials, prioritising access planning for R&D projects targeting defined R&D priorities or where clear value to patients in LMICs is demonstrated. Companies are also expected to have transparent policies in place to ensure post-trial access to treatments tested in clinical trials in countries in scope. As part of this analysis, the Index will look for commitments to register successful products in the countries in which these trials took place and for plans to take affordability into account. | RD2, RD3a, RD3b, RD5 |
| **Building R&D capacity** | |
| Pharmaceutical companies have the expertise and ability to support the development of a skilled R&D sector in low- and middle-income countries. Engagement efforts aimed at building local R&D capacity support the development of research skills that can enable local researchers to address relevant health needs and priorities. | RD6 |

For indicators and their full rationales, see p.32-33.

## PRODUCT DELIVERY 55%

The choices pharmaceutical companies make in delivering their products are a critical factor for countries striving to achieve universal health coverage. As a first step, companies must register their products for sale where they are needed. They can then use three main access strategies: equitable pricing, responsible IP management and product donations. These are considered to have the biggest potential impact on supply and affordability. Yet there is no 'one-size-fits-all-products' approach to product delivery. This Technical Area will assess how companies tailor these tools to reach furthest across the income pyramid to boost access. Further, it will capture how companies leverage their know-how and resources to address local access barriers. Significant barriers to access can relate to gaps in local healthcare infrastructure, skills gaps, poorly functioning supply chains and weak quality assurance systems.

**Key changes in 2020**

- This new Technical Area incorporates registration, pricing, IP strategies, licensing, product donations, quality and supply, local manufacturing and health system strengthening. This merge reflects the consensus view that these aspects of product delivery are interdependent.
- It will newly assess the speed of registration filings in low- and middle-income countries (LMICs).
- It will assess how companies tailor access strategies to their products, using three categorisations: supranationally procured products such as vaccines; healthcare practitioner-administered products; and self-administered products.
- For key products, the Index will assess the geographic coverage of the following access strategies: equitable pricing strategies, voluntary licensing, non-assert declarations and donation programmes.

### PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

| Registration | Indicator(s) |
|---|---|
| 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. It newly looks at the speed of registration filings. Companies are expected to prioritise registration in countries with high disease burden, and to aim for registration in LMICs within 12 months of first global registration. | PR1 |

| Equitable access strategies | |
|---|---|
| Equitable access means all people in LMICs – including those at the base of the income pyramid – are able to benefit from products, with no one left behind. Pharmaceutical companies are expected to apply access strategies (involving pricing, non-exclusive licensing, donations) for key products across LMICs, maximising the reach of that product across the income pyramid. When setting pricing strategies, companies are expected to aim for affordability, integrating the payer's ability to pay for the product into their pricing approach. | PP1, PP2a, PP2b, PP3, PP4, PP5 |

| IP strategy | |
|---|---|
| Responsible, transparent management of intellectual property (IP) can stimulate R&D by third-party researchers. Companies can license out IP assets they have chosen not to develop further on access-oriented terms to external researchers. Responsible IP management can also facilitate the affordable supply of medicines and other health products in LMICs by supporting decision making by international procurers, and the entry of generic pharmaceutical manufacturers into new markets. Companies are expected to mitigate the risk that patent protections limit R&D and product availability and affordability by publishing patent statuses and through patent filing/enforcement policies. | PPL1, PPL2, PPL3 |

| Licensing quality | |
|---|---|
| Non-exclusive voluntary licensing supports the market entry of alternative manufacturers of patented products, in turn supporting more secure supply and enhancing affordability through stimulation of 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 to those products, and to ensure these agreements are disclosed publicly. | PPL4, PPL5 |

For indicators and their full rationales, see p.34-38.

## PRODUCT DELIVERY 55%

| | Indicator(s) |
|---|---|
| **Product donations**<br>Product donations continue to play an important role in eliminating, eradicating or controlling some diseases that affect populations living in LMICs. For people living in poverty, donations may be their only chance of getting access to the treatment they need. Pharmaceutical companies supplying such products are expected to publicly commit to staying engaged until elimination, eradication and control goals are reached, and to expand coverage of programmes where it facilitates goal achievement. Companies are expected to be able to rapidly respond to emergencies with ad hoc product donations. | PP2a, PP3b |
| **Inclusive business models**<br>To achieve universal health coverage, people in the lowest income brackets must also gain access to medicine. Inclusive business models are an important way of extending market-based access strategies to populations grouped into the lower tiers of the income pyramid – those with some, but limited ability to pay. Inclusive business models are more likely to lead to a successful outcome if they also work to address capacity constraints, have a long-term vision and goal, financial commitment and clear objectives. | PBM1 |
| **Quality and supply**<br>Inefficiencies and weaknesses along supply chains – whether in procurement processes, delivery logistics, storage or other stages – can impact the accessibility, availability and quality of medicines. Pharmaceutical companies are expected to engage with relevant, local partners to identify bottlenecks and improve capacity for good supply chain management into LMICs. To reduce the public health threat represented by substandard or falsified (SF) medicines, companies are also expected to report SF cases in a timely manner to national authorities and/or WHO Rapid Alert. | PQ1, PQ2, PCB2 |
| **Local manufacturing**<br>Manufacturing medicines locally can lead to reduced costs and improved supply, but quality must be guaranteed. When pharmaceutical companies work with third-party manufacturers in LMICs, they have the opportunity to take steps to ensure local staff have the skills and technology necessary to meet the requirements of good manufacturing practices (GMP). Companies can add broader value to local manufacturing capacity by engaging with other manufacturers and universities to build capacities in quality manufacturing beyond those needed for their own products. | PCB1 |
| **Health system strengthening**<br>Robust health systems must be in place in order for products to be deployed, prescribed and administered safely and effectively. This can include infrastructure, trained health professionals, reduction of stigma, diagnostic capacity, data-management systems and more. While these activities are not a central responsibility, pharmaceutical companies have both the expertise and the capacity to help strengthen local health systems, provided initiatives are carried out with appropriate partners, in alignment with local needs and where outcomes are monitored and conflict of interest is managed. | PCB3 |

For indicators and their full rationales, see p.34-38.

# What the Index measures

The Access to Medicine Index assesses company policies and behaviour regarding specific diseases and product types and in 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
- Selected based on a combination of market capitalisation and relevance of pipeline and portfolio for access to medicine

**DISEASE SCOPE**
82 diseases, conditions and pathogens
- 23 Communicable Diseases
- 17 Non-Communicable Diseases
- 20 Neglected Tropical Diseases
- 10 Maternal & Neonatal Health Conditions
- 12 Priority Pathogens

**GEOGRAPHIC SCOPE**
106 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

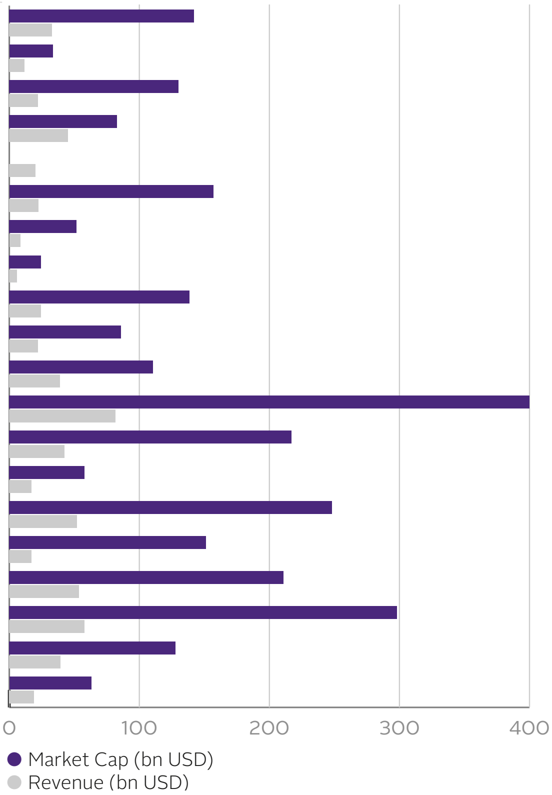
The Access to Medicine Index assesses 20 of the world's largest R&D-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their pipelines, portfolios, resources and global reach, these companies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

Companies are selected based on their market capitalisation and revenue, and the relevance of their product portfolios and pipelines for the diseases and countries covered by the Index. Following a review of these criteria, the 2021 Index will evaluate the same 20 companies as in 2018, facilitating trend analysis.

The largest R&D-based companies 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 the scope of the Index and the 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. 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.

FIGURE 4 **Companies in scope of the 2021 Access to Medicine Index**

| Company Name | Country | Stock Exchange | Ticker | Revenue, 2018 (bn USD) | Market cap* (bn USD)** |
|---|---|---|---|---|---|
| AbbVie Inc | USA | New York SE | ABBV | 32.753 | 141.967 |
| Astellas Pharma Inc | JPN | Tokyo | 4503 | 11.836 | 33.407 |
| AstraZeneca plc | GBR | London | AZN | 22.09 | 130.033 |
| Bayer AG | DEU | Xetra Germany | BAYN | 45.278 | 82.947 |
| Boehringer Ingelheim GmbH | DEU | n/a | n/a | 20.014 | n/a |
| Bristol Myers Squibb Co | USA | New York SE | BMY | 22.561 | 156.824 |
| Daiichi Sankyo Co, Ltd | JPN | Tokyo | 4568 | 8.423 | 51.753 |
| Eisai Co, Ltd | JPN | Tokyo | 4523 | 5.824 | 24.492 |
| Eli Lilly & Co | USA | New York SE | LLY | 24.556 | 138.499 |
| Gilead Sciences Inc | USA | NASDAQ | GILD | 22.1 | 85.784 |
| GlaxoSmithKline plc | GBR | London | GSK | 39.112 | 110.652 |
| Johnson & Johnson | USA | New York SE | JNJ | 81.6 | 400.018 |
| Merck & Co, Inc | USA | New York SE | MRK | 42.294 | 217.045 |
| Merck KGaA | DEU | Xetra Germany | MRK | 16.969 | 57.82 |
| Novartis AG | CHE | Swiss Exchange | NOVN | 51.9 | 248.252 |
| Novo Nordisk A/S | DNK | Copenhagen | NOVO B | 17.127 | 151.26 |
| Pfizer Inc | USA | New York SE | PFE | 53.647 | 210.795 |
| Roche Holding AG | CHE | Swiss Exchange | ROG | 57.734 | 297.977 |
| Sanofi | FRA | Euronext Paris | SAN | 39.418 | 127.799 |
| Takeda Pharmaceutical Co, Ltd | JPN | Tokyo | 4502 | 19.001 | 63.014 |




* Market cap on 31 December 2018, from Bloomberg terminal
** Exchange rates on 31 December 2018, from oanda.com

**WHAT WE MEASURE**

# Disease Scope

The Access to Medicine Index assesses pharmaceutical company action in relation to a defined set of diseases, conditions and pathogens identified as the most critical priorities regarding access to medicine. The Foundation has defined this list using data on disease burdens, incidence and independent prioritisations to pinpoint where greater access to medicine is most needed.

Following the 2019 Methodology Review, the disease scope for the 2021 Access to Medicine Index comprises 82 diseases, conditions and pathogens. All diseases, conditions and pathogens are in scope for all three Technical Areas.

**Defining the disease scope**
Diseases are brought into scope, for example, because they impose a high global disease burden despite the existence of effective treatments, or disproportionately affect poorer populations. To identify such diseases, the Foundation uses a newly updated screening protocol (see Figure 6). This is based primarily on the relevance of pharmaceutical intervention, global and/or country-level disease burdens and the prioritisation of the disease by organisations such as Policy Cures Research and the World Health Organization (WHO) for improving access to medicine. The disease scope for 2021 has been updated with reference to the most recent Global Burden of Disease Study (GBD 2017), which also provided country-level data on disability adjusted life years (DALYs).[1] DALYs are commonly used to measure the burden of disease on a population. One DALY is defined by WHO as "one lost year of healthy life", and accounts for the gap between the actual health situation and the ideal situation in a given country or population.

**KEY CHANGES**

**The full disease scope applies to all Technical Areas**. For the previous Index report, in order to capture projects targeting priority R&D gaps, an additional 22 diseases were brought into scope for R&D analyses only. For the 2021 Index, such diseases are now in scope for all Technical Areas. This change allows for products emerging from the pipeline to be followed after market approval and included in analyses of access strategies. It will cover new products for several emerging infectious diseases, such as COVID-19, and other diseases for which new and more effective products are urgently needed, and for oncology products that are not listed on the WHO Model List of Essential Medicines, among others.

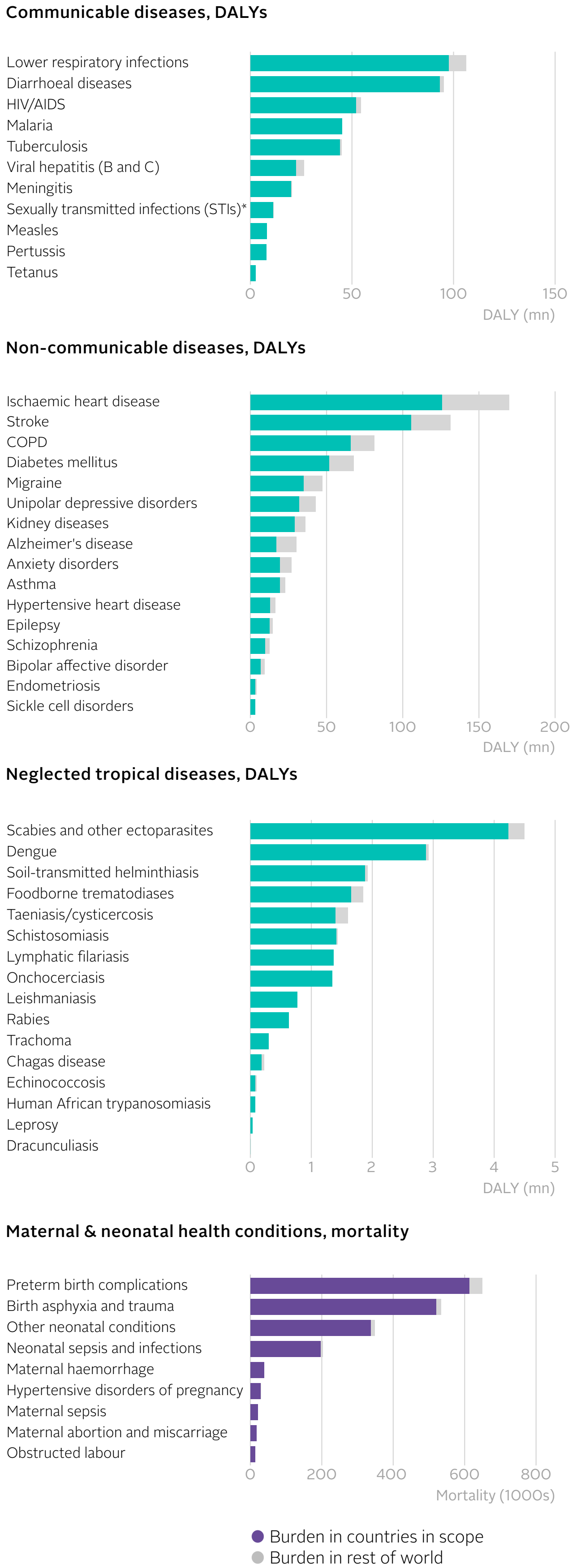
**Diseases where majority of burden rests in LMICs now included.** As a new inclusion criteria, the Index now also includes diseases where almost everyone affected lives in low- and middle-income countries (LMICs). This is considered a strong indicator that the availability of suitable treatment options is limited due to a low incentive to invest in pharmaceutical R&D. This change has brought diphtheria, sickle cell disease and yellow fever newly into scope, and has led to tetanus being retained.[1] Specifically, the Index includes diseases where ≥95% of the global DALY burden is in countries in scope, where data is available.

**Greater attention to diseases affecting women and girls.** The Index has additional diseases in scope that are linked to biological sex (i.e., sex-linked diseases). These are endometriosis and ovarian and uterine cancer. Their inclusion will increase the capacity of the Index to assess how women and girls with sex-linked diseases may have unmet needs in LMICs. These diseases have comparably higher DALY burdens and/or incidence rates than other sex-linked diseases, based on a review of GBD 2017 data and data from the Global Cancer Observatory (GLOBOCAN 2018).[1,2]

# DISEASE SCOPE

FIGURE 5 **Low- and middle-income countries shoulder the bulk of 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. Behind these numbers are millions of people who cannot rely on access to affordable, quality medicine.




## 23 Communicable Diseases

The 2021 Index includes the ten Communicable Diseases (CDs) with the highest DALY burdens in countries in scope. It also includes diphtheria, tetanus and yellow fever, as more than 95% of the global DALY burdens from these diseases are borne by countries in scope.[1] This category also includes diseases with prioritised product gaps for R&D, such as emergent non-polio enteroviruses and 'Disease X', a term used by WHO to refer to currently unknown pathogens that could cause a serious international epidemic, such as COVID-19. Some prioritised diseases have been reclassified to contain multiple diseases which were previously separated. For example, 'bunyaviral diseases' includes Crimean-Congo haemorrhagic fever, Rift Valley fever and severe fever with thrombocytopenia syndrome, among others.

## 17 Non-Communicable Diseases

The 2021 Index includes the ten Non-Communicable Diseases (NCDs) with the highest DALY burdens in countries in scope, which for the first time includes Alzheimer's disease.[1] As an exception, cancer types are included if they have high or disproportionate incidences of disease.[2] The cancers in scope now also include thyroid cancer, which is the cancer type with the tenth highest incidence globally and in countries in scope, and ovarian and uterine cancer types, to enable a more sensitive assessment of access barriers facing women. Hypertensive heart disease, although 12th by DALY burden, has been retained as it can lead to or exacerbate other NCDs such as ischaemic heart disease and stroke if uncontrolled. Epilepsy, bipolar affective disorder and schizophrenia are retained on the basis of stakeholder consensus on the high need for access to treatment for these conditions.[3,4]

## 20 Neglected Tropical Diseases

The 2021 Index once again covers all WHO-classified Neglected Tropical Diseases (NTDs).[5] NTDs are particularly prevalent in poor regions of low-income countries, especially rural areas.

## 10 Maternal and Neonatal Health Conditions (including contraceptives)

Since 2014, the Index has included contraceptives and nine Maternal and Neonatal Health Conditions (MNHs), in continuing recognition of the importance of protecting mothers and neonates.[1]

## 12 Priority pathogens

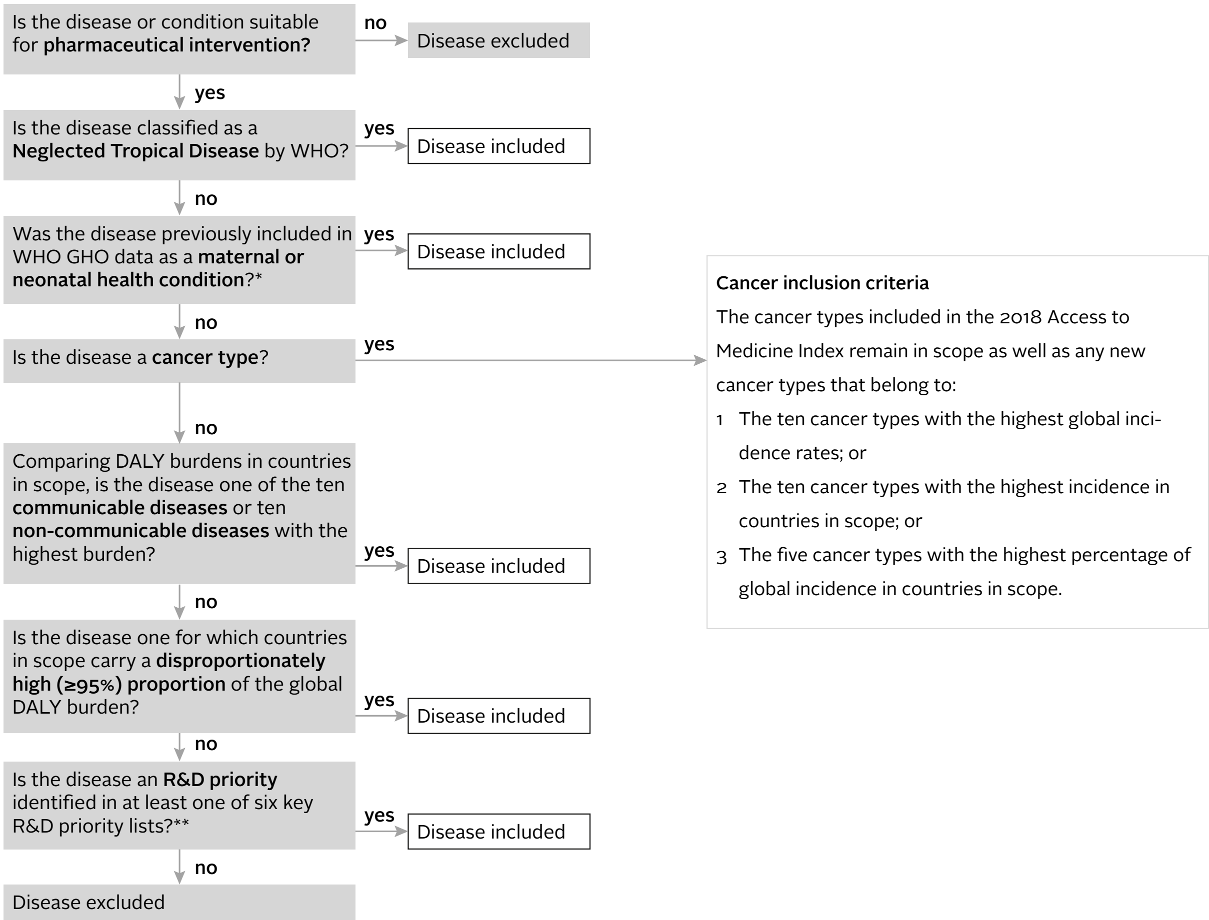
As in 2018, the 2021 Index includes the 12 pathogens on the 2017 WHO priority pathogens list. These pathogens are deemed a priority for efforts to curb antimicrobial resistance through the development of new and effective antibacterial agents.[6] Tuberculosis, a disease for which multidrug resistance is a critical priority, is evaluated as a separate communicable disease in this Index.

Footnotes on p.24

FIGURE 6 **Defining the disease scope - screening protocol**

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 protocol shown here.

**Which diseases qualify for inclusion?**




Exceptions: Bipolar affective disorder, epilepsy, hypertensive heart disease and schizophrenia were in scope for 2018 and have been retained due to, e.g., the continuing need for better access to treatment. Endometriosis and ovarian and uterine cancer have been included to enable a more sensitive assessment of access barriers related to sex.

* As listed in the WHO methods and data sources for global burden of disease estimates 2000-2011

** R&D priority lists: Policy Cures Research G-FINDER neglected disease, emerging infectious disease and sexual and reproductive health scopes; WHO R&D Blueprint; WHO Initiative for Vaccine Research gaps; WHO priority pathogen list

TABLE 1 **List of diseases, conditions and pathogens included in the 2021 Access to Medicine Index**

| Communicable Diseases | Top 10 DALY burden in countries in scope | ≥95% disease burden in countries in scope | WHO-identified NTD or MNH condition | R&D priority* | Stakeholder consensus** |
|---|---|---|---|---|---|
| Arenaviral haemorrhagic fevers (Lassa fever) | | | | ● | |
| Bunyaviral diseases | | | | ● | |
| Coronaviral diseases | | | | ● | |
| Diarrhoeal diseases | ● | ● | | ● | |
| Diphtheria | | ● | | | |
| Disease X*** | | | | ● | |
| Emergent non-polio enteroviruses | | | | ● | |
| 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 | Top 10 DALY burden in countries in scope | ≥95% disease burden in countries in scope | WHO-identified NTD or MNH condition | R&D priority* | Stakeholder consensus** |
|---|---|---|---|---|---|
| Alzheimer's disease | ● | | | | |
| Anxiety disorders | ● | | | | |
| Asthma | ● | | | | |
| Bipolar disorder | | | | | ● |
| Cancer‡ | | | | ● | ● |
| Chronic obstructive pulmonary disease (COPD) | ● | | | | |
| Diabetes mellitus | ● | | | | |
| Endometriosis | | | | | ● |
| Epilepsy | | | | | ● |
| Hypertensive heart disease | | | | | ● |
| Ischaemic heart disease | ● | | | | |
| Kidney diseases | ● | | | | |
| Migraine | ● | | | | |
| Schizophrenia | | | | | ● |
| Sickle cell disease | | ● | | | |
| Stroke | ● | | | | |
| Unipolar depressive disorders | ● | | | | |

| Neglected Tropical Diseases | Top ten DALY burden in countries in scope | ≥95% disease burden in countries in scope | WHO-identified NTD or MNH condition | R&D priority* | Stakeholder consensus** |
|---|---|---|---|---|---|
| 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 | | | ● | | |

| Maternal and Neonatal Health Conditions | Top ten DALY burden in countries in scope | ≥95% disease burden in countries in scope | WHO-identified NTD or MNH condition | R&D priority* | Stakeholder consensus** |
|---|---|---|---|---|---|
| Birth asphyxia and birth trauma | | ● | ● | | |
| Contraceptive methods | | | | ● | ● |
| Hypertensive disorders of pregnancy | | ● | ● | ● | |
| Maternal abortion and miscarriages§ | | ● | ● | | |
| 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)

Green text = newly in scope for the 2020 Index

Exclusions: none in 2020

* Diseases, conditions and pathogens indicated as R&D priorities on identified lists published by Policy Cures Research and WHO

** 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 18 cancer types. See Cancer Inclusion Appendix for more details.

§ Listed as 'Abortion' in previous Indices

|| Collectively, these will be referred to as communicable diseases in the 2021 Access to Medicine Index as 'Other prioritised antibacterial-resistant infections'.

WHAT WE MEASURE

# Geographic Scope

The Access to Medicine Index measures pharmaceutical companies' actions in countries where better access to medicine is most needed. This set of countries is referred to as the Index's geographic scope, and is defined using three criteria: (1) countries' levels of income (gross national income (GNI) per capita); (2) their levels of development; (3) and the scope and scale of inequality in each country. These assessments are 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 has been held constant for the 2021 Index, with the same 106 countries in scope as for the 2018 Index. Maintaining the same geographic scope provides the Index with additional capacity to track progress in countries facing development- and inequality-related access-to-medicine constraints, where pharmaceutical companies can have an impact.

### HOW THE SCOPE IS DEFINED

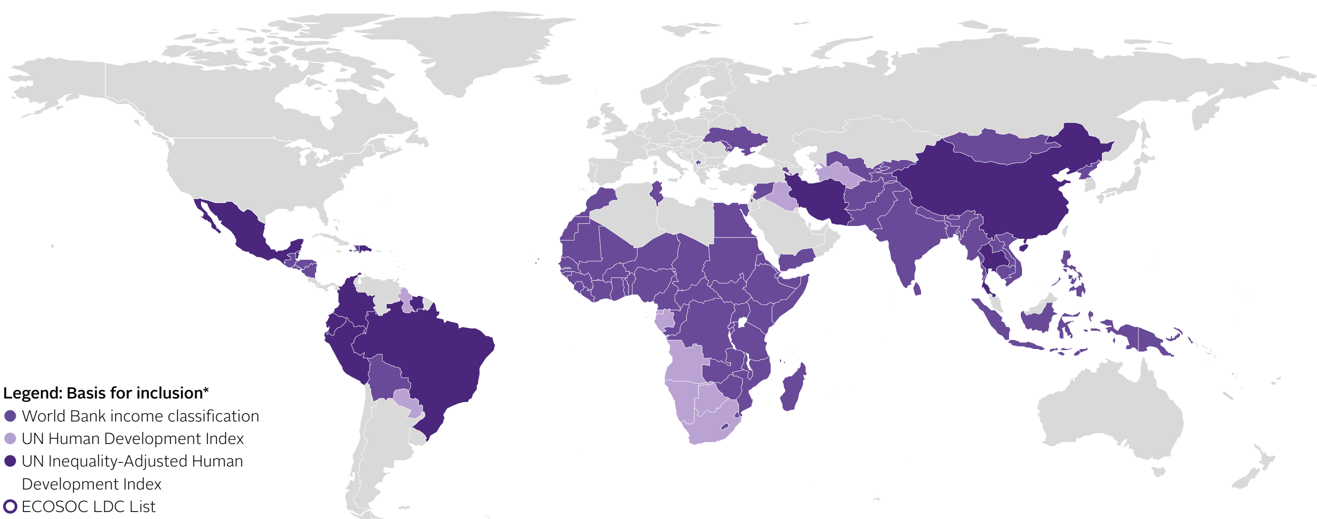
**Step 1:** Include all countries classified as low income or lower-middle income countries based upon the latest available World Bank data (2017).[7]

**Step 2:** Include all countries defined by the United Nations Development Programme (UNDP) as having either low or medium human development in its Human Development Index (HDI) data.[8]

**Step 3:** Include all high development countries with a high inequality-adjusted HDI ratio (HiHDI), as defined by the UN Inequality-Adjusted Human Development Index.[8] This change captures those higher-income countries with significant levels of inequality.

**Step 4:** The final step is to include all the Least Developed Countries (LDC) as defined by the United Nations Economic and Social Council (ECOSOC).[9]

FIGURE 7 **Countries included in the 2021 Access to Medicine Index – 106 Countries**




*Classification at the time of the 2018 Access to Medicine Index period of analysis. Updated country income and development classifications are available through the World Bank and UNDP data.

Due to scaling, countries may not be visible on the map (e.g., Tuvalu)

TABLE 2 **List of countries included in the 2021 Access to Medicine Index – 106 countries***

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

| | |
|---|---|
| LIC | Low income country<br>World Bank income classifications |
| LMIC | Lower-middle income country<br>World Bank income classifications |
| LDC | Least Developed Country<br>ECOSOC LDC List |
| LHDC | Low Human Development Country<br>UN Human Development Index |
| MHDC | Medium Human Development Country<br>UN Human Development Index |
| HiHDI | High Human Development Country with high inequality<br>UN Inequality-Adjusted Human Development Index |

* Classification at the time of the 2018 Access to Medicine Index. Updated country income and development classifications are available through the World Bank and UNDP data.

**WHAT WE MEASURE**

# Product Type Scope

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 the countries covered by the Access to Medicine Index. In 2021, the Index continues to use the same eight product types within the product scope, as in the last four iterations of the Access to Medicine Index.

### Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. 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 infection.

### Preventive Vaccines

This covers vaccines intended to prevent infection.

### 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 intended for global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmitting Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

### Contraceptive Methods & Devices

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

### Platform Technologies

Only products 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. These platform technologies have led to the rapid development of potential COVID-19 vaccine candidates.

# How the Index measures

The 2021 Access to Medicine Index assesses company behaviour using an analytical framework of 33 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:

**INDICATORS**
- Indicators per Technical Area
- Changes since 2018
- Indicator rationale

## INDICATORS

### A GOVERNANCE OF ACCESS 20%

| 2021 Indicator code | Previous Indicator(s) | 2021 Indicator | Change since 2018 (new/ retained/ modified) | Indicator rationale |
|---|---|---|---|---|
| GA1 | A.I.1<br>A.III.3<br>(merged) | **Governance structures & incentives**<br>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 within the Index scope. | **Modified**<br>Indicators looking at governance structures and access-related incentives at the governance level have been merged. The indicator also newly assesses whether in-country managers are incentivised to meet objectives for access. | Assigning responsibility for access to medicine in low- and middle- income countries 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. |
| GA2 | A.I.2 | **Access-to-medicine strategy**<br>The company has an access-to-medicine strategy and demonstrates that it is integrated within its corporate strategy. Well-integrated strategies extend across the company's portfolio and pipeline, for diseases within the Index scope. | **Modified**<br>The indicator newly covers how the company applies access thinking across its products and therapeutic areas. | An access-to-medicine strategy integrated in the overall corporate strategy indicates that a company considers access to medicine in low- and middle-income countries 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. |
| GA3 | A.II.1 | **Public disclosure of access-to-medicine outcomes**<br>The company has time-bound, measurable goals and objectives for access to medicine. It publicly shares progress toward such goals and objectives (i.e., outcomes*).<br><br>*Outcomes are the results achieved by a company's access-related activities.<br>These can include short-term (e.g., an increased proportion of people with more knowledge on diseases, symptoms or treatments) and/or medium- to long-term outcomes (e.g., patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; availability of medicines at outlets). Outcomes can also reflect on the country health system (e.g., number of health-care professionals trained). | **Retained**<br>No change | Public reporting of such information informs external stakeholders of companies' activities and progress and enables accountability. |
| GA4 | B.II.3<br>B.I.1<br>(merged) | **Responsible promotional practices**<br>The company incentivises responsible sales practices (e.g., by taking steps to decouple bonuses for sales agents from sales volumes). Further, it publicly discloses information regarding transfer of value (or its approach) to healthcare professionals in countries in scope of the Index (i.e., payments for attending and/or speaking at events, continuing medical education, promotional activities or other non-monetary values directed at HCPs). | **Modified**<br>Indicators assessing responsible sales practices and transparency on transfers of value to HCPs have been merged. | Public disclosure of transfers of value provide accountability regarding the interactions between companies and healthcare professionals, with the aim of, e.g., curbing inappropriate incentives that can lead to irrational prescribing.<br><br>Decoupling sales agents' financial rewards from the volume of medicine they sell removes the incentive to oversell. This is not only important to curb antimicrobial resistance, but also to prevent diversion of scarce resources from health budgets. |

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| **GA5** | | **Compliance controls** | **Modified** | |
| | B.III.3 | The company demonstrates that it has controls (internal controls, risk-based country audits, formal processes applying to third parties, etc.) in place to mitigate the risk of non-compliance in its operations in LMICs (i.e., in the areas of ethical marketing, anti-corruption and clinical trials). | The indicator assesses compliance controls where they respond to the specific needs of low- and middle-income countries. | Compliance controls are essential to reduce the risk of corruption occurring, which in turn can pose barriers to access to medicine. Such controls aim at preventing non-compliant activities from occurring, which can have a negative effect on access (e.g., undermine confidence in the pharmaceutical sector, divert scarce resources from health budgets, impact prices and limit the availability of medicines in the public sector). |
| **GA6** | | **Incidence of breaches** | **Modified** | |
| | B.III.1<br>C.III.7<br>E.III.6<br>(merged) | The company has not been found to be the subject of negative legal rulings or settled cases for unethical marketing practices/corrupt practices/anti-competitive practices/misconduct in clinical trials in countries within the scope of the Index during the past two years. | All breaches will be assessed under one area of measurement, with the exception of anti-competitive behaviour related to influencing trade policy. | 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. These cases take time to prosecute and settle, and therefore, though they may be historical in nature, they may reach settlement during the period of analysis of the Index. |
| **GA7** | | **Trade policy: IP and access to medicine** | **Modified** | |
| | E.II.1<br>E.III.5<br>(merged) | There is evidence that the company employs an intellectual property (IP) strategy that is conducive to access to medicine, in accordance with the company's public position on the Doha Declaration on the TRIPS Agreement and Public Health. | Anti-competitive behaviour related to trade policy will be assessed alongside a company's publicly disclosed stance on the Doha Declaration on TRIPS and Public Health. | Where a company applies an IP strategy which does not operate in accordance with the international consensus on intellectual property standards (through, for example, exerting pressure on governments not to incorporate TRIPS flexibilities within national legislation), there can be a knock-on negative impact to access to medicine in those countries. The Index is looking at an absence of such incidents over the past two years. |

## INDICATORS

### B RESEARCH & DEVELOPMENT 25%

| 2021 Indicator code | Previous indicator(s) | 2021 Indicator | Change since 2018 (new/ retained/ modified) | Indicator rationale |
|---|---|---|---|---|
| RD1a | C.III.2<br>C.III.3 | **R&D pipeline: Prioritised diseases**<br>The company engages in the development of products that target priority product gaps identified by global health research organisations*. This includes both innovative and adaptive R&D and both in-house and collaborative R&D.<br><br>*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research. | **Modified**<br>This indicator has been split into two indicators: for prioritised diseases and for other diseases. | Large research-based companies have the capacity to help address the public health needs of low- and middle-income countries through R&D for identified priorities, and are well-positioned to ensure that these products - which often have little to no commercial incentive - progress through the pipeline. |
| RD1b | C.III.2 | **R&D pipeline: Other diseases**<br>The company engages in the development of products that clearly address a need in LMICs beyond the R&D priorities identified by global health research organisations*. This includes innovative and adaptive R&D that, for example, addresses heat stability issues or targets populations for which further studies/specific formulations are needed (such as for children, pregnant/lactating women, etc.)<br><br>*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research. | **Modified**<br>This indicator has been split into two indicators: for prioritised diseases and for other diseases. | Where priorities have not been formally identified by the global health community, companies can independently consider the development of innovative and adaptive products that are well-suited for use in LMICs based on considerations including heat stability, use in special populations (e.g., children and pregnant women) and the inclusion of patients from these countries in clinical trials. |
| RD2 | C.I.2 | **Planning for access: Framework**<br>The company ensures equitable access is planned for all products successfully developed both in-house and collaboratively, for people living in low- and middle-income countries. | **Retained**<br>No change | Establishing a framework to develop access plans for all product candidates for both in-house and collaborative R&D increases the likelihood that a company will develop long-term access plans as early in development as possible. |
| RD3a | C.III.6 | **Planning for access: Project-specific plans for prioritised diseases**<br>The company ensures that its 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 the scope of the Index. | **Modified**<br>This indicator has been split into two indicators: for prioritised diseases and for other diseases. Planning will newly take into account depth and quality of access plans, alongside breadth. | Projects that are being developed to address key product gaps relevant to patients living in low- and middle-income countries are ones for which advance access planning is particularly critical. Companies can ensure that these products reach the people who need them quickly by planning ahead for access during clinical development, starting by Phase II. To strengthen potential public health impact, access plans should not only address registration but should go further, considering affordability and other aspects such as supply. |

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| **RD3b** | C.III.6 | **Planning for access: Project-specific plans for other diseases**<br>The company ensures that its R&D projects for diseases not prioritised by WHO and Policy Cures Research are supported by detailed plans to improve access to products in countries within the scope of the Index. | **Modified**<br>This indicator has been split into two indicators: for prioritised diseases and for other diseases. Planning will newly take into account depth and quality of access plans, alongside breadth. | Projects that target other high-burden diseases in low- and middle-income countries and address the needs of people living in these countries require advance planning to ensure that the products are accessible to as many as possible, as quickly as possible. Companies can ensure that these products reach the people who need them quickly by planning ahead for access during clinical development, starting by Phase II. To strengthen potential public health impact, access plans should not only address registration but should go further, considering affordability and other aspects such as supply. |
| **RD4** | C.II.1 | **Disclosure of resources dedicated to R&D**<br>The company publicly discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index. | **Modified**<br>This indicator newly focuses solely on information companies place into the public domain. | Public disclosure of R&D investments can be used to prioritise areas of limited financial investment, where more investments from the public and private sector are needed. It can help to build understanding about the capital needed to bring different types of products, from different therapeutic areas, to market. |
| **RD5** | C.I.4 | **Clinical trial conduct: Post-trial access**<br>The company publicly commits to ensuring equitable post-trial access to investigative treatments tested in countries within the scope of the Index for treatment-eligible clinical trial participants living in these countries. | **Modified**<br>This indicator newly expects not only registration, but also consideration of the affordability of products made available post-trial. | Commitment to this principle helps ensure that access to investigational products can continue once the trial has ended (post-trial access) for trial participants and for the general population in which the trial was held. Public disclosure of this commitment enables accountability and understanding of a company's intended approach. Stakeholders agree that post-trial access is one of the key responsibilities of companies related to clinical trials, and they increasingly call for consideration of access in ways that extend beyond registration commitments. |
| **RD6** | F.III.2 | **Capacity building in R&D**<br>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 public sector research organisations that meet good practice standards* in countries within the scope of the Index.<br><br>*Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiative goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability | **Retained**<br>No change | Local R&D is important to develop medicines that target local needs and diseases and that corresponds to disease patterns in countries in scope. Companies need to be incentivised to take action for building local R&D capacity that goes beyond their own interests/portfolio. They have expertise in R&D that they can share locally. |

## INDICATORS

| C | PRODUCT DELIVERY | 55% |
|---|---|---|

| 2021 Indicator code | Previous indicator(s) | 2021 Indicator | Change since 2018 (new/ retained/ modified) | Indicator rationale |
|---|---|---|---|---|
| PR1 | D.III.4 | **Registration**<br>The company rapidly and broadly files to register its most recently launched products targeting diseases within the scope of Index in countries within scope that have the highest disease burden. | **Modified**<br>The Index newly looks at not only the breadth of registration practice, but also the speed. | Filing to register new products rapidly in low- and middle-income countries is a critical step to enable more widespread access in those countries. Recently launched products should ideally be filed for registration in countries in need within 12 months of the first global filing. |
| PP1 | D.III.1<br>E.III.1<br>(merged) | **Access strategies: Coverage**<br>The company applies access strategies which aim to maximise patient reach across the selected products* (e.g., equitable pricing strategies, voluntary licensing, non-assert declarations, donation programmes) in the greatest proportion of countries within the Index scope.<br><br>*Referring to the subset of high-priority products selected across supranationally procured, healthcare practitioner-administered and self-administered categories. These products are a subset of those defined by the product inclusion process. | **New** | Equitable pricing strategies help ensure companies consider affordability when setting prices for products targeting diseases which are of the highest priority in countries in scope, whereas non-exclusive voluntary licensing can increase the potential access to patented products. Both lead to increased access to pharmaceuticals. Companies may use a mix of approaches - including donations for those with no ability to pay - and are expected to maximise the application of access strategies across their in-scope products. |
| PP2a | G.I.1 | **Access strategies: Ad hoc donations**<br>The company has public policies and supply processes in place to ensure ad hoc donations* are carried out rapidly in response to expressed need.<br><br>*A gift 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. | **Retained** | Donation programmes are a route to access to medicine for the poorest populations. When donations are made ad hoc in humanitarian situations (e.g., conflict, natural disasters, etc.), they should be made rapidly in response to expressed need. |
| PP2b | G.I.1 | **Access strategies: Long-term donation programmes**<br>The company engages in long-term, sustainable product donation programmes where elimination, eradication and control goals are possible, and publicly commits to the achievement of such goals. | **New** | Donation programmes can be a route to access to medicine for the poorest populations. They play a special role where there is very limited ability to pay and where a commitment is made to stay in the programme until elimination, eradication and control goals are achieved. Public disclosure of such a commitment is an important indicator of this will to remain active until goals are achieved. |

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| **PP3** | | **Supranationally procured products: Access strategies** | **New** | |
| | G.III.1<br>G.III.1<br>G.III.2<br>(merged) | The company applies access strategies to its supranationally procured products* and extends those strategies to countries graduating from, or countries and populations which do not qualify for, these programmes.<br><br>*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 and neglected tropical diseases. Companies which do not market these products will not have this indicator applied. | | This indicator will evaluate whether or not (for relevant products) companies engage with market-shaping/pooled procurement organisations (e.g., UNICEF, Gavi, the Global Fund, etc.), and, importantly, the extent to which comparative access to these products is also considered for countries which do not qualify for such support. |
| **PP4** | | **Healthcare practitioner-administered products: Access strategies** | **New** | |
| | D.III.1<br>D.III.2<br>D.III.3<br>(merged) | The company takes into consideration the ability of a country's reimbursement authority to pay and the demographic* characteristics of a country, in order to determine the ability to pay of different segments of the country's population, aiming to increase reach for their healthcare practitioner-administered products** across the income pyramid.<br><br>This is evidenced by:<br>(a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g., patients paying out of pocket) and how non-pricing initiatives (i.e., patient assistance programmes, donations, voluntary licensing) complement those pricing strategies to maximise reach, and<br>(b) evidence of how the approach has increased the patient number since the product was introduced, and<br>(c) plans to increase patient numbers for the following X years.<br><br>* The characteristics of a population such as age, sex, income level, education level, employment, etc.<br>**Products that often require either hospital administration of the product or the attention of a skilled healthcare professional during administration. Companies which do not market these products will not have this indicator applied to them. | | Companies have an important role of supporting governments in achieving universal health coverage by improving the reach of products across the income pyramid.<br><br>Companies should carefully determine ability to pay, taking into account socioeconomic factors which may determine different payers' abilities. Products which 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 public sector organisations to boost health system strength.<br><br>Companies can choose to use a mix of strategies to maximise reach of their access approach: intra-country segmentation, licensing and donations.<br><br>Successful strategies should be evidenced by an increase in patient numbers both to date and projected into the future. |

| 2021 Indicator code | Previous indicator(s) | 2021 Indicator | Change since 2018 (new/ retained/ modified) | Indicator rationale |
|---|---|---|---|---|
| PP5 | D.III.1<br>D.III.2<br>D.III.3<br>(merged) | **Self-administered products: Access strategies**<br>The company takes into consideration the ability of a country's reimbursement authority to pay and the demographic* characteristics of a country, in order to determine the ability to pay of different segments of the country's population, aiming to increase reach for their self-administered products** across the income pyramid.<br><br>This is evidenced by:<br>(a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g., patients paying out of pocket) and how non-pricing initiatives (i.e., patient assistance programmes, donations, voluntary licensing) complement those pricing strategies to maximise reach, and<br>(b) evidence of how the approach has increased the patient number since the product was introduced, and<br>(c) plans to increase patient numbers for the following X years.<br><br>* The characteristics of a population such as age, sex, income level, education level, employment, etc.<br>**Self-administered products are defined as those products which are easier to administer by the individual patient, and that are not necessarily prioritised by governments or by the global health community (typically treatments for other non-communicable diseases, such as diabetes, stroke, hypertension and heart disease). Companies who do not market these products will not have this indicator applied. | New | Companies have an important role of supporting governments in achieving universal health coverage by improving the reach of products across the income pyramid.<br><br>Companies should carefully determine ability to pay, taking into account socioeconomic factors which may determine different payers' abilities.<br><br>Companies can choose to use a mix of strategies to maximise reach of their access approach: intra-country segmentation, licensing and donations.<br><br>Successful strategies should be evidenced by an increase in patient numbers both to date and projected into the future. |
| PPL1 | E.I.1 | **Patent filing & enforcement**<br>The company publicly commits to not filing for or enforcing patents related to diseases within the Index scope in least developed countries, low income countries and in a subset of lower-middle income countries and upper-middle income countries. | Retained | 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. |
| PPL2 | E.II.2 | **Patent status disclosure**<br>The company publicly discloses the patent status of its products for diseases relevant to the Index, in countries within the Index scope. | Retained | Transparency is part of the social contract underlying patents. Standardised transparency can support procurement agencies in making important decisions about which products to supply. Transparency should cover all relevant therapeutic areas and product types. |
| PPL3 | E.III.2 | **IP sharing**<br>The company provides evidence of sharing its intellectual capital (e.g., molecule libraries, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g., WIPO Re:Search, Conserved Domains Database (CDD), Open Source Drug Discovery (OSDD), etc.) that develop products for diseases relevant to the Index on terms conducive to access to medicine for countries within the scope of the Index. | Retained | Sharing intellectual property on terms conducive to access can accelerate R&D to make new products available to populations in need in low- and middle-income countries. Sharing more valuable assets, such as those more likely to accelerate a product onto the market, can maximise this potential. |

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| **PPL4** | E.II.3 - E.III.3 | **Licensing: Access-oriented terms**<br>The company agrees access-oriented, transparent non-exclusive voluntary licences which include clauses that facilitate affordability and supply of quality products. | **Retained** | Access-oriented terms provide generic medicine manufacturers with additional flexibility (e.g., in the manufacturing or distribution processes) which in turn supports them in maximising affordability and supply. |
| **PPL5** | E.III.4 | **Licensing: Geographic scope**<br>The company includes a broad range of countries within the geographic scope of its licences, including middle-income countries outside of sub-Saharan Africa with high burdens of disease | **Retained** | The more countries that are included in an agreed licence the more potential impact the licence will have on public health. Middle-income countries are often left out of the terms of voluntary licences. To have the biggest impact on access to medicine and public health, voluntary licences should include populations where the need is greater. |
| **PQ1** | D.III.7 | **Ensuring continuous supply**<br>The company has mechanisms in place to improve supply chain efficiency, making efforts to understand product distribution and demand behaviour in countries in the scope of the Index beyond first product hand-off, and takes informed action to ensure uninterrupted supply and to make products available in sufficient quantities in a timely manner:<br>(a) The company manages a buffer stock of relevant products and works with several API suppliers to prevent shortages.<br>(b) Information systems: the company engages with governmental agencies and other relevant stakeholders to inform on issues that may affect the supply chain, such as API shortages and demand forecasting.<br>(c) The company works in partnerships to address supply challenges across multiple medications. | **Modified**<br>This indicator has been made to better capture actions taken by companies to ensure uninterrupted supply. | Ensuring continuous supply and preventing the risk of stock-out is essential for patients to access medicines when they need it and of the right quality. Two aspects are measured here: demand planning and ensuring uninterrupted supply. |
| **PQ2** | F.II.2 | **Reporting falsified and substandard medicines**<br>The company has a policy for reporting cases of confirmed cases of substandard and falsified (SF) medicines in countries within the scope of the Index to relevant stakeholders (i.e., to national regulatory authorities and WHO Rapid Alert*) in a timely manner**, which prioritises the minimisation of harm to public health.<br><br>*Reporting to local regulatory authorities should take place regardless of whether local regulations require it. Reporting to WHO Rapid Alert is encouraged in all cases, and particularly where local regulatory systems are weak/compromised.<br>**The company provides evidence of a policy or approach to report confirmed cases of SF medicines as soon as possible and within ten working days to WHO Rapid Alert and local regulatory authorities, when visual inspection (e.g., confirmation of mislabeling, confirmation of fake packaging) is sufficient to establish that the product packaging is falsified. In cases where laboratory analysis is required for confirmation of substandard or falsified medicines, the policy should require reporting of cases of SF medicines as soon as possible and within ten working days, once this confirmation has taken place, to WHO Rapid Alert and/or local regulatory authorities.<br><br>Definitions:*<br>"Substandard: Also called 'out of specification', these are authorised medical products that fail to meet either their quality standards or specifications, or both.<br>Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source."<br>*https://www.who.int/medicines/regulation/ssffc/definitions/en/ | **Modified**<br>The Index has clarified what a confirmed case of SF medicines is (i.e, if confirmation can take place by visual inspection) and made slight adjustments to the relevant timelines. | Reporting confirmed cases of substandard and falsified medicines in a timely manner to the relevant authority is important from a public health point of view, allowing withdrawal from the market quickly. Substandard and falsified medicines cause harm to people, and death. Pharmaceutical companies have a responsibility to mitigate the risk of harm by sharing information with health authorities rapidly. |

| 2021 Indicator code | Previous indicator(s) | 2021 Indicator | Change since 2018 (new/ retained/ modified) | Indicator rationale |
|---|---|---|---|---|
| PCB1 | F.III.1 | **Capacity building in manufacturing**<br>The company undertakes manufacturing capacity building initiatives with local manufacturers aimed at achieving international Good Manufacturing Practice (GMP). These initiatives meet good practice standards* in countries within the scope of the Index.<br><br>*Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated manufacturers, or works with external parties; guided by clear, measurable goals or objectives; measures outcomes; has long term aims/aims for sustainability | **Retained** | Companies have a role in supporting local manufacture outside of their own plants, contributing to the quality manufacture of other products locally. Local manufacturing can bring medicines more quickly to low- and middle-income country markets and simplify supply chains. |
| PCB2 | F.III.3 | **Capacity building in supply chain management**<br>The company undertakes supply chain capacity building initiatives in countries within the scope of the Index in partnership with local stakeholders (e.g., ministries of health and public procurement, logistics and distribution agencies) that meet good practice standards* with the aim of improving the affordability, accessibility and quality of products, including products outside of its own portfolio.<br><br>*Addresses local needs, priorities and/or skills gaps; is carried out in partnership with relevant stakeholders; is guided by clear, measurable goals or objectives; measures outcomes; has long term aims/aims for sustainability | **Retained** | An inefficient supply chain can significantly impact access to medicine. It can increase the risk of low quality, counterfeit medicines and stockouts. Companies have a role in supporting strong, resilient supply chains which also benefit products beyond their own portfolios. |
| PCB3 | F.III.5 | **Health system strengthening**<br>The company undertakes health system strengthening initiatives in partnership with local stakeholders (where there is no conflict of interest) that meet good practice standards* in countries within the scope of the Index. Such initiatives should work in a coordinated way with other parties, complementing the local health system, with outcomes clearly monitored.<br><br>*Addresses local needs, priorities and/or skills gaps; is carried out in partnership with relevant stakeholders; has good governance structures in place; has processes in place to mitigate or prevent conflict of interest; is guided by clear, measurable goals or objectives; measures outcomes; publicly discloses outcomes; has long term aims/achieves integration within the system | **Modified**<br>The Index newly looks for greater coordination and integration into local systems, and stakeholders now expect the measurement of outcomes as a basic requirement. | 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. |
| PBM1 | A.IV.1 | **Inclusive business models**<br>The company develops and implements scalable inclusive business models that aim to meet the access needs of populations at the base of the income pyramid* and/or vulnerable populations** in countries within the Index scope, with a long-term horizon.<br><br>*The base of the income pyramid, also referred to sometimes as the working poor, designates the four billion people living on an average of USD 1-5 per day.<br>**Vulnerable populations can include, but are not limited to, children, girls and women, men who have sex with men, people living with HIV, people living with mental health conditions, etc. | The Index newly covers business models targeting vulnerable populations, alongside models targeting the base of the income pyramid. Pilots will still be assessed, these should be scalable, with successfully scaled projects being the highest standard. | Inclusive business models that aim to identify access constraints and unlock market inefficiencies in LMICs can create opportunities for business and populations at the base of the income pyramid* and/or vulnerable populations**. These models should have a long-term horizon and ultimately be adopted within the national health system. There is also value in targeting vulnerable populations who might not receive adequate attention from existing health systems. |

# Appendices

## APPENDIX I CONTRIBUTORS TO THIS REPORT

Throughout the Methodology Review, many contributors have supported the Index Research Team. Strategic guidance was provided by the Expert Review Committee (ERC), a panel of independent experts from the WHO, governments, the industry, NGOs, academia and investors, among others. Recommendations on specific topics of the Index were provided by a wide range of specialists in different aspects of access to medicine. Other experts from a variety of organisations (academic, industry, non-governmental, multilateral, investors) supported the development of the Methodology for the 2021 Access to Medicine Index with multiple viewpoints. The Access to Medicine Foundation also engaged with all 20 companies evaluated in the 2018 Index, and companies' staff from across their organisations provided feedback. We gratefully acknowledge all contributions. Of the non-industry experts engaged with, the following individuals agreed for their names to be publicly acknowledged:

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| Esteban Burrone | Medicines Patent Pool |
| Courtney Carson | Women Deliver |
| Nick Chapman | Policy Cures Research |
| Tiantian Chen | University of Cambridge (PhD candidate) |
| Guilherme Cintra | International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) |
| Mark Clark | BIApharma LLP |
| Sarah de Tournemire | Population Council |
| Michael Deats | WHO |
| Jennifer Dent | BIO Ventures for Global Health |
| Sammer Elsayed | Consultant, WHO |
| Patrick Flochel | Ernst & Young Ltd |
| Michele Forzley | Forzley & Associates |
| Rachel Fowler | Women Deliver |
| Alexandra Fullem | Consultant, PDP Funders Group |
| Pat Garcia-Gonzalez | The Max Foundation |
| Sarah Hawkes | UCL Centre for Gender and Global Health |
| Suzanne Hill | WHO |
| Mostafa Hunter | Senior Consultant, UNDP |
| Hitesh Hurkchand | UNICEF |
| George Jagoe | Medicines for Malaria Venture (MMV) |
| Warren Kaplan | Boston University School of Public Health |
| Christabel Khaemba | Ministry of Health, Kenya |
| Jillian Kohler | University of Toronto, WHO Collaborating Centre for Governance, Transparency and Accountability in the Pharmaceutical Sector |
| Niranjan Konduri | Management Sciences for Health |
| Tiphaine Lagarde | NCD Alliance |
| Richard Laing | Boston University School of Public Health |
| Kimberley Lewis | Hermes Investment Management |
| Joel Lexchin | York University |
| Amina Maillard | Medicines Patent Pool |
| Michael Makanga | European and Developing Countries Clinical Trials Partnership (EDCTP) |
| Rohit Malpani | Independent consultant |
| Donna Meyer | Interfaith Center on Corporate Responsibility (ICCR) |

| | |
|---|---|
| Meredith Miller | Interfaith Center on Corporate Responsibility (ICCR) |
| Suerie Moon | The Graduate Institute |
| Meyris Montalvo | Women Deliver |
| Paul Newton | Oxford University |
| Tom Nyirenda | European and Developing Countries Clinical Trials Partnership (EDCTP) |
| Spencer Ochieng | Medsource Group |
| Kwaku Ohene-Frempong | Sickle Cell Foundation of Ghana |
| Susan Papp | Women Deliver |
| Anban Pillay | South African National Department of Health |
| Raffaella Ravinetto | Institute of Tropical Medicine Antwerp |
| Nina Renshaw | NCD Alliance |
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| Joseph Saba | Axios International |
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| Fatima Suleman | University of KwaZulu-Natal |
| Ellen 't Hoen | Medicines Law & Policy |
| Sharyn Tenn | International Partnership for Microbicides (IPM) |
| Robert Terry | The Special Programme for Research and Training in Tropical Diseases (TDR) |
| Sora Utzinger | Aviva Investors |
| Lander van Ommen | The Embassy of the Kingdom of the Netherlands in Burundi |
| Willem Verhoofstad | MedAccess |
| Taryn Vian | University of San Francisco |
| Veronika Wirtz | Boston University School of Public Health |
| Gavin Yamey | Duke Global Health Institute |
| Shalini Jayasekar Zurn | Union for International Cancer Control (UICC) |

In Memoriam: Dilip Shah (1941-2019), valued member of the Foundation's Expert Review Committee, and leading advocate of equitable access to medicine.

Acknowledgment in this report is not intended to imply endorsement of the Access to Medicine Index, its final methodology, the analysis or the results. Final decisions regarding the content of the Technical Areas and indicators are ultimately made by the Access to Medicine Foundation. Contributors engaged in a personal capacity, and their views may not necessarily reflect the views of all members of the stakeholder groups or the organisations they represent.

## APPENDIX IIA DISEASES IN SCOPE FOR THE 2021 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 2021 Index has expanded from 77 to 82 diseases, conditions and pathogens. DALY burden and mortality data was collected from the Institute for Health Metrics and Evaluation's 2017 Global Burden of Disease study (GBD 2017) and are presented as totals for countries in scope and disaggregated by sex where possible. Incidence data for cancer types was collected from GLOBOCAN 2018.

**TABLE 3. Diseases, conditions and pathogens in scope of the 2021 Access to Medicine Index**

| **NON-COMMUNICABLE DISEASES** (17) | **Total DALYs (Countries in scope)** | **% DALYs (female)** | **% DALYs (male)** |
|---|---|---|---|
| Alzheimer's disease | 16,877,547 | 60 | 40 |
| Anxiety disorders | 19,310,005 | 61 | 39 |
| Asthma | 19,115,654 | 50 | 50 |
| Bipolar affective disorder | 6,638,357 | 51 | 49 |
| Cancer* | DALY not applicable | N/A | N/A |
| Chronic obstructive pulmonary disease (COPD) | 65,609,411 | 47 | 53 |
| Diabetes mellitus | 51,453,359 | 49 | 51 |
| Endometriosis | 2,944,175 | 100 | 0 |
| Epilepsy | 12,487,825 | 46 | 54 |
| Hypertensive heart disease | 12,849,438 | 52 | 48 |
| Ischaemic heart disease | 125,559,544 | 38 | 62 |
| Kidney diseases | 28,817,082 | 47 | 53 |
| Migraine | 34,701,299 | 62 | 38 |
| Schizophrenia | 9,560,269 | 48 | 52 |
| Sickle cell disease | 2,980,127 | 48 | 52 |
| Stroke | 105,422,483 | 44 | 56 |
| Unipolar depressive disorders | 31,871,524 | 60 | 40 |

| **CANCER TYPES IN SCOPE** (18)* | **Total incidence (countries in scope)** | **% incidence (female)** | **% incidence (male)** |
|---|---|---|---|
| Bladder | 186,571 | 24 | 76 |
| Brain, nervous system | 177,529 | 45 | 55 |
| Breast | 1,078,400 | 100 | 0 |
| Cervical | 456,235 | 100 | 0 |
| Colorectal | 873,405 | 43 | 57 |
| Gallbladder | 128,360 | 58 | 42 |
| Head and neck | 585,568 | 25 | 75 |
| Kaposi sarcoma | 36,091 | 34 | 66 |
| Leukaemia | 243,713 | 43 | 57 |
| Liver | 629,658 | 28 | 72 |
| Lung | 1,117,600 | 33 | 67 |
| Non-Hodgkin lymphoma | 245,838 | 43 | 57 |
| Oesophageal | 459,664 | 32 | 68 |
| Ovarian | 172,934 | 100 | 0 |
| Prostate | 410,564 | 0 | 100 |
| Stomach | 680,465 | 33 | 67 |
| Thyroid | 321,687 | 76 | 24 |
| Uterine | 158,893 | 100 | 0 |

| **COMMUNICABLE DISEASES** (23 + 12 priority pathogens**) | **Total DALYs (Countries in scope)** | **% DALYs (female)** | **% DALYs (male)** |
|---|---|---|---|
| Arenaviral haemorrhagic fevers (Lassa fever) | DALY not available in GBD 2017 | N/A | N/A |
| Bunyaviral diseases | DALY not available in GBD 2017 | | 100 |
| Coronaviral diseases | DALY not available in GBD 2017 | N/A | N/A |

| | | | |
|---|---|---|---|
| Disease X | N/A | N/A | N/A |
| Diarrhoeal diseases | 93,131,606 | 48 | 52 |
| Diphtheria | 298,033 | 48 | 52 |
| Emergent non-polio enteroviruses | DALY not available in GBD 2017 | N/A | N/A |
| Filoviral diseases*** | 503 | 37 | 63 |
| Henipaviral diseases | DALY not available in GBD 2017 | N/A | N/A |
| HIV/AIDS | 52,008,191 | 49 | 51 |
| Leptospirosis | DALY not available in GBD 2017 | N/A | N/A |
| Lower respiratory infections | 97,591,475 | 47 | 53 |
| Malaria | 45,001,032 | 47 | 53 |
| Measles | 8,119,059 | 50 | 50 |
| Meningitis | 19,903,199 | 46 | 54 |
| Other prioritised antibacterial-resistant infections | N/A | N/A | N/A |
| Pertussis | 7,917,655 | 56 | 44 |
| Rheumatic fever | DALY not available in GBD 2017 | N/A | N/A |
| Sexually transmitted infections (STIs) | 11,058,329 | 41 | 59 |
| Tetanus | 2,442,298 | 43 | 57 |
| Tuberculosis | 43,981,326 | 38 | 62 |
| Viral hepatitis (B and C) | 22,317,027 | 30 | 70 |
| Yellow fever | 310,869 | 29 | 71 |
| Zika | 1,700 | 48 | 52 |

| **NEGLECTED TROPICAL DISEASES** (20) | **Total DALYs (Countries in scope)** | **% DALYs (female)** | **% DALYs (male)** |
|---|---|---|---|
| Buruli ulcer | DALY not available in GBD 2017 | N/A | N/A |
| Chagas disease | 184,507 | 41 | 59 |
| Dengue and chikungunya† | 2,880,343 | 47 | 53 |
| Dracunculiasis | 1 | 55 | 45 |
| Echinococcosis | 79,542 | 52 | 48 |
| Foodborne trematodiases | 1,650,536 | 40 | 60 |
| Human African trypanosomiasis | 78,985 | 47 | 53 |
| Leishmaniasis | 768,969 | 43 | 57 |
| Leprosy | 31,366 | 30 | 70 |
| Lymphatic filariasis | 1,361,196 | 19 | 81 |
| Mycetoma, chromoblastomycosis and other deep mycoses | DALY not available in GBD 2017 | N/A | N/A |
| Onchocerciasis | 1,342,282 | 46 | 54 |
| Rabies | 632,677 | 30 | 70 |
| Scabies and other ectoparasites | 4,228,505 | 50 | 50 |
| Schistosomiasis | 1,409,670 | 52 | 48 |
| Snakebite envenoming | DALY not available in GBD 2017 | N/A | N/A |
| Soil-transmitted helminthiasis | 1,878,838 | 53 | 47 |
| Taeniasis/cysticercosis‡ | 1,394,465 | 58 | 42 |
| Trachoma | 299,003 | 60 | 40 |
| Yaws | DALY not available in GBD 2017 | N/A | N/A |

| **MATERNAL AND NEONATAL HEALTH CONDITIONS** (10) | **Total mortality (countries in scope)** |
|---|---|
| Birth asphyxia and birth trauma | 520,507 |
| Contraceptive methods | Mortality not applicable |
| Hypertensive disorders of pregnancy | 28,748 |
| Maternal abortion and miscarriage | 16,859 |
| Maternal haemorrhage | 37,928 |
| Maternal sepsis | 20,782 |
| Neonatal sepsis and infections | 196,759 |
| Obstructed labour | 12,779 |
| Other neonatal conditions | 336,664 |
| Preterm birth complications | 612,925 |

* The 18 cancer types are collectively counted as one non-communicable disease.

** Collectively, these will be referred to as communicable diseases in the 2021 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.

## APPENDIX IIB CANCERS IN SCOPE FOR THE 2021 ACCESS TO MEDICINE INDEX

Cancer remains in scope for the 2021 Index, and the cancer types included are in scope for all Technical Areas. The 17 cancer types in scope for the 2018 Index have been retained and supplemented with new cancer types based on high incidence both globally and in countries in the scope of the Index, using data from GLOBOCAN 2018.

There are 18 cancer types in scope for the 2021 Index, including 15 which were originally in scope for the R&D Technical Area of the 2018 Index based on high incidence. Head and neck cancers have been combined as a single cancer type for this Index.

Thyroid cancer is newly in scope as the cancer type with the tenth highest incidence globally and in countries in scope. Ovarian and uterine cancer were added as they have comparably higher incidences compared to other sex-linked cancer types.

As in the methodology for the 2018 Index, products for the management of pain and supportive treatments (for e.g., antiemetics) will not be included.

**TABLE 4. Cancer types in scope and basis for inclusion**

Three main criteria were used to include cancer types in the previous Index for the R&D Technical Area. These cancer types were retained and supplemented with additional cancer types that met an updated set of criteria, or which had a comparably high incidence amongst sex-linked cancer types. The resulting 18 cancer types are in scope for all Technical Areas in 2021.

| Cancer types in scope (18) | Ten cancer types with highest global incidence rates | Ten cancer types with highest incidence in countries in scope | Five cancer types where countries in scope account for highest % of global incidence | Included in 2018 Access to Medicine Index | Included following sex-linked cancer analysis |
|---|---|---|---|---|---|
| Bladder | | | | ● | |
| Brain, nervous system | | | | ● | |
| Breast | 2,088,849 | 1,078,400 | | ● | |
| Cervical | 569,847 | 456,235 | 80% | ● | |
| Colorectal | 1,849,518 | 873,405 | | ● | |
| Gallbladder | | | | ● | |
| Head and neck* | 887,659 | 585,568 | 87%** | ● | |
| Kaposi sarcoma | | | 86% | ● | |
| Leukaemia | | | | ● | |
| Liver | 841,080 | 629,658 | 75% | ● | |
| Lung | 2,093,876 | 1,117,600 | | ● | |
| Non-Hodgkin lymphoma | | | | ● | |
| Oesophageal | 572,034 | 459,664 | 80% | ● | |
| Ovarian | | | | | ● |
| Prostate | 1,276,106 | 410,564 | | ● | |
| Stomach | 1,033,701 | 680,465 | | ● | |
| Thyroid | 567,233 | 321,687 | | | |
| Uterine | | | | | ● |

* Includes all head and neck cancers defined by GLOBOCAN 2018.

** This percentage reflects the proportion of nasopharynx cancer cases in countries in scope.

## APPENDIX III THE GOOD PRACTICE STANDARDS FRAMEWORK FOR CAPACITY BUILDING

This framework has been developed to convey stakeholders' expectations for good practice in capacity building. The framework is tailored for four subthemes of capacity building included in the Index and is comprised of six standards. All company initiatives are measured against this framework.

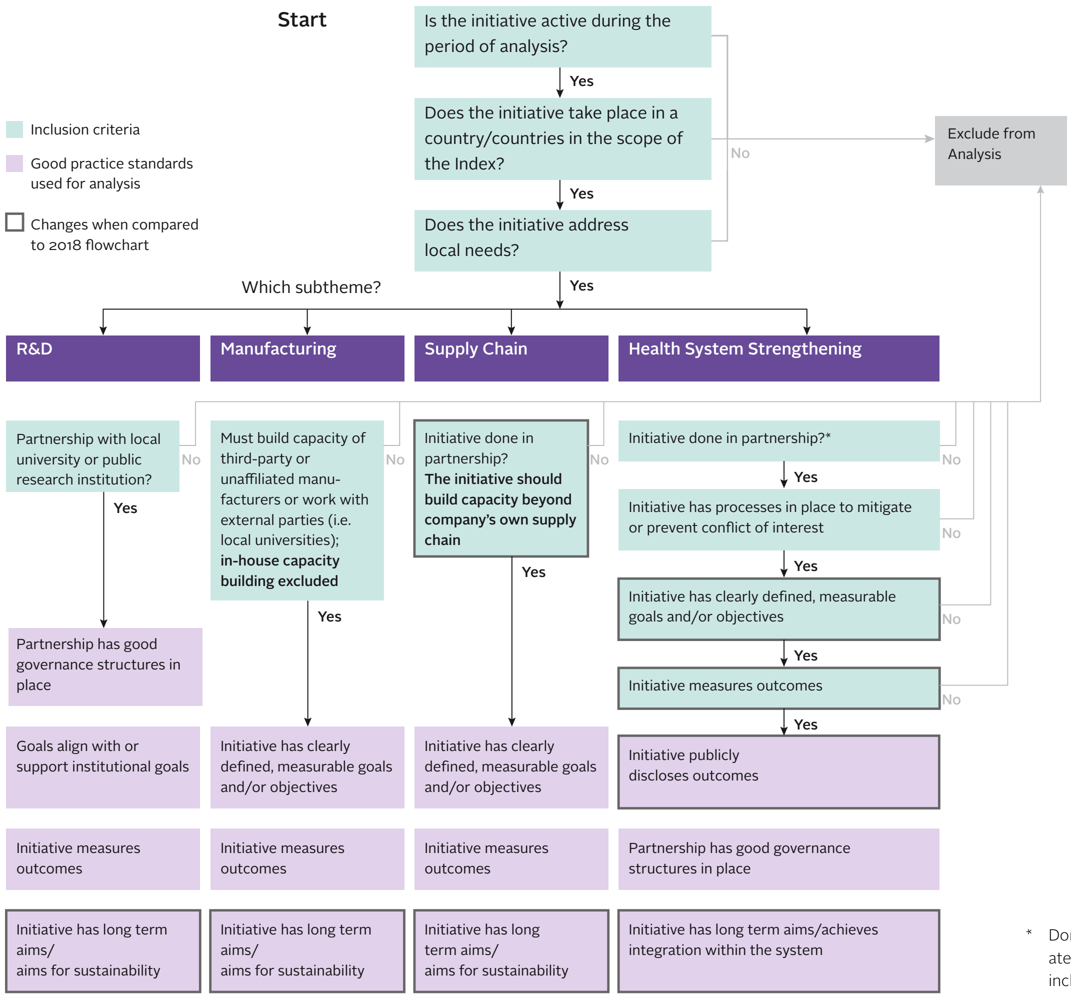
Good practice standards for initiatives:

1. Addresses local needs, priorities and/or skills gaps
2. Carried out in partnership with relevant stakeholders
3. Has good governance structures in place (including for mitigating or preventing conflicts of interest)
4. Guided by clear, measurable goals or objectives
5. Includes regular monitoring, evaluation and public sharing of approaches, progress and learnings
6. Has long term aims or achieves integration within the health system

There are three basic 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 a clearly defined local need. Initiatives in all subthemes are expected to be done in partnership, save in manufacturing where there may be a direct engagement with contracted third-party manufacturers. Health system strengthening initiatives must also have processes in place to prevent conflict of interest; have clearly defined, measurable goals and/or objectives; and measure outcomes in order to be eligible. Initiatives are excluded if they do not meet all inclusion criteria, with excluded initiatives not being considered for scoring or further analysis. Initiatives that meet all inclusion criteria are assessed against the remaining good practice standards.

**TABLE 5. Capacity building initiative flowchart**

The chart provides a guide to the criteria by which submitted company initiatives are included for analysis in the Index and the criteria by which they are analysed. The chart is broken down by subtheme/area of capacity building. The expectations from stakeholders vary slightly for each area based on the nature of the activities which typically fall within that area. This chart was developed as a tool for companies to guide them in selection of their five initiatives per area during the data collection process.




* Done with appropriate, relevant partners, including local partners

## APPENDIX IV R&D PRIORITIES

**TABLE 6. Priority diseases, conditions and pathogens**

| ATMI Disease | Specific disease target | Medicines | Vaccines (Preventive) | 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 R&D Blueprint | WHO Initiative for Vaccine Research | WHO Priority Pathogen List |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Arenaviral haemorrhagic fevers (Lassa fever) | | ● | ● | ● | ● | | | | | | ● | ● | | |
| Bunyaviral diseases | Crimean-Congo haemorrhagic fever | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Rift Valley fever | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Severe fever with thrombocytopenia syndrome (SFTS) | ● | ● | ● | ● | | ● | | | | ● | | | |
| | Other bunyaviral diseases | ● | ● | ● | ● | | ● | | | | ● | | | |
| Buruli ulcer | | ● | ● | | ● | | | | ● | | | | | |
| Cancer | HPV-related cervical cancer | ● | ● | ● | ● | | | | | ● | | | | |
| Chikungunya | | ● | ● | ● | ● | | ● | | | | ● | | | |
| Chagas disease | | ● | ● | ● | ● | | ● | | ● | | | | | |
| Contraceptive methods | | ● | | | | | | ● | | ● | | | | |
| Coronaviral diseases | Middle East respiratory syndrome coronavirus (MERS-CoV) | | ● | ● | ● | | ● | | | | ● | ● | | |
| | Severe acute respiratory syndrome (SARS) | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Other highly pathogenic coronaviral diseases | ● | ● | ● | ● | | | | | | ● | | | |
| Dengue and Chikungunya | Chikungunya | ● | ● | ● | ● | | ● | | | | ● | | | |
| | Dengue | ● | ● | ● | ● | | ● | | ● | | | | ● | |
| Diarrhoeal diseases | 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) | | ● | ● | ● | ● | | | | | | ● | | | |
| Filoviral diseases | Ebola | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Marburg | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Other filoviral diseases | ● | ● | ● | ● | | ● | | | | ● | | | |
| Henipaviral diseases | Nipah | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| | Other henipaviral diseases | ● | ● | ● | ● | | ● | | | | ● | ● | | |
| HIV/AIDS | | ● | ● | ● | ● | ● | | | ● | | | | ● | |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Human African trypanosomiasis | | ● | ● | ● | ● | | ● | | ■ | | | | | |
| Hypertensive disorders of pregnancy | Pre-eclampsia | ◉ | | | ● | | | | | ■ | | | | |
| Leishmaniasis | | ● | ● | ● | ● | | | | ■ | | | | | |
| Leprosy | | ● | ● | ● | ● | | | | ■ | | | | | |
| Leptospirosis | | | | | ◉ | | | | ■ | | | | | |
| Lower respiratory infections | *S. pneumoniae* | | ◉ | | ● | | | | ■ | | | | | |
| | Influenza | | ● | | | | | | | | | | ■ | |
| | Respiratory syncytial virus (RSV) | | ◉ | | | | | | | | | | ■ | |
| Lymphatic filariasis | | ● | | | ● | | ● | | ■ | | | | | |
| Malaria | *P. falciparum* | ● | ● | ● | ● | | ● | | ■ | | | | ■ | |
| | *P. vivax* | ● | ● | ● | ● | | ● | | ■ | | | | ■ | |
| Maternal haemorrhage | Postpartum haemorrhage | ● | | | | | | ◉ | | ■ | | | | |
| Meningitis | *N. meningitidis* | | ◉ | | ● | | | | ■ | | | | ■ | |
| | Cryptococcal meningitis | ● | | ● | | | | | ■ | | | | | |
| Mycetoma, chromoblastomycosis and other deep mycoses | Mycetoma | ● | | | ● | | | | ■ | | | | | |
| Neonatal sepsis and infections | Group B *Streptococcus* | | ◉ | | | | | | | | | | ■ | |
| Onchocerciasis | | ● | ● | | ● | | ● | | ■ | | | | | |
| Rheumatic fever | | | ● | | | | | | ■ | | | | ■ | |
| Schistosomiasis | | ● | ● | ● | ● | | ● | | ■ | | | | | |
| Sexually transmitted infections (STIs) | Chlamydia | | ● | ● | ● | | | | | ■ | | | | |
| | Gonorrhoea | ◉ | ● | ● | ● | | | | | ■ | | | | |
| | HSV-2 | ● | ● | ● | ● | | | | | ■ | | | | |
| | HTLV-1 | ● | ● | ● | ● | | | | | ■ | | | | |
| | Syphilis | ◉ | ● | ● | | | | | | ■ | | | | |
| | Other STIs | ◉ | ◉ | ◉ | ◉ | | | | | ■ | | | | |
| Soil transmitted helminthiasis | Hookworm diseases | ● | ● | | | | | | ■ | | | | | |
| | Strongyloidiasis | ● | ● | | ● | | | | ■ | | | | | |
| | Trichuriasis | ● | | | | | | | ■ | | | | | |
| | Ascariasis | ● | | | | | | | ■ | | | | | |
| Snakebite envenoming | | ◉ | | | ◉ | | | | ■ | | | | | |
| Taeniasis/cysticercosis | | ● | | | ● | | ● | | ■ | | | | | |
| Trachoma | | | ● | | ● | | | | ■ | | | | | |
| Tuberculosis | | ● | ● | ● | ● | | | | ■ | | | | ■ | |
| Viral hepatitis (B and C) | Hepatitis B | ◉ | | ◉ | ● | | | | ■ | | | | | |
| | Hepatitis C | ◉ | ◉ | | ● | | | | ■ | | | | | |
| Zika | | ● | ● | ● | ● | | ● | | | | ■ | ■ | ■ | |
| Disease X* | | | | | | | | | | | | ■ | | |

Green text = priority R&D product gap newly in scope for the 2020 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.

TABLE 7 **Priority pathogens**

12 antibacterial-resistant pathogens remain in scope for the 2020 Access to Medicine Index. Pathogens on the WHO priority pathogen list are deemed by WHO as priority R&D targets for new and effective antibacterials active against the pathogens themselves and the diseases they cause. This WHO priority pathogen list does not define specific products needed.

| **Other prioritised antibacterial-resistant infections** | **Policy Cures Research G-FINDER neglected diseases** | **Policy Cures Research G-FINDER sexual & reproductive health** | **Policy Cures Research G-FINDER emerging infectious diseases** | **WHO R&D Blueprint** | **WHO Initiative for Vaccine Research gaps** | **WHO Priority Pathogen List** |
|---|---|---|---|---|---|---|
| *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) | ● | | | | | ● |

## APPENDIX V ENSURING THE INDEX METHODOLOGY IS SENSITIVE TO GENDER AND SEX

Ensuring effective access to medicine and other health products requires an approach that recognises and addresses barriers to access beyond affordability, supply and health system strength. Such barriers may emerge due to differences in socioeconomic status, to the prevalence of diseases in certain geographic locations and to the gender and the sex of patients. For cisgender women and girls, for example, the unmet need for access to contraceptives in low- and middle-income countries (LMICs) has been measured to be as high as 58%. Rationales for non-use often include male partners' preferences, in addition to fear of side effects and other health concerns.[1]

Gender and sex also play an important role in how diseases present and how burden is distributed. Females in countries included in the scope of the Index carry ~60% of the DALY burden for anxiety and depressive disorders while males carry ~60% of the burden for stroke and heart disease.[2] However, men are less likely than women to disclose mental health problems to primary care providers, leading to under-reporting and undertreatment.[3] Certain vulnerable populations including transgender women, female sex workers and cisgender men who have sex with men have higher rates of HIV infections and experience considerable stigma.[4,5]

To ensure that the additional challenges that gender and sex can present to access was considered in the development of the next Index, the Foundation engaged with sex and gender experts from NGOs, academia and other organisations. These experts emphasised the need to approach the methodology in a manner that was neither gender-blind (e.g., aggregating burden without considering disproportionate gender-based burden or discrimination) nor gender-unequal (i.e., only considering one gender's unique needs).

The consensus view on the role of the pharmaceutical industry in addressing these issues was that adequate representation and consideration of sex and gender in clinical trial cohorts and product development were key. Such consideration might lead to: (a) greater representation of female, transgender and vulnerable populations in clinical trials, and thereby to more suitable products for those populations; (b) greater focus on the safety and efficacy of medicines in pregnant or lactating women; (c) the targeting during product development of sex- or gender-linked comorbidities related to the disease/condition; and (d) information on the presence or absence of drug-drug interactions with contraceptives.

Reflecting on these points, the Foundation examined sex-disaggregated DALY burden data to consider the inclusion of additional diseases or conditions. Most diseases or conditions for which the burden was disproportionately high (>70%) for males or females were already included in the disease scope (particularly for maternal health conditions) or not suitable for specific pharmaceutical intervention (e.g., road injuries, sexual violence, etc.). One female-linked disease, endometriosis, was newly included based on a comparably high DALY burden (2,955,462) compared to other sex-linked diseases such as polycystic ovarian syndrome (354,140) and benign prostatic hyperplasia (1,545,083) in countries in scope of the Index.[2]

Assessing the incidence globally and in countries in scope of the Index of several sex-linked cancer types led to the inclusion of uterine and ovarian cancer, which possessed much higher incidences than other sex-linked cancers including testicular, vulval, penile and vaginal cancers.[6] Breast, cervical and prostate cancer types were also included, on the basis of other criteria (see page 44). Further, the inclusion of vulnerable populations in clinical trials will be considered for all R&D projects examined by the Index in 2020.

Social and cultural stigma remains a pressing barrier to access, which is best addressed by governments and local organisations familiar with cultural and social norms. Pharmaceutical companies can play a role, in partnership, to support the development and integration of inclusive business models set up with long-term views, which take into account the vulnerability of different patient groups. The 2020 Index will take into account how companies are addressing these barriers through an evaluation of inclusive business models that target populations at the base of the pyramid and/or vulnerable populations such as cisgender women and girls in some settings, men who have sex with men, transgender people and other members of the LGBTQ community.

Finally, the Foundation also compared the Index country scope to the Gender Inequality Index, which evaluates gender-based inequalities per country, confirming that countries with high gender-based inequalities are already included.[7]

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## APPENDIX VI DEFINITIONS

**Access plans**
*Working definition, used for analysis*
Plans to ensure that public health needs are taken into consideration during R&D. Access plans can be developed in-house or in collaboration and include commitments and strategies as well as more concrete access provisions: agreed-upon measures typically developed in partnership to enforce accountability. These plans facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., registration commitments, equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified territories, waiving patent rights, royalty-free provisions and applying for WHO prequalification).

**Access initiatives**
*Working definition, used for analysis*
An access initiative - within the context of the Access to Medicine Index - is an initiative a company is involved in which seeks to address access to medicine constraints in low- and middle-income countries. This may or may not be in partnership with others, and may or may not involve improving access to specific pharmaceutical products. Where access initiatives relate to products, it may be either an equitable pricing strategy, a non-exclusive voluntary licensing approach or a structured donation programme. Examples of access initiatives which do not involve products include, for e.g., awareness-raising activities in health system strengthening. Where products are involved in an access initiative, this will be clearly identified within the text of the Access to Medicine Index report.

**Access-to-medicine strategy**
*Working definition, used for analysis*
A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (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 to the whole pipeline and portfolio.

Ad hoc donation programmes
*Working definition, used for analysis*
A gift 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.

**Adaptive product R&D**
*Working definition, used for analysis*
The adaptation of existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products, microbicides or other health products that may address an unmet need in countries in scope, e.g., new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., oral formulations).

**Affordability**
*Working definition, used for analysis*
A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

**Base of the income pyramid**
The base of the income pyramid, also referred to sometimes as the working poor, designates the four billion people living on an average of USD 1-5 per day.

**Compliance controls**
Compliance controls evaluated in the Index are processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company's employees and, if applicable, the third parties the company formally engages with.
These processes include:

- Fraud-specific risk assessment to pro-actively identify vulnerabilities for fraud and actual cases;
- Auditing and review mechanisms conducted by external, independent specialists, applying to third parties in all countries the company is operating;
- A live/continuous monitoring system for compliance, other than financial auditing, to continuously monitor activities to detect discrepancies;
- Country risk-based assessments to identify vulnerabilities for non-compliant or corrupt activities in countries in scope where the company is operating; and
- Processes to ensure third party compliance (including e.g., contractual agreements, training on codes of conduct).

**Budget impact**
*Working definition, used for analysis*
An estimated measure of the cost of treatment with a given therapy for a given number of patients in a specific population.

**Conflict of interest**
A conflict of interest is the conflict that arises when the commercial interests of a company are potentially 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.

**Demographic factors**
*Working definition, used for analysis*
Characteristics of a population such as age, sex, income level, education level, employment, etc.

**Equitable pricing strategy**
*Working definition, used for analysis*
A targeted pricing strategy which aims at improving access to medicine for those in need by taking the abilities to pay of individuals and healthcare systems into account in a manner that is locally appropriate.

**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.

**Falsified medicine**
Medical products that deliberately/fraudulently misrepresent their identity, composition or source. [Definition from WHO, 2017]

**Good governance structures**
*Working definition, used for analysis*
Good governance structures include three components: 1) the structures put in place which establish clear roles, responsibilities and decision making structures; 2) the systems of communications whereby information is regularly conveyed to all concerned; and 3) the transparency and accountability for processes, decisions and outcomes of initiatives.

**Good practice standards**
A set of six standards that encompass good practice in capacity building initiatives. These standards form a framework used for the assessment of company capacity building initiatives. The standards include: working in partnership, having good governance structures in place, addressing local needs, having clear goals and objectives, measuring outcomes and having long-term aims or achieving integration in the system.

**Healthcare practitioner-administered products**
*Working definition, used for analysis*
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 product R&D**
*Working definition, used for analysis*
The development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventive vaccines, diagnostics, vector control products and microbicides which have not previously been approved for use.

**National reimbursement authority**
*Working definition, used for analysis*
Governmental bodies with the authority to control, approve and determine pricing and reimbursement of medicinal products in a country.

**Non-exclusive voluntary licences**
*Working definition, used for analysis*
Non-exclusive voluntary licences are defined as the 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.

**Non-pricing initiatives**
*Working definition, used for analysis*
Actions taken to increase the number of patients reached through access methods other than price. Non-pricing initiatives applied may include, but are not limited to, non-exclusive voluntary licensing, donations partnering with governments, patient assistance programmes and non-assert declarations.

**Outcomes**
*Working definition, used for analysis*
Outcomes are the results achieved by a company's access-related activities. These can include short-term (e.g., an increased proportion of people with more knowledge on diseases, symptoms or treatments) and/or medium- to long-term outcomes (e.g., patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; availability of medicines at outlets). Outcomes can also reflect on the country health system (e.g., number of healthcare professionals trained).

**Patient Assistance Programmes**
*Working definition, used for analysis*
Patient assistance programmes are defined as programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

**Period of analysis**
For the 2020 Index, the time period for which data will be analysed covers company activities which must be ongoing between 1 June 2018 and 31 May 2020, as this is the cycle of the Index. Projects that have ended before 1 June 2018 are not included.

**Post-trial access**
The continued provision of treatment to clinical trial participants who still require an intervention following the close of the clinical trials in which they participated.

**Priority R&D**
*Working definition, used for analysis*
R&D that addresses product gaps that are needed by people living in low- and middle-income countries due to ineffective, maladaptive or non-existent products for certain diseases, conditions and pathogens in the scope of the Index. These product gaps are defined as being those listed in a series of six priority lists developed by WHO and Policy Cures Research, an independent research group.

**Private sector**
*Working definition, used for analysis*
Private sector refers to payer types such as private insurance and patients paying out of pocket.

**Self-administered products**
*Working definition, used for analysis*
Self-administered products are defined as those products which patients can typically take or administer to themselves without needing a skilled healthcare worker for regular usage.  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 authorized medical products that fail to meet either their quality standards or specifications, or both. [Definition from WHO, 2017]

**Supranationally procured products**
*Working definition, used for analysis*
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 and neglected tropical diseases.

**Structured donation programmes**
*Working definition, used for analysis*
A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

**Vulnerable populations**
*Working definition, used for analysis*
Vulnerable populations represent people at greater risk of facing stigma and additional barriers to access due to social, economic or health considerations. These can include, but are not limited to, children, girls and women, men who have sex with men, people living with HIV, etc.

## APPENDIX VII REFERENCES

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