United Nations University
International Institute for Global Health

Corporate accountability in global health governance? A case study of the Access to Medicine Index

Power & Accountability Briefing Paper, October 2024

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BRIEFING PAPER

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Written by Penelope Milsom (UNU-IIGH), Nathan Dumont-Leblond (Université Laval, Quebec City, Canada) and David McCoy (UNU-IIGH).

Executive summary

Across virtually all markets, a relatively small number of trans-national corporations (TNCs) now wield tremendous oligopolistic power. Using this power, these TNCs have also been able to accrue and deploy tremendous social and political influence, making them one of the most powerful groups of actors worldwide. Many voices are now calling for TNCs to be effectively regulated and held accountable.

One approach to strengthening corporate accountability has been the use of corporate 'league tables' or 'rankings'. This involves assessing the policies and practices of TNCs and producing a quantified measure of their performance that is then used to rank them. It is believed that TNCs will improve their policies and practices to achieve higher rankings, thus improving their reputations and making them more desirable to work for, invest in, or do business with. One example of this approach is the Access to Medicine Index (AtMI) which ranks the 20 biggest pharmaceutical TNCs according to how well they contribute to improved access to medicines and other products in low- and middle-income countries (L&MICs).

This briefing paper presents a description and critique of AtMI, including its history, governance, funding, implementation, and impact. Much of it consists of a description and assessment of the AtMI methods, including the 31 indicators used to assess TNC performance. The paper describes how TNCs are given a score between zero and five for each indicator and how these scores are then combined to produce a composite score that is used to produce a ranking of overall performance.

The report discusses the limitations of AtMI including: i) problems with the completeness and reliability of the data that are used; ii) a lack of transparency about how data are converted into scores for each indicator; iii) the low standards against which companies are assessed; and iv) the narrow scope of corporate conduct that is assessed. It also notes the lack of evidence of the Index actually improving access to medicines and other products in L&MICs, and points to how the Index may weaken efforts to regulate pharmaceutical companies and thus paradoxically work against the public interest.

1. Introduction

The growth in the size, profitability and power of trans-national corporations (TNCs) across a wide range of markets and sectors over recent decades has resulted in them being highlighted as important global health actors, both in terms of their ability to influence global governance processes and in shaping global health outcomes through their marketing and supply of goods and commodities (1,2). A growing body of literature on the commercial determinants of health now attributes a high proportion of preventable disease and illness to the behaviours of TNCs (3).

Civil society groups and movements have thus increasingly been calling for stronger regulation of TNC behaviour (4). However, corporate accountability mechanisms adopted in recent decades have tended to focus on promoting voluntary change in corporate behaviour (4). The assessment and measurement of corporate policies and practices according to a selection of indicators and the creation of rankings or league tables is an example of one such mechanism, premised on the idea that TNCs will improve their policies and practices in competing for the most highly ranked positions ("a race to the top") in order to gain reputational capital, and be considered more desirable to work for, invest in, or do business with (5).

The idea of global rankings originated in the financial sector with the construction of credit ratings of firms and states designed to assess the risk of securities issued by companies and governments (5). Rankings have since expanded into other sectors, including global health. One early example is the two-yearly Access to Medicine Index (AtMI) established in 2008 by the Access to Medicine Foundation (AtMF). The AtMI ranks the largest pharmaceutical companies globally according to a set of indicators in areas where companies have "the biggest potential and responsibility" (6) for promoting access to medicines and other products in low- and middle-income countries (LMICs) (7). AtMF reports that the Index improves pharmaceutical company policies and practices by identifying best practices and by tracking progress and highlighting where improvements are needed (7). AtMF claims that the ranking of companies spurs them to "compete and collaborate" to improve access to medicine and has been endorsed by various prominent global health actors (8).

Rankings have been increasingly used and now include the Access to Vaccines Index and the Antimicrobial Resistance Benchmark (both developed by AtMF), the Access to Nutrition Index, the Access to Seeds, and the Responsible Mining Index. Following the wide uptake of the AtMI, AtMF's founder has also established the Index Initiative Foundation as a centre of expertise for developing indices in a range of other sectors to encourage companies to contribute to the United Nations Sustainable Development Goals (SDGs)(4).

Rankings like the AtMI are promoted as valid, credible, and legitimate tools by UN agencies, the World Bank, governments, academics, consultants, and global businesses (4). High-ranking companies also publish the results to build public and political confidence in their willingness to prioritise social, environmental or health objectives. As such, the production and use of ranking tools (and other similar quantitative measures) are now a prominent aspect of global governance, making it important to independently scrutinise them. The aim of this briefing paper was to critically analyse the governance, management and methodology of the AtMI; and the underlying theory of how it promotes socially responsible corporate policies and practices. To undertake this analysis, we reviewed all 8 AtMI Reports published between 2008-2022 and their associated Methodology Reports as well as relevant pages on AtMF's website.

A critical review of the AtMI's governance, funding and methodology (including a review of all indicators and the scoring guide applied to each) was conducted as well as a review of existing evidence for the impact of AtMI on pharmaceutical company performance. As will be evident in subsequent sections of this report, the AtMI methodology is elaborate, intricate, complex and not fully described in detail. The analysis may therefore include some inaccuracies. To help optimise robustness of our assessment, the report has been peer reviewed by four experts who work on access to medicines. We also invited ATMF to comment on the analysis and provide further information and advise on any corrections to our assessment, however this invitation was declined.

Section Two provides a detailed description of the AtMI's governance, funding, methodology and methodological review process before Section Three presents the 2021 Index metrics, scoring system and results. Section Four reviews existing evidence of the AtMI's impact on pharmaceutical companies' policies and practices and offers a critical analysis of the AtMI outlining key identified concerns and limitations.

2. Description of the AtMI's governance and methodology

2.1. History, Funding and Governance of the AtMI

The AtMI was established by the AtMF, an independent non-profit organization registered in the Netherlands that was founded in 2003 by Wim Leereveld, a Dutch entrepreneur with previous experience in the healthcare industry (9). According to its website, AtMF is currently funded by seven donors, all from high income countries: The United Kingdom Foreign, Commonwealth and Development Office, the Dutch Ministry of Foreign Affairs, The Bill & Melinda Gates Foundation, Leona M. and Harry B. Helmsley Charitable Trust, Wellcome Trust, AXA Investment Managers, and Stewart Investors (10). The contribution of each donor is not disclosed. However, according to its annual report, AtMF raised more than 3.7 million EUR in 2022 (11). Expenditure in 2022 was 3.6 million EUR, of which 2.7 million was spent on the salaries of 40 staff employed by AtMF (11).

AtMF is managed and led by a Chief Executive Officer (CEO) who joined AtMF in 2015 having developed and managed an extensive portfolio of private-public partnerships between the pharmaceutical industry and other stakeholders (12). The CEO is supported by a Director of Operations and Research who brings previous experience in marketing and medical affairs at a multinational pharmaceutical company and a Director of Government Engagement & Policy with previous experience working for Canada's Ministry of Health and Long-Term Care (12). A Supervisory Board with advisory powers helps oversee the management and strategic direction of the Foundation. The current Board comprises six non-remunerated individuals who between them hold current or past affiliations with academic institutions, NGOs, private-public partnerships, a governmental agency and WHO (12).

2.2. Index and Ranking Methodology

2.2.1. Companies

The AtMI currently only ranks the 20 largest research-based pharmaceutical companies globally (6) identified as such by their market capitalization and revenue but also the relevance of their product portfolios and pipelines to the diseases and countries included in the Index (7). Generic drug manufacturers were previously included but were removed after 2012 because of difficulties in comparing them with research-based companies (13). However, a new and separate index is currently being created to assess generic and biosimilar medicines companies (14). Inevitably, the twenty companies ranked in each cycle have changed partly due to recent mergers and acquisitions in the sector.

2.2.2. Product types

Eight product types were covered in the 2022 Index (7): medicines, microbiocides (specifically topical microbiocides to prevent HIV), therapeutic and preventative vaccines, diagnostics designed for use in "resource-limited settings", vector control products (including pesticides and biological control compounds against relevant disease-carrying vectors and vaccines targeting animal reservoirs of Index-relevant diseases), contraceptives, and platform technologies (e.g., general diagnostic platforms, adjuvants, immunomodulators and delivery technologies and devices).

2.2.3. Diseases, pathogens and conditions

The Index only covers medicines for a selected number of diseases, pathogens, or conditions that predominantly affect people in LMICs (6). Diseases are selected for inclusion if they: are a neglected tropical disease (NTDs); are included in WHO Global Health Observatory data as a maternal or neonatal health condition; are cancers with high incidence globally or in Index countries; have a high disability adjusted life year (DALY) burden in Index countries; or been identified as an R&D priority in at least one of six key R&D priority lists. These include: Policy Cures Research G-FINDER for neglected disease, emerging infectious diseases and reproductive health areas; WHO R&D Blueprint; WHO Initiative for Vaccine Research; and the WHO priority pathogen list (7).

The number of diseases covered in the Index has increased from 24 in 2008 to 83 in 2022 (6,15), covering 23 communicable diseases, 18 NCDs, 20 NTDs, 10 reproductive maternal and newborn health conditions, and 12 priority pathogens (Annex One) (6,15). Of the 83 diseases, 39 are included on priority lists, the remaining fall into one of the other inclusion categories.

2.2.4 Countries

Countries included in the 2022 Index were selected based on their level of income, level of development and scale and scope of inequality (7). The number of countries included in the AtMI has increased from 88 in 2008 to 108 LMICs in 2022 (6,15). See Annex Two for a list of countries included in the 2022 Index.

2.2.5 Evaluation framework

The evaluation of pharmaceutical company performance is organised around a set of “technical areas” each of which consists of a set of priority themes and indicators (7). Each indicator and technical area are weighted according to its perceived importance in improving access to medicines. Companies are scored according to how well they perform on each indicator. Scores are then combined to produce an overall score out of five for each company.

Over time the analytical framework has become more streamlined with the number of technical areas reduced from eight in 2008 to just three since 2021. The three current technical areas are: governance of access, research and development (R&D) and product delivery. The overall number of indicators has also been reduced from 94 in 2008 (16) to 31 in 2022 (7). Each cycle, indicators are reportedly refined “to tailor a metric more closely to stakeholders’ expectations of company behaviour, or to improve elements such as data capture, comparison of companies or associated analyses”. Some indicators have accordingly been merged or removed entirely (7). Additionally, there have been changes in the weighting of technical areas and corresponding indicators. In 2022 for example, the weighting for Governance of Access was reduced from 20 to 15% and increased for R&D (from 25 to 30%) (7). Annex Three provides an overview of revisions to the analytical framework since 2008.

2.2.6 Data

Most of the data used to construct the Index are obtained directly from companies via a self-completed survey. AtMF reports that “data submitted by companies is verified, cross-checked and clarified” by AtMF researchers using “public sources and supporting documentation provided by the companies” (17). Some data are reportedly sourced from the US Food and Drug Administration, European Medicines Agency and Health Canada (e.g., for information on drug approval and registration), MedsPal (for data on medicines’ patent and licensing status) and LexisNexis (an American data analytics company that provides legal, government and

business data) (5, 22). AtMF also reports sourcing data from WHO, other multilateral organisations and non-governmental organisations, although it is unclear what data are used from these sources. It is unclear what approach is taken when a company submits data that conflicts with information provided by another source. However, the data that are finally used to calculate the score for each indicator are not available publicly.

2.3 Index Methodology Review Process

Since 2008, the Index methodology has been reviewed and updated every two years (18). While earlier review processes focused on more substantive revisions (e.g., reducing the total number of indicators), since 2021 reviews have reportedly focused on more discrete refinements to enable more precise comparisons between companies while preserving the capacity to follow trends over time (19). The Index was initially developed and modified between 2008 and 2012 by independent research companies contracted by AtMF (Innovest in 2010 and MSCI ESG Research in 2012). However, since 2012, an in-house Expert Review Committee (ERC) has overseen revisions of the Index (13). The ERC is composed of 10 to 12 members with a wide range of backgrounds and institutional affiliations, including WHO, industry, consumer organizations, academia, investors, NGOs, and governmental institutions (20–22). Most ERC members have consistently come from high income countries (HICs).

According to AtMF, the first stage of the methodological review is conducted internally by the AtMI research team (7). In 2022 this reportedly involved a series of assessments that included analyses of the distribution of scores for each indicator and whether indicators with large clusters of low scores were “fair” (7). Response rate analyses for each data request were also conducted to assess whether questions were clear and feasible for companies to answer. AtMF reported that these and other tests were used to “eliminate the risk of redundant measures, to pinpoint opportunities for enhancing data and to identify where scoring guidelines could be tightened” (7).

The second stage involves stakeholder engagement (7). This has often started with obtaining feedback from the companies evaluated, followed by wider stakeholder engagement (19,23). Details of the stakeholder engagement are limited, but has included use of online surveys, roundtable discussions in both the Global North and Global South, consultation meetings with pharmaceutical companies, investor webinars and stakeholder meetings. For the 2022 Index review, stakeholders included global health donors, international organisations, investors, LMIC governments and regulators, NGOs, pharmaceutical companies and organisations, product development partnerships and academic institutions (7).

Reports indicate that pharmaceutical companies are the largest or second largest group of stakeholders engaged. In 2024 for example, 21% of stakeholders were pharmaceutical industry, 18% International organisations, 15% NGOs, 10% private sector, 10% governments, 9% research and academia, 7% funders, 7% investors, and 2% private public partnerships (23). Stakeholders across all groups have predominantly come from high-income countries (7,19,23). In the 2021 review, just 20% of stakeholders were from LMICs (19). The specific names of the companies, investors, NGOs and governments that engage in the review process are not made publicly available.

Information about what feedback was provided by which stakeholders and how this influenced revisions of the methodology was also limited. AtMF reports that consensus reached through the stakeholder engagement process is then translated into revision of the methodology (7). However, it is not clear how consensus is reached given the diverse perspectives of the stakeholders and particularly whose perspective is prioritised when conflicts arise (7). A group of external technical experts are also involved in reviewing the Index methodology during each review cycle (7,19,23) after which all feedback is integrated into a revised methodology by the AtMF research team. The ERC then reviews the proposed revisions and makes additional recommendations before endorsing a new and final methodology (7).

3. The 2022 Index

3.1 Overview of the Indicators and Metrics

The 2022 Index covered three technical areas (7) composed of 14 'priority topics' and 31 weighted indicators (see Table 1). Product Delivery (9 topics and 17 indicators) was weighted most highly (55%), followed by Research & Development (three topics and seven indicators) and Governance of Access (two topics and seven indicators) with weightings of 30% and 15% respectively. The most heavily weighted indicators were: 'companies' R&D pipelines for prioritized diseases' (6.75%) and the three indicators that made up the priority topic 'equitable access strategies' (6.5% each). The lowest weightings (1.5%) were given for two indicators within AtNI's Priority topic of 'IP strategy' (patent status disclosure and Intellectual Property (IP) sharing).

Table 1. The 2022 AtMI Metrics (7)

Technical area	Priority topic	Indicator	%
Governance of Access 15%	*Governance & Strategy*	*Governance structures & incentives (GA1)*	*2.14*
		Access-to-medicine strategy (GA2)	*2.14*
		Public disclosure of access-to-medicine outcomes (GA3)	*2.14*
	Responsible Business Practices	*Responsible promotional practices (GA4)*	*2.14*
		Compliance Controls (GA5)	*2.14*
		Incidence of breaches (GA6)	*2.14*
		Trade policy: IP and access to medicine (GA7)	*2.14*
Research & Development 30%	*Product Development*	*R&D pipeline: Prioritised diseases (RD1A)*	*6.75*
		R&D Pipeline: Other diseases (RD1B)	*4.50*
		Planning for access: Structured framework (RD2)	*2.25*
	Access Planning	*Planning for access: Project-specific plans for prioritised diseases (RD3A)*	*5.25*
		Planning for access: Project-specific plans for other diseases (RD3B)	*5.25*
		Disclosure of resources dedicated to R&D (RD4)	*3.00*
	Building R&D Capacity	*Capacity building in R&D (RD6)*	*3.00*

Product Delivery 55%	*Registration*	*Registration (PR1)*	*5.00*
	Product Donations	*Access strategies: Ad hoc donations (PP2A)*	*2.00*
		Access strategies: Long-term donation programmes (PP2B)	*4.00*
	Equitable Access Strategies	*Access Strategies: Supranational products (PP3)*	*6.50*
		Access Strategies: Healthcare practitioner-administered products (PP4)	*6.50*
		Access Strategies: Self-administered products (PP5)	*6.50*
	IP Strategy	*Patent filing & enforcement (PPL1)*	*2.00*
		Patent status disclosure (PPL2)	*1.50*
		IP sharing (PPL3)	*1.50*
	Licensing Quality	*Access-oriented quality licensing (PPL4)*	*2.50*
		Licensing: Geographic scope (PPL5)	
	Quality and Supply	*Ensuring continuous supply (PQ1)*	*3.00*
		Reporting substandard and falsified medicines (PQ2)	*3.00*
		Capacity building in manufacturing (PCB1)	*3.00*
	Local Manufacturing	*Capacity building in supply chains (PCB2)*	*3.00*
	Health System Strengthening	*Health systems strengthening (PCB3)*	*3.00*
	Inclusive Business Models	*Inclusive business models (PBM1)*	*2.00*

Companies are scored out of five for each indicator based on specific criteria. It seems that each indicator score is then weighted before being combined to give an overall score for each technical area which is also marked out of five. The score for each technical area is then combined to give an overall Index score out of five. However, as shown in Section Three, not all indicators have explicit criteria for each possible score from zero to five and for several indicators, it is not clear what specific data are used to generate a score. For example, it is unclear what data are used to assess 'behind closed doors' behaviours such as corporate lobbying against the use of flexibilities under the Agreement on Trade-Related Intellectual Property Rights (TRIPS). It is also not clear how indicators are scored when companies fail to or only partially disclose the required data. It is also unclear how companies are scored for indicators they opt not to provide data for.

Because the Index includes a mix of input, process and output indicators, some aspects of corporate performance are covered by multiple indicators. For example, there may be one indicator to assess the existence of a certain policy and another to assess the implementation of that policy. In such instances if a company has been negatively marked for not having a particular policy or strategy, it will not be negatively marked a second time for not implementing that policy or strategy. Instead, that second indicator is given a 'neutral score' (the average score of all indicators within the relevant technical area).

3.2 Indicators and Scoring System

In the Tables that follow, we assess each of the 31 indicators used to construct a company's score. We first present AtMF's description of each indicator and its associated the scoring systems (colour coded in blue). This is followed by a brief comment on the indicator (green) and a summary of the 2022 results (red). It will be immediately apparent that a full understanding of how the indicators are constructed and scored and then used to construct the scores requires a large investment of time and study.

3.2.1 Governance of Access

GA1: Governance structures & incentives
The company has a governance system that includes both 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.

Scoring guidelines:
5 The company has a board member or board-level committee directly responsible for its access-to-medicine approach. Its CEO and/or senior executives have (long-term) access-related objectives and incentives. Its regional and/or in-country managers also have objectives and incentives to improve access.

4 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. There is evidence of access-related incentives in place at an executive or managerial level (for senior management or regional/in-country managers.

3 The company has a board member or board-level committee responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level.

2 The company has an executive manager or executive committee, that directly reports to a board member or to a board-level committee, responsible for its access-to-medicine approach.

1 There is no evidence of access-related incentives in place at an executive or managerial level in countries.

0 The company has no board or executive level responsibility for its access-to-medicine approach

This is an input and process indicator that assesses a company's attention to access-related objectives, including at the CEO, senior management and country/regional management levels Ensuring responsibility for improving access lies at the senior management/CEO level is important for promoting the adoption of meaningful access measures. But this indicator does not measure the quality of senior management input, a company's level of attention or ambition or its commitment to improving access to medicines, nor does it measure actual improvements in access. It also does not explain what is meant by 'access-to-medicine objectives and incentives'. In theory a company could score highly even if it made little or no progress in improving access to medicines.

Sixteen companies were reported to have had 'board-level responsibility for access-to-medicine activities', although it is unclear the extent of this responsibility or what penalty the board (and company) would face for not fulfilling it. Fourteen companies were reported to have 'access-related incentives' (which are not further specified) for the CEO, senior management and in-country/regional managers.

GA2: Access-to-medicine strategy:
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 Index scope.

Scoring guidelines:
5 The company has a clear access-to-medicine strategy with evidence of alignment with corporate/business strategy. It includes measurable objectives to improve access to medicine. The company demonstrates evidence that the strategy is integrated through the application of it across the company's portfolio and pipeline.

4 The company has a clear access-to-medicine strategy with evidence of alignment with corporate/business strategy. It includes measurable objectives to improve access to medicine. The company demonstrates evidence that the strategy applies to a subset of the company's portfolio and pipeline.

3 The company has an access-to-medicine strategy with a business rationale that covers all or some of their projects.

2 The company has no existing access-to-medicine strategy with a business rationale but is in the process of implementing one.

1 The company has made commitments to improve access to medicine but does not have an access-to-medicine strategy.

0 The company neither has access-to-medicine strategy, nor has commitments for improving access to medicine.

This is a fairly weak input indicator of the existence of a strategy to improve access to medicines in LMICs. Furthermore, it encourages such a strategy to be directly related to its business strategy. It would be relatively easy for companies to score well by having a strategy but importantly, the quality and relevance of the strategy to LMICs is not assessed. In theory a company could score highly for having a strategy to improve access to medicines in LMICs in ways that may be cost-ineffective from the perspective of LMIC populations.

For the first time, all 20 companies were reported to have an access-to-medicine strategy with measurable objectives and that 19 companies had integrated this strategy into their overall corporate strategy.

GA3: Public disclosure of access-to-medicine outcomes
The company has time-bound measurable objectives, goals and targets related to improving access to medicines. It publicly shares progress against such objectives, goals and targets, as well as outcomes.

Scoring guidelines:
5 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives, and outcomes (or plans to report outcomes when available) related to improving access to medicine in a consistent manner and facilitates accountability and transparency by reporting targets and outcomes directly on their website in a centralised manner with regular updates.

4 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives, and outcomes (or plans to report outcomes when available) related to improving access to medicine in a consistent manner and facilitates accountability and transparency by reporting targets and outcomes, but reporting is not centralised or not updated regularly.

3 The company publicly discloses its commitment to access to medicine, targets, and measurable goals, objectives, and outcomes (centrally or non-centrally) related to improving access to medicine, but not for all initiatives in which it is involved.

2 The company publicly discloses its commitment to access to medicine, targets, and measurable goals, objectives related to access to medicine.

1 The company publicly discloses commitments related to improving access to medicine.

0 The company does not publicly disclose any of the above information.

This is a useful process indicator that encourages companies to publish their objectives, goals and targets with respect to improving access to medicines, and even includes a small incentive to publish the outcomes of these efforts. However, it does not include an assessment of the quality or level of ambition of the objectives, goals and targets that have been set.

All companies publicly disclose their commitments, targets and objectives related to their ‘access-to-medicine initiatives’ but the quality and transparency of reporting on outcomes was variable. Fifteen companies were reported to undertake centralised, comprehensive and regular reporting on outcomes of their ‘access to medicine activities’.

GA4: Responsible promotional practices
The company mitigates the risk of unethical sales practice (e.g., by decoupling bonuses for sales agents from sales volumes only). Further, it takes a voluntary approach to publicly disclose information regarding actual transfers or its approach to transfers of value to healthcare professionals (e.g., payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary values directed at HCPs).

Scoring guidelines:
5 The company takes a voluntary approach to publicly disclose information regarding actual transfers or its approach to transfers of value to healthcare professionals. It has a policy to limit transfers of value to HCPs. Sales agent incentives not driven exclusively by sales volume targets, and targets are not set at the individual level.

3-4 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals only when required by law, regulation, or trade association. It has a policy to limit transfers of values to HCPs. Sales agent incentives are not driven exclusively by sales volume targets, but some targets are set at the individual level.

2 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals only when required by law, regulation, or trade association. There is a policy to limit transfers of values to HCPs. Sales agent incentives are driven exclusively by sales volume targets and targets are set at the individual level.

1 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals only when required by law, regulation, or trade association. It has no policy to limit transfers of values to HCPs and sales agent incentives are driven (almost) exclusively by sales volume targets.

0 The company makes no disclosure regarding its approach to transfers of values to HCPs nor does it disclose its approach to incentives for sales agents.

This is a potentially useful indicator to discourage companies from linking financial rewards for sales agents from the volume of medicines they sell. This discourages supplier-induced demand and inappropriate use of medicines. It also discourages inappropriate interactions between companies and healthcare professionals. However, the extent to which sales agent incentives are not linked to sales volume targets is not assessed.

Eighteen companies reported having incentives for sales agents that were not fully linked to sales targets. Just two companies voluntarily disclosed information regarding payments to healthcare professionals (e.g. for attending events or promotional activities), although most reported doing so if required by local regulation. Just seven companies were reported to have a policy that explicitly limited such transfers.

GA5: Compliance controls
The company demonstrates that it has robust controls in place to mitigate the risk of non-compliance in its operations in the areas of ethical marketing, anti-corruption, and clinical trials, and which include the following elements:
a) Fraud-specific risk assessment;
b) Country risk-based assessment;
c) A live/continuous monitoring system for compliance (other than auditing);
d) Auditing and review mechanisms, which involve the use of both internal and external resources, apply to all third parties and all countries where it has operations, based on risk assessment;
e) Formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries in scope of the Index

Scoring guidelines:
5 The company has all of the above-mentioned elements in place.

4 The company has 4 of the above-mentioned elements in place.

3 The company has at least 3 of the above-mentioned elements in place.

2 The company has at least 2 of the above-mentioned elements in place.

1 The company has 1 of the above-mentioned elements in place.

0 The company does not have any of the above-mentioned elements in place or does not disclose information.

This is an input indicator aimed at discouraging unethical or corrupt practices. However, it assesses the existence of compliance controls, but does not appear to assess the adequacy, quality or effectiveness of those controls.

Some progress was reported on compliance controls in the areas of ethical marketing, anti-corruption, and clinical trials with 13 companies reportedly implementing a comprehensive set of controls although just eight demonstrated evidence of applying them all.

GA6: Incidence of breaches
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 or misconduct in clinical trials during the past two years.

Scoring guidelines:
5 The company has not been the subject of any settlements for criminal, civil or regulatory infractions during the past two years (pending cases, allegations and cases under appeal are not included).

3 The company has not been the subject of any criminal or civil infractions, but has been the subject of one breach of a code of practice in one country.

2 The company has been the subject of more than one breach of a code of practice.

0 The company has been the subject of at least one negative ruling or settlement.

An indicator monitoring breaches of codes, regulations or laws is good. Civil, criminal and regulatory infractions are important deterrents of unethical or illegal behaviour. Unfortunately, the existence of laws and regulations, as well as the capacity to enforce compliance with laws and regulations in many countries is weak, making this a much weaker indicator than it should be in theory.

The 2022 Index reported that Novartis had settled fraud charges over a former subsidiary violating the books and records and internal accounting controls provisions of the Foreign Corrupt Practices Act between 2011 and 2014 in Vietnam.

GA7: Trade policy: IP and access to medicine
There is evidence the company employs an IP strategy conducive to creating access to medicine. This is in accordance with the rights of national governments to deploy IP systems flexibly, as defined by the Doha Declaration (DD) on the TRIPS Agreement and Public Health.

Scoring guidelines:
5 The company publicly discloses support for the DD and use of TRIPS flexibilities. There is no evidence-based information that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.

4 The company publicly discloses general support for the DD and use of TRIPS flexibilities, though reservations on its provisions can be expressed. There is no evidence-based information that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.

3. The company publicly discloses general support for the DD and use of TRIPS flexibilities, though reservations on its provisions can be expressed. However, it has been involved in one IP-related anti-competitive practice* via industry associations.

2 The company does not publicly support the DD and use of TRIPS flexibilities and has been involved in one IP-related anti-competitive practice* via industry associations.

1 The company has been involved in more than one IP-related anti-competitive practice* via industry associations.

0 The company has been directly involved in anti-competitive IP-related practices*.

*Patenting in Least Developed Countries, lobbying against the use of TRIPS flexibilities by governments (including through trade associations), lobbying for strengthening of IP standards beyond TRIPS, evergreening.

An indicator to measure compliance with the principles of the Doha Declaration, including the appropriate use of TRIPs flexibilities is good. However, the barriers to access presented by TRIPs as well as the practical and political difficulties in using TRIPs flexibilities makes this a much weaker indicator than it should be. It is also unclear how one can assess whether companies do or don't exert pressure on governments; nor does it assess the practice of HIC governments lobbying LMIC governments on behalf of companies.

Just four companies were reported to support the Doha Declaration on TRIPS and Public Health without reservation. The 2022 Index also found evidence of all companies engaging in lobbying (via industry association) for tighter IP protection and against the use of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries.

3.2.2 Research and Development

RD1A: R&D pipeline: Prioritised diseases
The company engages in the development of products that target priority product gaps identified by global health research organisations (R&D priorities are categorised using lists from WHO and Policy Cures Research). This includes innovative and adaptive R&D and in-house and collaborative R&D.

Scoring guidelines:
5-1 The total size of each company's 'priority R&D' pipeline that targets an externally defined R&D gap from Policy Cures Research and/or WHO, scaled across all companies and scored.

0 The company has no projects in its research pipeline which it targets needs as defined by Policy Cures Research and/or WHO.

This indicator is designed to evaluate companies' investment in R&D to help address priority needs in LMICs, even if there is little commercial incentive. It is not, however, clear how the total size of each company's pipeline is measured and scored.

Twenty companies collectively had 1,060 R&D projects in the pipeline for the 83 diseases, conditions and pathogens assessed in the Index. Sixty-four percent of these targeted NCDs. Just 30% targeted a disease identified by WHO or Policy Cures Research (although not necessarily by LMICs themselves) as a priority R&D treatment gap with over half of these focused on just four diseases (coronaviral disease, HIV/AIDS, malaria and tuberculosis). Over 70% of the internationally identified R&D priorities for LMICs remain unaddressed with the number of projects targeting NTDs dropping since 2021. Just five companies were engaged in R&D for emerging infectious diseases other than coronaviruses and there were no products in the pipeline.

RD1B: R&D Pipeline: Other diseases
The company engages in the development of products that address a clear 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, targets populations for which further studies/specific formulations are needed (such as children and pregnant women, etc.) as determined by stakeholder consensus.

Scoring guidelines:
5-1 The total size of each company's pipeline that does not target externally defined R&D gaps from Policy Cures Research and/or WHO but meets stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope, scaled across all companies and scored.

0 The company has no projects within the scope of the Index in its research pipeline that meet stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope.

*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research.

As with RD1A, this indicator is designed to incentivise companies to conduct R&D that would help address needs in LMICs, even if there is little commercial incentive. It is not, however, entirely clear how these additional gaps are identified as being within scope for the Index. It seems that the companies themselves make this decision.

While all companies were reported to engage to some extent in R&D for products to address significant public health needs in LMICs, the vast majority were cancer-related products while products for maternal health conditions were particularly under-researched.

RD2: Planning for access: Structured framework
The company has a process through which equitable access is planned for products successfully developed both in-house and collaboratively.

Scoring guidelines:
5 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative).* The process includes consideration of different plans for different product types, disease targets and target populations. Access plans are initiated no later than Phase II of development.

4 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative). The process includes consideration of different plans for different product types, disease targets and target populations.

2 The company has a structured process in place to develop access plans for a subset of its R&D projects. The process includes consideration of different plans for different product types, disease targets and target populations.

1 The company has a general process in place to include access-oriented principles for its R&D projects.

0 The company has no processes in place in this area or applies access planning on an ad hoc basis.

* Good quality access plans are defined as consisting of several components: 1) plans to register the product in many of the countries in scope; 2) plans to apply for WHO pre-qualification; 3) Post-trial access guarantees for clinical trial participants; 4) plans to engage in technology transfers or local manufacturing arrangements; 5) plans to make product donations; 6) supply and demand planning; 7) to engage in non-exclusive voluntary licensing agreements; 8) plans to apply equitable pricing strategies; 9) commitments to future patent waivers.

This is a weak process indicator. Companies may score highly merely for having a ‘structured process in place’ or having ‘commitments to developing access plans’. It is also not clear the the quality of companies’ access plans are considered in the scoring system.

Fifteen companies had ‘systematic frameworks to plan for access in LMICs’ for all R&D projects.

RD3A: Planning for access: Project-specific plans for prioritised diseases
The company provides evidence 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.

Scoring guidelines:
5-1 The company's late-stage R&D projects that meet priorities identified by Policy Cures Research and/or WHO are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored.

0 The company provides no evidence of access plans for any late-stage R&D projects that meet externally defined priorities, nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

This indicator assesses advanced access planning (starting from Phase II), a key action for ensuring that products quickly reach the people who need them. Such access plans are expected to go beyond registration to include affordability and supply barriers. However, there is little detail as to what level of commitment or quality of strategy is needed to score highly. Scores between 1 and 5 simply state that access plans are assessed on 'breadth and depth' with no further detail provided.

Seventy-seven percent of projects towards the end of the R&D pipeline were reported to have a plan to promote access after product launch in at least one LMIC with each plan including just six LMICs on average. Only 15% of the projects with access plans covered at least one low-income country (LIC), 85% included at least one UMIC. Further, only 5.5% of access plans for NCD products included a LIC.

While good quality access plans are defined as consisting of several components, most access plans were reported to contain very few 'access components'. Fifty-two percent of access plans focused solely on the very initial step of improving access- product registration and this may be in just one LMIC ((usually in the UMICs where clinical trials were conducted). Just 22% of access plans contained any provision to address affordability and only eight percent considered the burden of disease when deciding what countries to launch the product in. Overall, it was noted that despite an increase in the percentage of late-stage projects with access plans, most plans were limited in breadth and depth to significantly increase access to new products for LMIC populations.

RD3B: Planning for access: Project-specific plans for other diseases
The company provides evidence 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.

Scoring guidelines:
5-1 The company's late-stage R&D projects that do not meet externally defined R&D priorities but do meet stakeholder-informed criteria of a clear relevance to patients are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored.

0 The company provides no evidence of access plans for any late-stage R&D projects that do not meet externally defined priorities but do meet stakeholder-informed criteria of a clear relevance to patients. Nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

See above.

The 2022 Index did not explicitly report on this indicator. Rather, it appears to be reported on in aggregate with RD3A.

RD4: Disclosure of resources dedicated to R&D
The company publicly discloses the resources dedicated to its R&D activities which are conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.

Scoring guidelines:
5 The company publicly discloses its R&D investments, disaggregated at least at the following levels: disease, project and phase of development.

3 The company publicly discloses its R&D investments disaggregated to some degree: disease category, product type, aggregated phase of development (e.g., clinical versus pre-clinical) etc. and the company voluntarily discloses disaggregated R&D investment data to organisations that present anonymized aggregate data for global health purposes, such as Policy Cures Research.

2 The company publicly discloses its R&D investments disaggregated to some degree: disease category, product type, aggregated phase of development (e.g., clinical versus pre-clinical) etc.

1 The company does not publicly disclose R&D investment data that has been disaggregated at any level. However, it voluntarily discloses disaggregated R&D investment data to organisations that present anonymized aggregate data for global health purposes, such as Policy Cures Research.

0 The company does not publicly disclose R&D investment data that has been disaggregated at any level and does not contribute data to Policy Cures Research.

This indicator assesses public disclosure of R&D investments. While this is helpful for assessing investments gaps, companies are scored not on the size or adequacy of their investments but rather on their willingness to disclose data. It is not clear how these data are verified. Given the commercial sensitivity of such data, this is an important question.

Just one company was found to publicly disclose R&D investment data disaggregated by disease category, product type or phase of development; seven disclosed fully disaggregated R&D investment data to global health organisation Policy Cures Research and two companies did both.

RD6: Capacity building in R&D
The company increases local capacity for health research (including clinical trial capacity) and product development by undertaking R&D capacity-building initiatives in partnership with local universities and public sector research organisations. The Index assesses whether these initiatives meet all Good Practice Standards. Such standards would include focusing on local needs, priorities and/or skills gaps; having good governance structures in place for the partnership; measuring outcomes; and working toward long-term aims/sustainability.

Scoring guidelines:
5 The company provides evidence of five R&D capacity building initiatives that meet inclusion criteria, of which at least three meet all Good Practice Standards*.

4 The company provides evidence of three R&D capacity building initiatives that meet all Good Practice Standards OR four R&D capacity building initiatives of which at least two meet all Good Practice Standards OR five R&D capacity building initiatives of which two meet all Good Practice Standards.

3 The company provides evidence of one to five R&D capacity building initiatives, of which one meets all Good Practice Standards OR two or three R&D capacity building initiatives of which two meet all Good Practice Standards.

2 The company provides evidence of at least two R&D capacity building initiatives of which none meet all Good Practice Standards.

1 The company provides evidence of one R&D capacity building initiative though it does not meet all Good Practice Standards.

0 The company does not provide any examples of R&D capacity building initiatives that meet all inclusion criteria.

*Good practice standards include 1) good governance structures in place for partnership with local university/public research institution (including for mitigating or preventing conflicts of interest); 2) Goals align with or support the partnered institutional goals; 3) Guided by clear, measurable goals or objectives; 4) Includes regular monitoring, evaluation of outcomes; 5) Publicly shares outcomes, including approaches, progress and learnings; 6) Has long term aims or achieves integration within the health system. Initiatives in manufacturing are not expected to be done in partnership where there may be a direct engagement with contracted third-party manufacturers.

This indicator assesses whether companies are building local R&D capacity in ways that go beyond their own interests/portfolio. This is a potentially important indicator though companies are invited to cherry-pick just five initiatives for assessment that may not reflect the overall quality of all their R&D capacity-building initiatives. Further there is no real assessment of the impact of the capacity building initiatives.

Fifteen companies were reported to be engaged in ‘R&D capacity-building’ (which was not further specified) across 52 initiatives with local universities and public sector research organisations in LMICs. Of the 523 initiatives, 79% met all of AtMF’s Good Practice Standards.

3.2.3 Product Delivery

PR1: Registration
The company files to register its 'most recently launched' products* targeting diseases within the scope of Index.

Scoring guidelines:
5 The company filed all of its products in scope for registration in a majority of countries with the highest disease burden and in a majority of countries in scope of the Index.

4-1 Scaled compared to peers. Number of 'newer products' that are filed for registration in number of countries with the highest disease burden and in a number of countries in scope. Number of 'older products' that are filed for registration in number of countries with the highest disease burden and in a number of countries.**

0 The company provides no evidence of filing to register any of its relevant products in any of the relevant countries.

*Most recently launched refers to the date the product was first approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.
**Newer product refers to products first approved to be marketed in the last 5 years anywhere globally. Older product refers to products first approved to be marketed within the last 5 to 20 years anywhere globally.

This process indicator monitors If companies are filing to register new products rapidly in LMICs. While registration of new products is an essential first step in ensuring access, this indicator does not include any assessment as to whether such filing leads to an actual improvement in access to medicines.

Ninety-two percent of these products were registered in less than 10 LMICS. Just over 6% of products were registered in at least 5 of the 10 countries with the highest burden of disease and 62% were not registered in any high disease burden LMICs rendering them entirely inaccessible to people living there. Further, where newly-launched products were registered in an LMIC this usually occurred later than in HICs with only two companies filing all their new products for registration in at least one LMIC within 2 months of first global approval.

PP2A: Access strategies: Ad hoc donations
The company has policies and supply processes in place to ensure that ad hoc donations* are carried out rapidly in response to expressed need.

Scoring guidelines:
5 The company meets all of the following criteria with respect to ad-hoc donations: a) it has policies/agreements/supply processes in place to ensure that all donations are carried out rapidly in response to expressed needs; b) the company or its partners have policies/processes to ensure monitoring of the delivery of donations until receipt and use by the patient.

2.5 The company has policies/agreements/supply processes in place to ensure that its donations are carried out rapidly in response to expressed needs. However, neither the company nor its partners have policies/processes in place to ensure of the delivery of donations until receipt and use by the patient.

0 The company meets none of the above criteria with respect to ad hoc donations.

*Donations are defined as 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.

This indicator appears to have a different scoring system with companies only being able to get a mark of 5, 2.5 or 0. The value and relevance of ad hoc donations to creating long-term and sustainable systems for ensuring equitable access to medicines are highly questionable. While donations may be appropriate in humanitarian situations (e.g., conflict and natural disasters.), the indicator does not include any assessment of the scale or monetary or health-related value of the donation.

All 20 companies reportedly had a policy for ad hoc requests for medicine donations. However, just nine companies complied with best practice and publicly specified their alignment with WHO Guidelines for Medicine Donations, including compliance with country requirements for securing and storing medicines in the recipient country. Only seven companies showed evidence of tracking donations until obtained by patients.

PP2B: Access strategies: Long-term donation programmes
The company engages in long-term, sustainable product donation programmes for diseases where elimination, eradication or control goals are possible and publicly commits to the achievement of such goals.

Scoring guidelines:
5 The company publicly commits to remain engaged in at least one long term donation programme for the achievement of elimination, eradication, or control goals with no time limit.

3 The company publicly commits to engage in long term donation programmes to support elimination, eradication, or control goals for a time-limited period.

1 The company is engaged in donation programmes which support elimination, eradication or control, but makes no public commitment regarding this engagement.

NS Companies without structured donation programmes receive a neutral score. Moreover, companies with structured donation programmes that have no elimination, eradication, or control goals also receive a neutral score.

See above.

Eleven companies had long-term donation programmes for NTDs or malaria and six others engaged in structured donation programmes for other conditions (e.g. AbbVie donates beractant for infant respiration distress syndrome in six LMICs).

PP3: Access strategies: Supranational products
The company applies access strategies to the products for which it has marketing rights and that are supranationally procured (i.e. products for which international procurement, advanced market commitments or market-shaping facilities exist). The company extends these strategies to countries graduating from development assistance or countries that do not qualify for such assistance. These products include vaccines and treatments for HIV, tuberculosis, malaria and other NTDs. Companies which do not market these products will not have this indicator applied to them. A maximum of five products are evaluated per company and identified using criteria such as either on-patent or off-patent, on WHO's Essential Medicines List (EML) and high market share. Companies received an opportunity to verify and adjust as appropriate.

Scoring guidelines:
5 For all its supranationally procured products in scope, the company meets all following criteria: a) it applies equitable pricing strategies, takes affordability into account and demonstrates using demographic and economic factors to determine the price per programme; b) it applies the same terms of the supranational agreement in countries that do not qualify for assistance from these mechanisms, or have graduated from these programmes; c) it applies additional non-pricing initiatives to maximize access across different segments of the population; d) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries covered.

4-1 For a subset of its supranationally products in scope, the company meets a number of the following criteria: a) it applies equitable pricing strategies, takes affordability into account and demonstrates using demographic and economic factors to determine the price per programme; b) it applies the same terms of the supranational agreement or equitable access strategies in countries that do not qualify for assistance from these mechanisms, or are/have graduated from these programmes; c) it applies additional non-pricing initiatives to maximize the reach across different segments of the population; d) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries covered by these programmes.

0 The company meets none of the above listed criteria.

NS Companies without products that are supranationally procured receive a neutral score.

This indicator evaluates the engagement of companies in market-shaping and/or pooled procurement by organisations such as UNICEF, Gavi and the Global Fund. It also assesses the extent to which companies consider comparative access to products for countries which do not qualify for such support.

For PP3, PP4 and PP5, the Index analysed a sample of up to five products per company in each category. Of the 188 products analysed, 102 were on the WHO's EML and the Index reported that 83% were covered by an access strategy in at least one LMIC but that they were of variable quality and that low-income countries were largely not covered.

Regarding the 39 supranationally procured products, 12 out of the 13 companies supplying these products extended the terms of these agreements (or what AtMF described as different but 'equitable terms', based on the relevant payers' ability to pay) for 36 products to at least one non-eligible lower-MIC.

PP4: Access strategies: Healthcare practitioner-administered products
The company takes into consideration both the relevant payer(s) ability to pay and demographic factors (age, sex, education level, employment, etc) to determine its access strategy, with the aim to increase the reach of its healthcare practitioner-administered products (products that typically require hospital administration or the continued attention of a skilled healthcare professional) across the income pyramid.
This is evidenced by:
a) pricing strategies that incorporate factors which determine the ability to pay for different segments of the population (e.g., patients paying out of pocket) and non-pricing initiatives (e.g., patient assistance programmes, donations, voluntary licensing, technology transfer and health systems strengthening initiatives) to maximize reach, and
b) increased patient numbers since the product was introduced, and
c) plans to further increase patient numbers, and
d) initiatives to boost the health system's ability to improve the availability of the products.

A maximum of five products are evaluated per company and identified using criteria such as either on-patent or off-patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

Scoring guidelines:
5 For all its healthcare practitioner-administered products in scope, the company meets all the following criteria for the countries' selected:
a) pricing strategies that take into account the ability to pay for different segments of the population, and provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors;
b) non-pricing initiatives to maximize the reach across different segments of the population;
c) evidence that this approach has increased or is planned to increase the number of patients reached;
d) initiatives to boost the health system's strength to improve the availability of the products

4-1 For a subset of its healthcare practitioner-administered products in scope, the company meets X number of the criteria described above.

0 For its healthcare practitioner-administered products in scope, the company meets none of the above listed criteria.

NS Companies without healthcare practitioner-administered products receive a neutral score.

This indicator evaluates how companies support access to practitioner-administered products across the income spectrum. However, a maximum of only five products are evaluated per company and each company is asked to provide just three examples of a country-specific access strategy covering each product (one in an UMIC, one in a lower-MIC, and one in a LIC) allowing cherry picking of their most comprehensive access strategies.

For each self- and practitioner-administered product selected for analysis (PP4 and PP5), 90 and 59 products respectively, the Index reported that comprehensive access strategies combining pricing and non-pricing components were applied to 42% of products in at least one upper-middle income country (Upper-MIC), 43% in at least one lower-middle income country (lower-MIC) and just 13% in at least one low-income country (LIC). Pricing as the main access strategy was applied to 34% of products in at least one upper-MIC, 25% of products in at least one lower-MIC and 15% of products in at least one LIC (with no information provided on whether these are country-identified priority products). While 19% of analysed products were not covered by an access strategy in any upper-MIC, 65% were not covered by any access strategy in any LIC. Among products covered by an access strategy, most companies tracked patient reach although there was some variation by country income group with patient reach tracked for 84% of products in upper-MIC and 73% of products with access strategies in LICs.

PP5: Access strategies: Self-administered products
The company takes into consideration both the ability-to-pay of the payer and the demographic factors (age, sex, education level, employment, etc) to determine its access strategy, with the aim to increase the reach of its self-administered products across the income pyramid. This is evidenced by:
a) pricing strategies that incorporate factors which determine payer's ability to pay for different segments of the population and non-pricing initiatives
b) increased patient number since the product was introduced, and
c) plans to increase patient numbers for the following X years.

Scoring guidelines:
5 The company meets all the following criteria for the countries' examples selected: a) applies pricing strategies that take ability to pay per payer types into account, within different segments of the population and provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors; b) applies additional non-pricing initiatives to maximize the reach across different segments of the population; c) demonstrates how this approach has increased or is planned to increase the number of patients reached in the countries' examples selected.

4-1 For a subset of its self-administered products, the company meets X number of the above criteria in X number of selected countries.

0 For its self-administered products in scope, the company meets none of the above listed criteria.

This indicator evaluates how companies support access to self-administered products across the income spectrum. However, a maximum of only five products are evaluated per company and, as for PP4, each company is asked to provide just three examples of a country-specific access strategy covering each product (one in an UMIC, one in a lower-MIC, and one in a LIC) allowing cherry picking of their most comprehensive access strategies.

The 2022 Index reported on this indicator in aggregate with PP4- see results above.

PPL1: Patent filing & enforcement
The company publicly commits to not filing for (or enforcing) patents relating to diseases in scope in least developed countries (LDCs), LIC and in a subset of lower-MICs and upper-MICs.

Scoring guidelines:
5 Company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products for diseases in scope of the Index in all LDCs, and a subset of lower-MICs and upper-MICs.

4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs, LICs, and a subset of lower-MICs. Or all LDCs, LICs and a subset of lower-MICs and upper-MICs for a subset of products.

3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs, a subset of LICs, and Lower-MICs.

2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs and/or LICs.

1. The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in scope of the Index and/or in a specific region or regions (e.g., some LDCs and/or LICs).

0 The company makes no commitment in this area.

This is an important indicator, although getting a maximum score of 5 can be obtained for commitments made in all LDCs, LICs and just a subset of lower-MICs and upper-MICs where a large proportion of the global poor live. Further, the full impact of this action will be dependent on procurement capabilities and capacity of generic medicine manufacturers.

Seventeen companies made some form of public commitment not to file for nor enforce patents in LDCs and/or LICs but it was not always clear whether this covered all products in scope of the Index. Certainly for one company it only applied to products for infectious diseases, NTDs and maternal and neonatal diseases and for another company their pledge only covered a single antiretroviral drug. Notably however, LDCs countries (a sub-set of 45 LICs) are not required to implement TRIPS until 2033, meaning patents are not currently enforceable within these countries, making patent commitments here irrelevant. Just five companies pledged to also not file for nor enforce patents for their products in a sub-set of lower-MICs and upper-MICs (although it is not disclosed how many or which countries are covered) and just two companies made this pledge for a sub-set of lower-MICs countries only.

PPL2: Patent status disclosure
The company publicly discloses the patent status of its products for diseases relevant to the Index.

Scoring guidelines:
5 Company publicly discloses the patent status for all on-patent products within the Index scope. This information is updated periodically, and the standard of transparency is analogous to or greater than that set out by the US FDA's Orange Book (includes product patent data, patent number and expiry date of the patent).

4 Company publicly discloses the patent status for a subset of on-patent products within the Index scope. This information is updated periodically, and the standard of transparency is analogous to or greater than that set out by the US FDA's Orange Book. Or companies disclose patent status for all on-patent products at a standard of transparency that falls shorts of that set out by the US FDA's Orange Book.

3 Company publicly discloses the patent status for a subset of on-patent products within the Index scope. This information is updated periodically, but the standard of transparency achieved is less than that set out by the US FDA's Orange Book.

2 Company publicly discloses patent status for a subset of on-patent products within the Index scope but the information is not updated periodically, and the standard of transparency is less than that set out by the US FDA's Orange Book.

0 The company makes no public disclosure in this area.

This indicator evaluates patent transparency. Companies may be given scores of three or four for not being fully transparent. Arguably, patent transparency should be mandatory rather than a voluntary action.

Nineteen companies publicly shared at least some data on their products' patent status. However, the degree of transparency is limited for most of these. Just one company disclosed the patent status of all their products with a 'good standard of transparency', two made disclosures for a subset of products with a 'good standard of transparency', while 16 companies made disclosures for a subset of products with less transparency. Of the 740 products analysed, 323 were found to be on-patent, 293 off-patent while information about the patent status of the remaining 125 was not available (or not applicable e.g. for biological products). For more than 60% of on-patent products, the patent expiry date was unavailable.

PPL3: IP sharing
In addition to existing agreements, the company provides evidence of newly sharing its IP (e.g., molecules library, patented compounds, unpublished data) through agreements with public research institutions and/or drug discovery initiatives (e.g., WIPO Re:Search, Medicines for Malaria Venture).

Scoring guidelines:
5-2 The company has previously made available its IP through agreements that remain valid. In addition, new agreements during the period of analysis are weighted, added together, ranked and scored accordingly.

1 The company has previously made available its IP through agreements that remain valid.

0 The company does not provide evidence of sharing its IP.

This indicator assesses the voluntary sharing of IP through agreements with public research institutions and/or drug discovery initiatives. However, it is not clear how or if the terms of these agreements are analysed, and whether any of these agreements are assessed in terms of their impact on improving access to medicines.

13 companies reported having at least one new IP-sharing agreement with a public research institution (which can be presumably be in any country) or drug discovery initiative (such as WIPO Re:Search, Conserved Domains Database or Open Source Drug Discovery) that met all inclusion criteria for evaluation (although these are not described). It is not reported how many companies actually delivered on these agreements. Eleven companies engaged in such agreements for new products for NTDs. The greatest number of new IP-sharing agreements for one company was 17 although most had between one and three new agreements established since the previous Index. Seventeen companies had existing agreements already in place.

PPL4 and PPL5: Access-oriented quality licensing; and Licensing: Geographic scope
The company engages in voluntary licensing agreements to enable the generic supply of products in their portfolio. Licences are non-exclusive, transparent and include access-oriented clauses to facilitate the affordable supply of quality products in wide range of countries in scope of the Index. These clauses include: 1) licence agreed prior to or shortly after approval of originator product; 2) ability to manufacture and source active pharmaceutical agreements without restriction, 3) ability to supply countries where no granted patents are infringed (including where compulsory licences are issued), 4) optional provision for technology transfer, 5) absence of no challenge clauses, 6) provision to facilitate rapid registration of product, 7) inclusion of quality assurance measures in line with WHO requirements, 8. affordability in small markets (if applicable).

Scoring guidelines:
5 The company has at least one non-exclusive voluntary licensing (NEVL) that includes most of the designated access-oriented clauses in the terms of the voluntary licences it has agreed for products relevant to the Index, in all the countries of scope of the Index.

4-3 The company has at least one NEVL that includes x of the designated access-oriented clauses in the terms of the voluntary licences it has agreed for products relevant to the Index, in x countries of scope of the Index.

2-1 The company has at least one voluntary licence (VL) that includes x of the designated access-oriented clauses in the terms of the voluntary licences it has agreed for products relevant to the Index, in x countries of scope of the Index.

0 Companies without any VL for patented products within the Index scope, considering that their portfolio contains relevant products to pursue a VL.

Companies without any VL for patented products within the Index scope, with no relevant products for pursuing a VL in the portfolio are given a neutral score.

This indicator sets a low bar. A company can score 5/5 simply for having issued one NEVL (provided it includes most of the designated access-oriented clauses) for a relevant product in all countries in scope of the Index.

Just 50% of companies engaged in at least one voluntary license to allow the generic manufacturing of on-patent medicines in their portfolio. A total of 27 voluntary licenses were issued by 10 companies, 19 of which were Medicine Patent Pool licences. The Medicine Patent Pool is a UN-supported public health organisation that serves as an intermediary between patent holders and generic manufacturers to facilitate voluntary licensing that tends to be more transparent and include broader access-oriented terms than licensing agreements issued privately.

Twenty-six of these were non-exclusive (meaning that the license is open to multiple manufacturers). The licenses covered compounds for just four diseases: HIV (15 compounds), hepatitis C (5 compounds), Coronaviral diseases (5 compounds), and cancer (one compound). Particularly for non-MPP licences, AtMF reported that ‘access-oriented’ clauses were often not transparent making it difficult to assess the quality and likely impact of each license. Although technology transfers are not needed for many products, it is worth noting that for each of the 26 NEVL that covered an average of 80 LMICs, actual technology transfers to generic manufacturers under these licences were not reported except for Covid-19 products where this happened in just a handful of countries and most commonly in India.

PQ1: Ensuring continuous supply
The company has a process in place to ensure continuous supply of all its products within the Index scope in LMICs and works to improve local supply capacity in LMICs through technology transfers and strengthening supply chains. This process includes the following elements:
a) Working with relevant stakeholders (e.g., government agencies, distributors, hospitals, warehouses, wholesalers or other relevant networks) to communicate issues that may affect the supply chain;
b) Managing a safety stock of relevant finished products;
c) Working with several active pharmaceutical ingredient suppliers and/or producing in-house APIs to prevent shortages;
d) Working to enhance local third-party supply capacities and strengthen supply chains in LMICs; and
e) Transferring technology to third-party manufacturers in LMICs

Scoring guidelines:
5 The company has elements (a) through (e) in place and provides an example of implementing these activities to improve supply in at least one country in scope of the Index.

4-1 The elements that the company does implement are added, weighted and summed together and companies are scored relative to one another.

0 The company does not have elements (a) through (e) in place or does not disclose information about them.

Ensuring continuous supply and preventing the risk of stock-outs means patients who need essential medicines can continue to access high-quality products.

It was reported that companies were taking action “to ensure continuous supply of their products in LMICs through for example holding buffer stocks of finished products, diversifying API sourcing, and communicating with stakeholders in the supply chain about potential supply risks”. Companies performed less well on building capacity for manufacturing and supply through third parties in LMICs with efforts focused on technology transfer agreements for Covid-19 products in a few emerging markets (India, Brazil, China).

PQ2: Reporting substandard and falsified medicines
The company has a policy/protocol for reporting substandard and falsified (SF) medicines with specific timeframes for reporting to relevant stakeholders (i.e., national regulatory authorities and WHO Rapid Alert).

Scoring guidelines:
5 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 mislabelling, confirmation of fake packaging) is sufficient to establish that the product packaging is falsified. here 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.

4 The company provides evidence of a policy or approach to reporting confirmed SF cases to WHO Rapid Alert and/or local regulatory authorities within ten days of the confirmation in countries within the scope of the Index.

3 The company provides evidence of a policy or approach to reporting SF cases to WHO Rapid Alert and/or local regulatory authorities but does not specify a reporting timeframe.

2 The company provides evidence/examples to the Index of reporting cases of SF medicines on a case-by-case basis, in countries within the scope of the Index, to relevant authorities.

0 The company does not provide evidence of such a policy or approach or provide examples of reporting SF medicines.

From a public health point of view, reporting to the relevant authority confirmed cases of SF medicines in a timely manner is important, as it allows authorities to quickly withdraw these from the market. SF medicines cause harm and death. Pharmaceutical companies have a responsibility to mitigate the risk of harm by sharing information with health authorities as rapidly as possible.

Just eight companies were reported to demonstrate best practice for combatting substandard and falsified products.

PCB1: Capacity building in manufacturing
The company undertakes manufacturing capacity building initiatives with local manufacturers aimed at achieving international Good Manufacturing Practice (GMP). These initiatives meet good practice standards which include: guided by clear, measurable goals and/or objectives; measures outcomes; and has long term aims/aims for sustainability.

Scoring guidelines:
5 The company provides evidence of five manufacturing capacity building initiatives that meet inclusion criteria*, of which at least three meet all Good Practice Standards.

4 The company provides evidence of three manufacturing capacity building initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four manufacturing capacity building initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five manufacturing capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.

3 The company provides evidence of one to five manufacturing capacity building initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three manufacturing capacity building initiatives of which two meet all Good Practice Standards.

2 The company provides evidence of at least two manufacturing capacity building initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.

1 The company provides evidence of one manufacturing capacity building initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.

0 The company does not provide any examples of manufacturing capacity building initiatives which meet all inclusion criteria.

* Inclusion criteria included that the initiative was active during the period of analysis; 2) the initiative takes place in a country in the scope of the Index; 3) the initiative addresses local needs; and 4) the initiative builds the capacity of third-party or unaffiliated manufacturers or work with external parties (i.e. local universities).

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. However, this indicator allows companies to submit initiatives for assessment that are most likely to score highly.

PCB1, PCB2 and PCB3: most companies implemented at least one capacity-building initiative in each of the three areas. It was reported that 69% of manufacturing, 76% of supply chain, and 71% of health system strengthening capacity building initiatives met all Good Practice Standards. However, overall, initiatives were implemented in just a small number of countries.

PCB2: Capacity building in supply chains
The company engages in supply chain capacity building initiatives, addressing local needs of supply chain stakeholders (e.g., ministries of health, procurement, logistics and distribution agencies). These initiatives build capacity beyond the company's own supply chain. The Index assesses whether these initiatives meet Good Practice Standards (ie. guided by clear, measurable goals and/or objectives and outcomes; has long term aims for sustainability etc).

Scoring guidelines:
5 The company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria*, of which at least three meet all Good Practice Standards.

4 The company provides evidence of three supply chain capacity building initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four supply chain capacity building initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.

3 The company provides evidence of one to five supply chain capacity building initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three supply chain capacity building initiatives of which two meet all Good Practice Standards.

2 The company provides evidence of at least two supply chain capacity building initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.

1 The company provides evidence of one supply chain capacity building initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.

0 The company does not provide any examples of supply chain capacity building initiatives which meet all inclusion criteria.

* Inclusion criteria included that the initiative was active during the period of analysis; 2) the initiative takes place in a country in the scope of the Index; 3) the initiative addresses local needs; and 4) the initiative must be in partnership with local university of public research institution.

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. However, as for PCB1, this indicator allows companies to submit their initiatives for assessment that are most likely to score highly.

This Indicator is reported on above.

PCB3: Health systems strengthening
The company engages in health systems strengthening (HSS) initiatives in partnership with local stakeholders, addressing local needs, with outcomes clearly measured. The initiative has processes in place to mitigate or prevent conflicts of interest. The Index measures whether these initiatives meet Good Practice Standards (ie. has good governance structures in place; publicly discloses outcomes; and has long term aims or achieves integration within the health system).

Scoring guidelines:
5 The company provides evidence of five HSS initiatives that meet inclusion criteria*, of which at least three meet all Good Practice Standards.

4 The company provides evidence of three HSS initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four HSS initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five HSS capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.

3 The company provides evidence of one to five HSS initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three HSS initiatives of which two meet all Good Practice Standards.

2 The company provides evidence of at least two HSS initiatives that meet inclusion criteria, of which none meet all Good Practice Standards. 1 The company provides evidence of one HSS initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.

0 The company does not provide any examples of HSS initiatives which meet all inclusion criteria.

*Inclusion criteria included that the initiative was active during the period of analysis; 2) the initiative takes place in a country in the scope of the Index; 3) the initiative addresses local needs; and 4) is in partnership with local institution/s; and have processes in place to mitigate or prevent conflict of interest.

The rationale for having an indicator on HSS is not clear. This is not a function or responsibility of pharmaceutical companies. Furthermore, it is unclear as to how HSS initiatives are defined, evaluated and scored.

This Indicator is reported on above.

PBM1: Inclusive business models
The company has contributed to the development and implementation of scalable inclusive business models done in partnership that aim to meet the needs of populations at the base of the income pyramid and /or vulnerable populations that face additional barriers to access. For all models, the company discloses resources invested into the model and there is evidence of, or projections for financial sustainability. AtMF define inclusive business models as those that address access-to-medicine barriers that prevent very low-income communities from attaining adequate healthcare while including clear plans or evidence of financial sustainability for business operations to continue and develop. Models should be revenue-generating or revenue-neutral, thus creating value for both very low-income communities and businesses.

Scoring guidelines:
5 The company has contributed to the development of one or more inclusive business models during the analysis period as described above and has scaled up one or more existing inclusive business models.

4 The company has scaled up one or more existing inclusive business models as described above but has not contributed to the development of new inclusive business models during the analysis period.

3 The company has contributed to the development of one or more inclusive business models during the analysis period as described above but has not scaled up any existing inclusive business models during the analysis period.

0 No inclusive business models identified in this area that met inclusion criteria described above.

Inclusive business models aim to identify access constraints and remedy market inefficiencies within LMICs. They can create opportunities for business and populations at the base of the income pyramid. These models need a long-term horizon with the ultimate aim of being adopted by a country's national health system. Such models also provide value in targeting vulnerable populations who may not receive adequate attention from health systems.

Fifteen companies were reported to have scaled up 32 inclusive business models (including expanding to new countries, increasing the number of patients served, or expanding the number of diseases covered) and 19 new business models were piloted. Most initiatives were concentrated in sub-Saharan Africa (23 in Kenya alone) but few specifically served vulnerable groups within low-income communities. Nearly half the inclusive business models analysed focused on NCDs.

3.3 The 2022 AtMI Rankings

Table 2 shows the list of twenty companies ranked in 2022. The top ranked company was GlaxoSmithKline followed by Johnson & Johnson, AstraZeneca and Novartis AG. The full range of scores extended from 4.06 at the top to 1.79 at the bottom.

Table 2: Companies included in the 2022 AtMI ranking (24)

Company Name	Stock Exchange	Country	Revenue, 2020 (bn USD)*	Market cap# (bn USD)Ω	Rank (Score)
Johnson & Johnson	New York	USA	82,584	433,237	2 (4.03)
Roche Holding AG	Swiss Exchange	CHE	66,049	292,984	10 (3.23)
Bayer AG	Xetra Germany	DEU	50,849	63,404	9 (3.36)
Novartis AG	Swiss Exchange	CHE	48,659	201,943	4 (3.87)
Merck & Co, Inc	New York	USA	47,994	190,309	18 (2.15)
GlaxoSmithKline plc	London	GBR	46,297	86,525	1 (4.06)
AbbVie Inc	New York	USA	45,804	188,681	19 (1.84)
Sanofi	Euronext Paris	FRA	44,267	118,723	8 (3.47)
Bristol Myers Squibb Co	New York	USA	42,518	136,580	15 (2.60)
Pfizer Inc	New York	USA	41,908	192,793	6 (3.62)
Takeda Pharmaceutical Co, Ltd	Tokyo	JPN	29,016	55,422	7 (3.51)
AstraZeneca plc	London	GBR	26,617	135,160	3 (3.93)
Gilead Sciences Inc	NASDAQ	USA	24,642	80,940	14 (2.84)
Eli Lilly & Co	New York	USA	24,540	195,068	20 (1.79)
Boehringer Ingelheim GmbH	n/a	DEU	24,032	n/a	13 (2.93)
Merck KGaA	Xetra Germany	DEU	21,536	73,652	5 (3.72)
Novo Nordisk A/S	Copenhagen	DNK	20,955	172,363	11 (2.97)
Astellas Pharma Inc	Tokyo	JPN	11,338	31,067	16 (2.46)
Daiichi Sankyo Co, Ltd	Tokyo	JPN	8,734	60,019	17 (2.20)
Eisai Co, Ltd	Tokyo	JPN	5,861	20,849	12 (2.95)

* Exchange rates on 31 December 2020, from oanda.com. For Yen, exchange rate is as of 31 March 2021
# Market cap on 18 February 2021, from Bloomberg terminal
Ω Exchange rates on 18 February 2021, from oanda.com

While any assessment of trends over time is constrained by the regular changes made to the methodology, it is notable that the leading companies have been quite consistent over the past eight published indexes (Annex 8 includes all rankings from 2008-2022). In fact, GlaxoSmithKline has been top in all eight past rankings while Johnson & Johnson, Novartis AG, Pfizer, AstraZeneca, Merck KGaA, Gilead Sciences, Sanofi/Sanofi-Aventis, Novo Nordisk A/S and Takeda have frequently been ranked in the top five (6,25–31). While the highest score over the past eight cycles has not shown a consistent trend [4.5 (2008), 3.75 (2010), 3.8 (2012), 3.29 (2014), 3.43 (2016), 4.01 (2018), 4.23 (2020), 4.06 (2022)], the score for the lowest ranked company has trended slightly upward over time (going from 1.25 in 2008 to 1.79 in 2022. Annex Four provides an overview of Index rankings since 2008.

As far as the presentation of the scores are concerned, it is interesting to note that the AtMF describes the Index as representing “a relative scoring system”. This is confusing as the Index clearly ranks companies on the basis of a simple aggregation of their absolute marks for each indicator.

4. Is the AtMI an effective tool for assessing pharmaceutical companies and holding them accountable?

Over the last four decades of neoliberal globalisation, financialisation and deepening and expansion of private property rights, oligopolistic transnational pharmaceutical companies have become large big, highly profitable and powerful global players. Governance of the pharmaceutical sector in the public interest and in accordance with human rights goals have subsequently become challenging. Initiatives aimed at monitoring and assessing the practices, behaviour and impact of pharmaceutical companies are therefore important, offering to help improve the governance and accountability of pharmaceutical companies.

While the AtMI may contribute somewhat towards holding pharmaceutical companies accountable, it is compromised by the lack of reliable and complete data, and the heavy reliance on the voluntary submission of data by companies. Although efforts are made to check the quality and completeness of the data used by AtMI, much of the data used cannot be independently and fully verified. As such, the Index is susceptible to incomplete, incorrect or misleading data (32). Furthermore, the raw data used by AtMF to calculate each companies' score are not made publicly available, making any independent replication of AtMF's rankings and scores difficult if not impossible.

Notwithstanding the issue of data, a further question about the value of AtMI as an accountability instrument is whether the standards against which to assess pharmaceutical company behaviour are strong enough. Put in other words, how does the AtMI balance the needs and rights of people with inadequate access to medicines in LMICs with the commercial interests of pharmaceutical companies and their investors? Alternatively, to what extent does the AtMI truly hold pharmaceutical companies accountable on behalf of LMIC populations as opposed to providing an impression of corporate social responsibility that helps ward off mandatory and more effective regulation? In this section, we discuss the strengths and weaknesses of the AtMI.

4.1 Impact

The AtMI is based on the assumption that access to medicines in LMICs may be improved by incentivising pharmaceutical companies to compete with each other for higher rankings because they would gain social and financial capital from achieving higher rankings. Whether this assumption is valid and to what extent is open to debate. Furthermore, gauging the specific contribution of the AtMI to changing company behaviour and practice is hard given other influences on company behaviour (for example, public-interest product development partnerships like the Drugs for Neglected Diseases Initiative, the actions of governmental agencies and the pressure of civil society campaigns will also impact on company behaviour).

To date, however, there has been no evaluation (independent or otherwise) of AtMI's actual impact on access to medicines in LMICs. Importantly, the Index does not include any direct indicators of access to medicines, including indicators based on the actual price of medicines and other products and their affordability. Instead, the AtMI assesses changes in policies, plans and practices that should improve access to medicines (albeit for a selected range of products, diseases/conditions and countries). Since the first iteration in 2008, ATMF has commissioned two longitudinal studies of the AtMI, the first published in 2014 (32) and the second in 2019 (33). Further improvements in company performance up to 2022 have also been published.

These include increased number of companies with goals, targets and long-term strategies for improving access to medicines in LMICs and a greater number of companies auditing compliance with codes of conduct and standards of behaviour. When it comes to R&D, the ATMF is able to report, for example, a doubling in the

number of R&D pipelines for priority diseases and conditions, an increase in the number of companies targeting NTDs and an increase in the percentage of products in late-stage R&D with access plans. And with product delivery, the AtMF can report that 19 companies now publish 'some level of disclosure' about the patents they held in 2022 and that the cumulative number of NEVLs (although since 2021 these have mainly been for Covid-19 products) and 'inclusive business models' has risen.

But to what extent will these reported improvements in company policy and practice actually improve access to medicines in LMICs? This is discussed in the next section.

4.2 The AtMI Standards

While several of the indicators used by the AtMI may help incentivise pharmaceutical companies to do more to improve access to medicines in LMICs, generally speaking, the indicators and the standards of behaviour embodied within them are weak leaving the AtMI to be a 'soft and friendly' measure of company performance. For example, some indicators have no minimum number of countries or diseases that must be covered to obtain a high mark, while the indicator assessing whether a company has 'access plans or strategies' required coverage of only one LMIC for a company to receive a score. Similarly, the indicator assessing licencing behaviour awards a top score of 5 if a company has issued only one NEVL for a relevant product. It is also telling that when clusters of companies score poorly on an indicator, the approach is to remove or modify the indicator. However, no similar adjustments appear to be made for indicators with a cluster of high scores.

Similarly, indicators measuring the mere existence of policies and plans without a detailed analysis of the quality, scope and rigour of these policies and plans, provides an opportunity for companies to score high marks without necessarily actually improving access to medicines. For some indicators, companies are also able to attain good marks simply for being able to 'showcase' some examples of good practice. While the 'showcasing' of a handful of examples of good practice may have some utility, it can also generate a misleading or exaggerated picture of socially responsible or benevolent behaviour. Many indicators are also so vague and unclear as to be of questionable value and some are arguably irrelevant (eg. indicators of health system strengthening) while giving companies an easy way to score high marks.

There are, however, some indicators which are stronger and have the potential to change behaviour in significant and meaningful ways. These include indicators related to IP rights and 'business models' and how these act as barriers to equitable access. However, it is notable that the weightings given to these indicators are relatively low despite the IP rights regime and the profit-centred nature of pharmaceutical companies being major barriers to access. It could also be argued that these indicators do not go far enough. For example, while the Index assesses lobbying against any softening of IP rights or against the use of TRIPS flexibilities, it does not capture lobbying against other policy solutions such as the introduction of price controls, or other behaviours such as making financial contributions to politicians or political parties, or to expert advisory groups, researchers and patient organisations.

Importantly, the AtMI does report relatively poor performance in these areas. For example, it notes that in 2022, only 4 companies publicly supported the Doha Declaration 'without reservations'. It also notes relatively little improvement in R&D directed at NTDs or at conditions affecting children in LMICs. AtMF also reports very little improvement in the registration of new products in LMICs while structured donation programmes for NTDs have only increased from 8 in 2010 to 11 in 2022 and the percentage of products with 'equitable pricing strategies' has only increased from 33% in 2014 to 43% by 2018, and where the majority of products with such pricing strategies did not fully meet AtMI quality criteria.

Crucially, in incentivising 'social responsibility' through voluntary participation in a voluntary and soft public scrutiny exercise, the AtMI does not attempt to change the political and economic structures governing the pharmaceutical sector and which act as major barriers to equitable access to medicines, including the regime of (expanding) private property rights, the oligopolisation of the pharmaceutical sector and the increased ability of companies to gouge excessive profits. Notably, a Special Report on Covid-19 that was part of the 2022 Index covered company performance on R&D and the delivery for Covid products (including registration, licensing, procurement agreements and technology transfer), but excluded mention of the extensive pharmaceutical lobbying against IP-sharing of Covid technologies or the excessive profiteering and profound inequity in vaccine access that occurred. Similarly, the AtMI as a tool does not address the weaknesses in the governance and regulation of the sector as a whole. For example, while there is an indicator on whether companies have been subjected to negative legal rulings or have settled cases for unethical, corrupt or anti-competitive practices, the fact that LMICs have little capacity to monitor corporate malfeasance or misconduct, let alone bring a case to court, is not addressed by the Index.

4.3 Scope and Governance

The AtMI is focused narrowly on behaviours and practices that are directly related to access to medicines in LMICs. However, the transnational pharmaceutical corporations may also impact on access to medicines in LMICs indirectly. For example, one of the causes of poor access to medicines is poverty at the level of both households and health systems. Among the determinants of poverty and under-resourced health systems is the large amount of 'tax abuse' perpetrated by TNCs, including pharmaceutical corporations. But this dimension of company behaviour is not included in the AtMI. Other asepcts of corporate conduct or behaviour that impact on health are also not included (e.g. employment and occupational health practices and environmental sustainability). There is thus a need for a broader and more holistic set of standards against which to hold pharmaceutical companies accountable.

Ultimately, efforts to hold powerful TNCs accountable require robust and independent mechanisms. Although the AtMF is an independent non-profit organization, its funders include actors with vested financial interests and close affiliations to multinational pharmaceutical companies. These include financial investors, notably Stewart Investors whose portfolio includes Roche and the Wellcome Trust who owns shares in Roche, Novartis and Johnson and Johnson. Some of AtMI's governmental funders also come with conflicts of interest – for example, the United Kingdom is home to GlaxoSmithKline, AstraZeneca and is actively seeking to grow its pharmaceutical sector (34). Similarly, the BMGF has interests in the pharmaceutical sector, including some of its endowment being invested in some pharmaceutical companies. Furthermore, although pharmaceutical companies have no direct involvement with AtMF or AtMI, they are heavily consulted during the regular methodological review process and several senior AtMI staff have previously worked for multinational pharmaceutical companies. The AtMI's dependence on the voluntary participation of pharmaceutical companies, particularly over the collection of data, may also create an in-built incentive for the AtMF to stay on good terms with the companies they are assessing

Meanwhile, the influence of civil society actors, especially from LMICs, on the design and implementation of the AtMI is relatively weak, and there is little in the way of forums at which companies are required to respond to questions or requests for explanations or justifications about their performance.

5. Conclusion

Developing a structured methodology to assess and rank corporate behaviour against a set of explicit standards and criteria is one way by which powerful pharmaceutical companies may be incentivised to behave more responsibly towards society and held accountable. However, if the standards or measures of performance are soft and weak, such an approach may end up acting as a form of 'whitewashing' that gives the impression that companies are contributing sufficiently to improving access to medicines when in fact deep inequities in access to medicines and other pharmaceutical products remain. This may be the case with the AtMI, which also neglects the social, political, financial and environmental conduct of pharmnaceutial companies. By doing so, the AtMI may contribute to a perceived lack of need for governments and inter-governmental organisations to enact or push for more effective and equitable governance and regulation of the pharmaceutical sector.

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Annex One: List of diseases, conditions and pathogens included in the 2022 AtMI

Rationale for inclusion

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				●	
Enteric 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					
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					●
Thalassemia		●			●
Sickle cell disease		●			
Stroke	●				
Unipolar depressive disorders	●				

Rationale for inclusion

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		●	●		
Reproductive, Maternal and Newborn Health Conditions					
Birth asphyxia and birth trauma		●	●		
Contraceptive methods			●	●	
Hypertensive disorders of pregnancy		●	●	●	
Abortion and miscarriage§		●	●		
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 2022 Index

Exclusions: none in 2021

* 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'.

Annex Two: Countries included in the 2022 Access to Medicine Index

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
Venezuela	HiHDI

Middle East & North Africa	
Algeria	LMIC
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 World Bank income classifications
LMIC	Lower-middle income country World Bank income classifications
LDC	Least Developed Country ECOSOC LDC List
LHDC	Low Human Development Country UN Human Development Index
MHDC	Medium Human Development Country UN Human Development Index
HiHDI	High Human Development Country with high inequality UN Inequality-Adjusted Human Development Index

* These include 106 countries assessed in the 2021 Access to Medicine Index, with two new countries in scope, that are Algeria and Venezuela. The latest country income and development classifications are available through the World Bank and UNDP data.

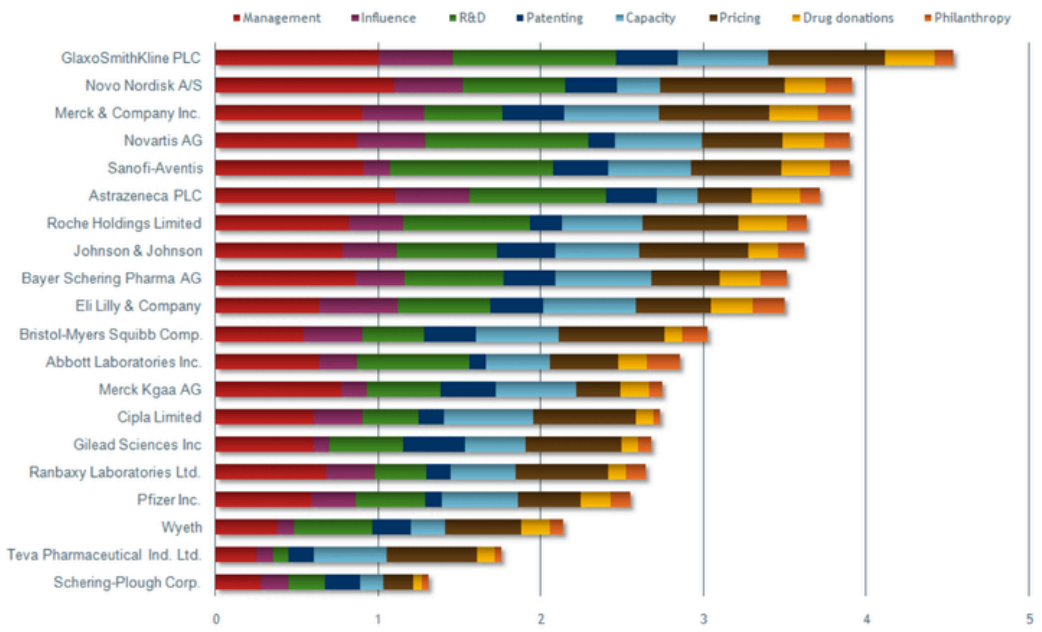
Annex Three: Overview of the methodological progression of the AtMI (24,35–42)

Index version	2008	2010	2012	2014
Technical areas	ATM Management – 20% Public Policy Influence & Advocacy – 10% Research & Development – 20% Patents & Licensing – 10% Manufacturing, Distribution and Capability Advancement – 15% Equitable Pricing – 15% Drug Donations – 6 % Philanthropy – 4%	ATM Management – 10 (10%*) Public Policy & Market Influence – 10 (10%*) Research & Development – 15 (25%*) Equitable Pricing, Manufacturing & Distribution – 20 (30%*) Patents & Licensing – 15 (10%*) Capability Advancement in Product Development and Distribution – 10 (15%*) Donations & Philanthropy – 10 (10%*)	ATM Management – 10% Public Policy & Market Influence – 10% Research & Development – 20% Equitable Pricing, Manufacturing & Distribution – 25% Patents & Licensing – 15% Capability Advancement in Product Development and Distribution – 10% Donations & Philanthropy –10%	ATM Management – 10% Public Policy & Market Influence – 10% Research & Development – 20% Pricing, Manufacturing & Distribution – 25% Patents & Licensing – 15% Capability Advancement in Product Development and Distribution – 10% Donations & Philanthropy –10%
Strategic pillar		Commitments Transparency Performance Innovations	Commitments Transparency Performance Innovations	Commitments Transparency Performance Innovations
Priority topics				
Number of Indicators	There are no sources in the current document. 94	112	101	95
Number of diseases	24	33	33	47
Number of countries	88	88	103	106

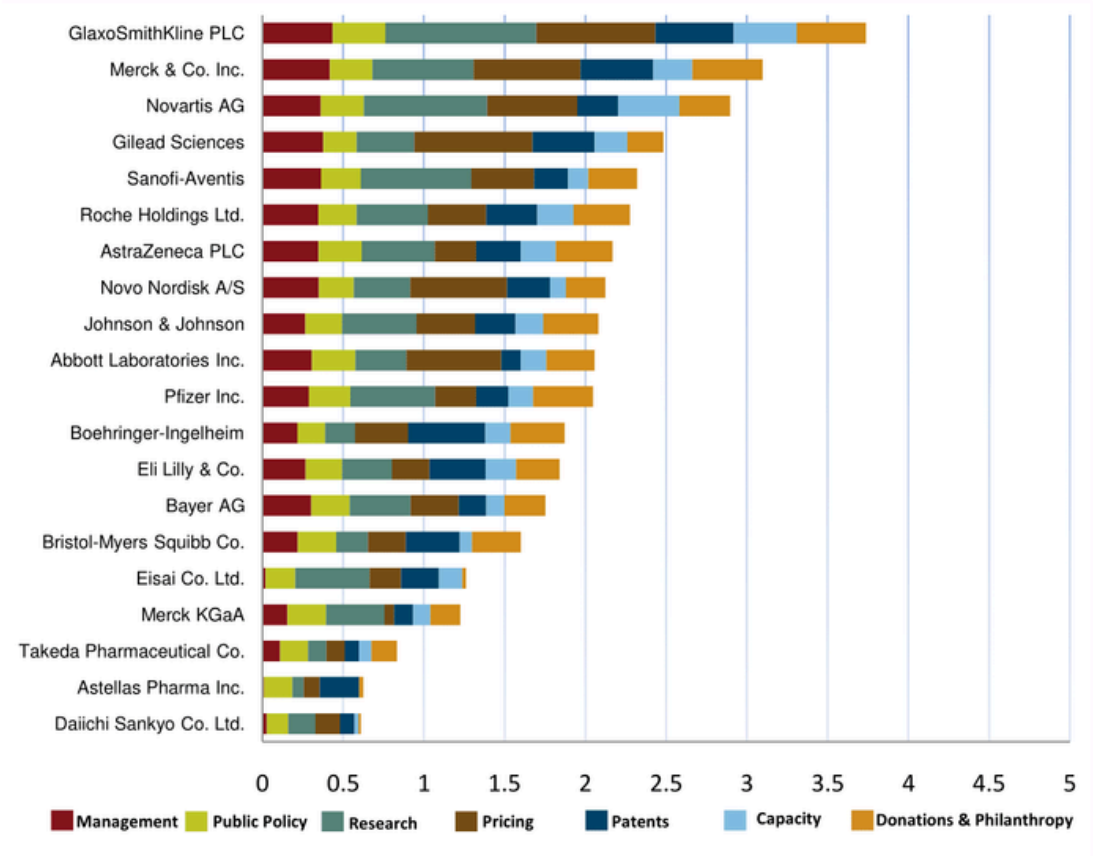
Index version	2016	2018	2021 (delayed 2020)	2022
Technical areas	1. ATM Management- 10% 2. Market influence & compliance- 10% 3. Research & Development – 20% 4. Pricing, Manufacturing & Distribution – 25% 5. Patents & Licensing – 15% 6. Capacity building– 10% 7. Product donations- 10%	1. ATM Management- 10% 2. Market influence & compliance- 10% 3. Research & Development – 20% 4. Pricing, Manufacturing & Distribution – 25% 5. Patents & Licensing – 15% 6. Capacity building- 15% 7. Product donations-5%	1. Governance of Access -20% 2. R&D– 25% 3. Product delivery -55%	1. Governance of Access -15% 2. R&D – 30% 3. Product delivery -55%
Strategic pillar	1. Commitments 2. Transparency 3. Performance 4. Innovations	1. Commitments 2. Transparency 3. Performance 4. Innovations		
Priority topics			1. Responsible business practices 2. Governance and strategy 3. Access planning 4. Product development 5. Building R&D capacity 6. Equitable access strategies 7. IP strategies 8. Quality and supply 9. Licensing quality 10. Product donations 1. Registration 12. Inclusive business model 13. Local manufacturing 14. Health system strengthening	1. Responsible business practices 2. Governance and strategy 3. Access planning 4. Product development 5. Building R&D capacity 6. Equitable access strategies 7. IP strategies 8. Quality and supply 9. Licensing quality 10. Product donations 11. Registration 12. Inclusive business model 13.Local manufacturing 14. Health system strengthening
Number of Indicators	83	69	33	31
Number of diseases	51	77	82	83
Number of countries	107	106	106	108

Annex Four: Overall ranking of the AtMI of all past editions

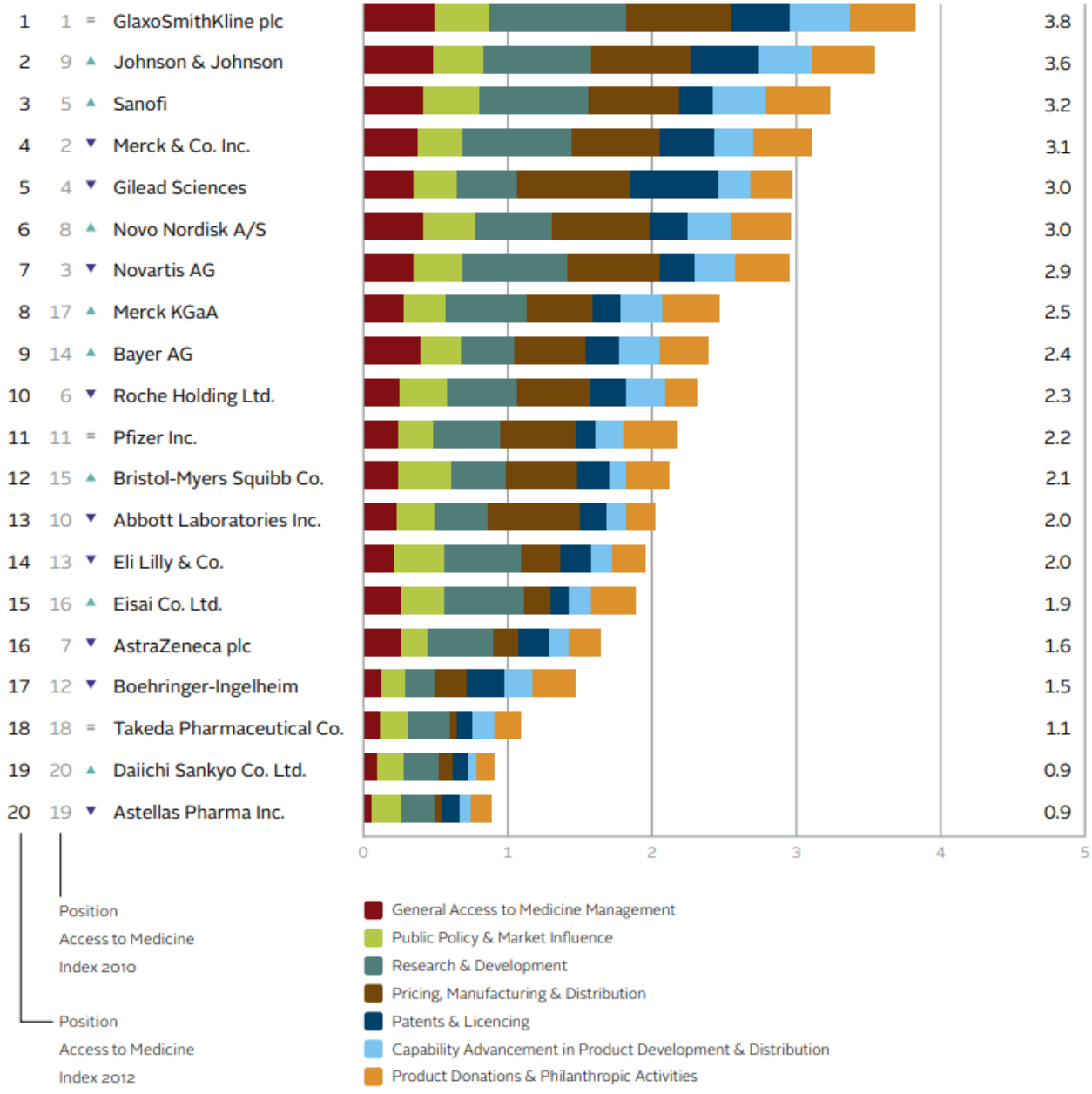
2008 Ranking



2010 Ranking

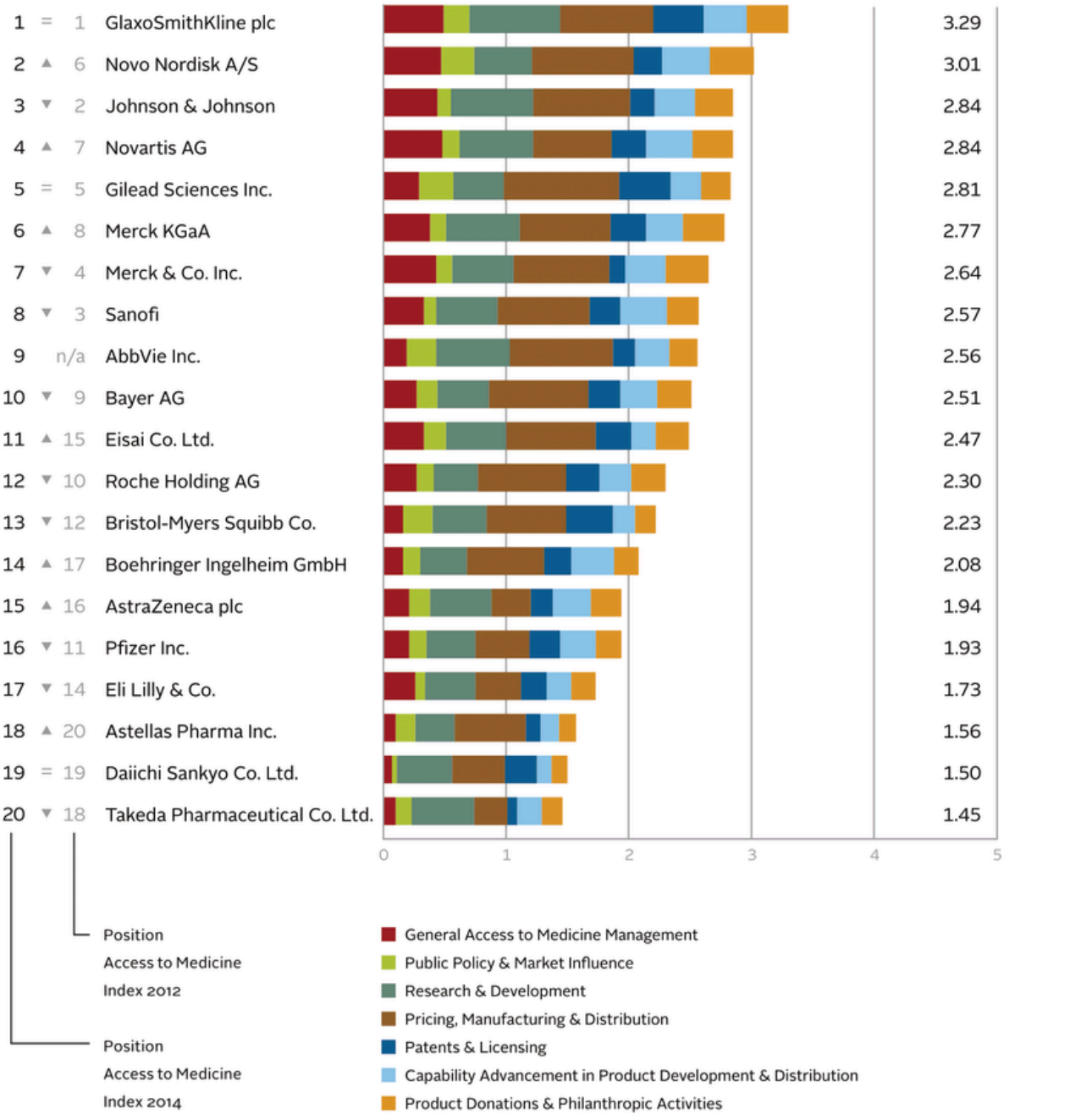


2012 Ranking



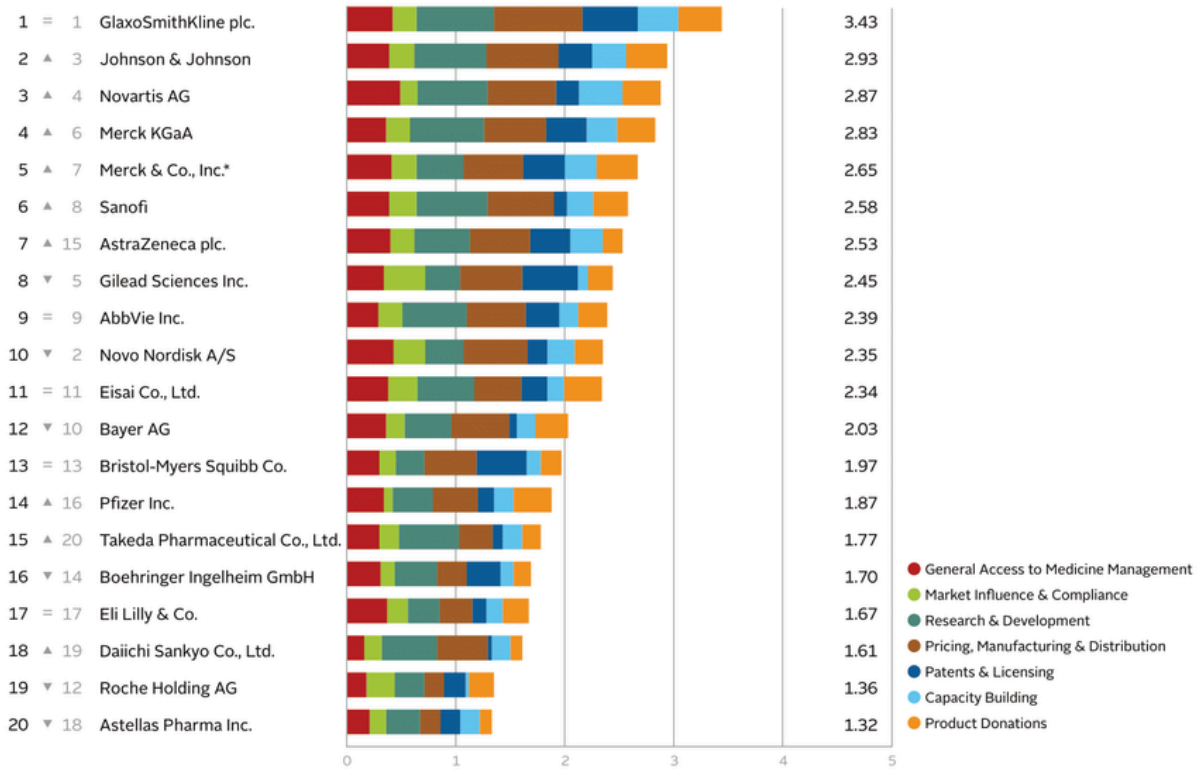
A score of zero means lowest and five signifies highest indicator score among the company set.

2014 Ranking

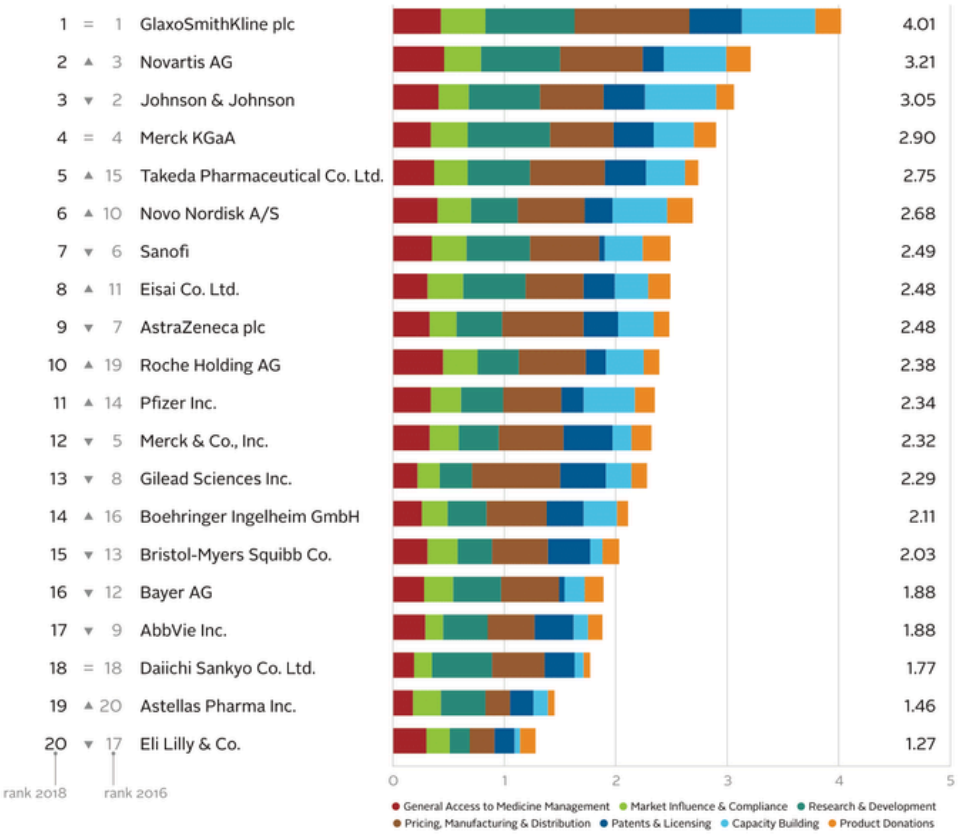


A score of zero means lowest and five signifies highest indicator score among the company set.

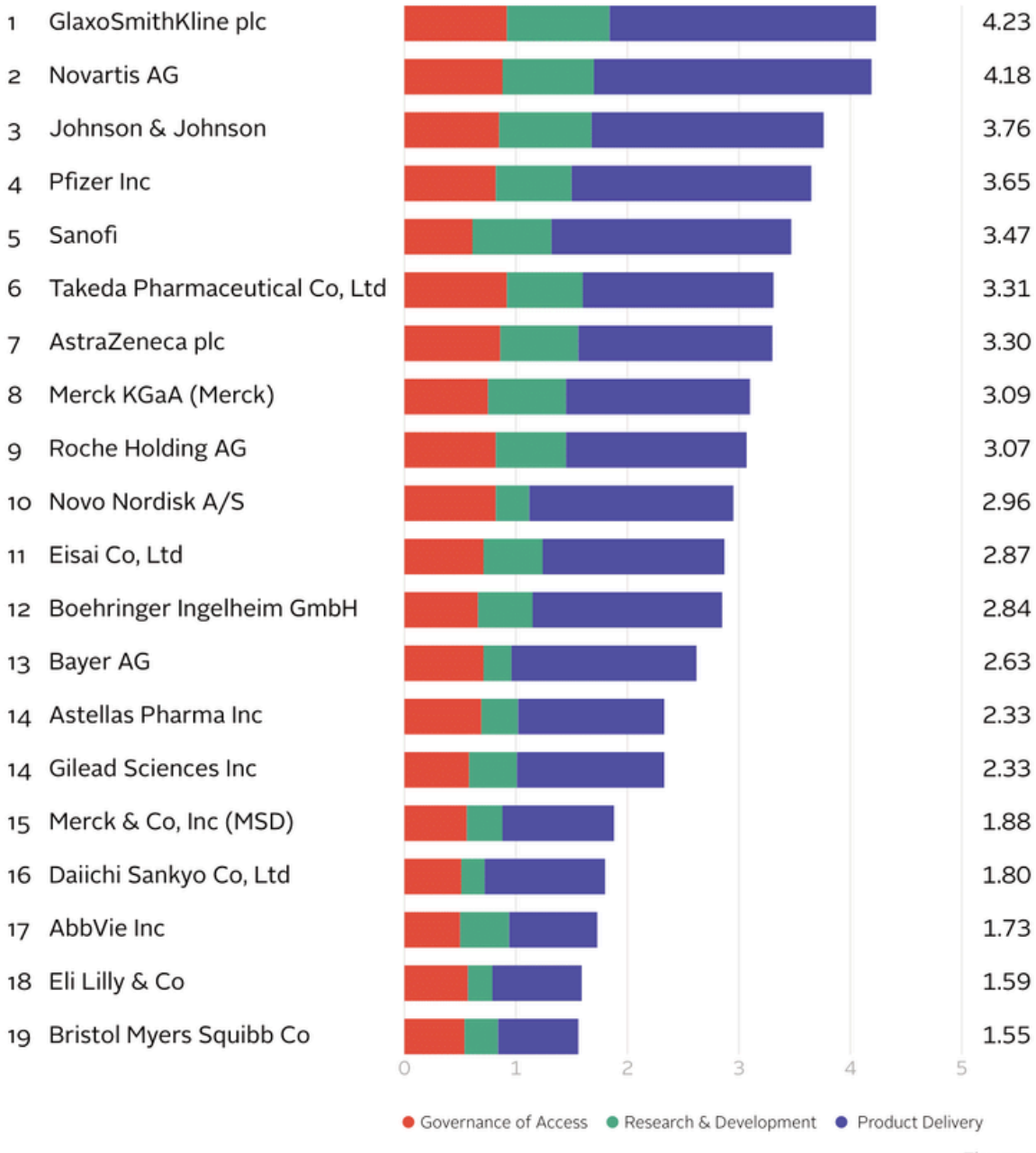
2016 Ranking



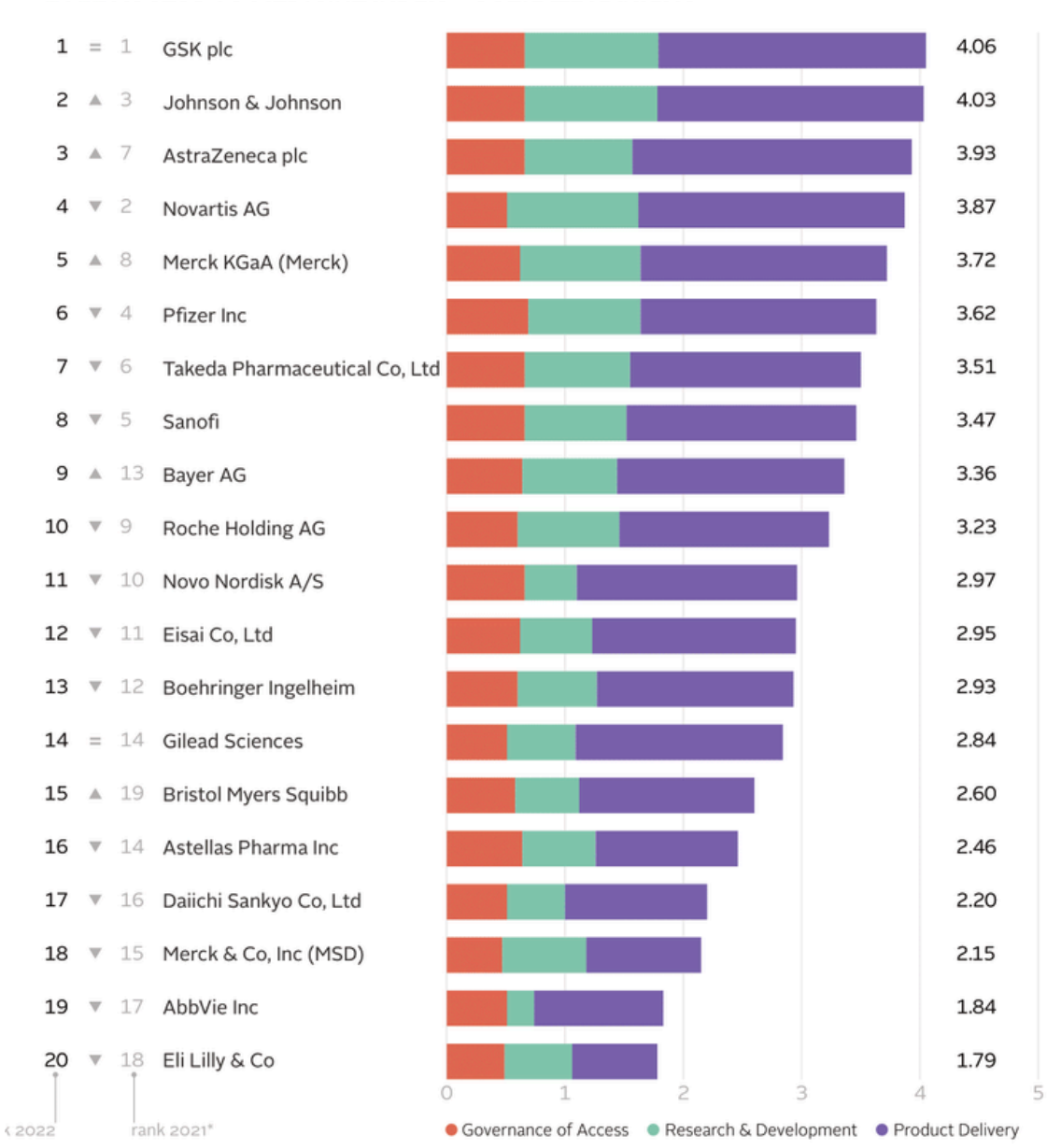
2018 Ranking



2021 Ranking



2022 Ranking



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