

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

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Addendum



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Addendum to

BRIEFING PAPER

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Written by Penelope Milsom (UNU-IIGH) and David McCoy (UNU-IIGH).

In October 2024, UNU-IIGH published an extensive analysis of the 2022 Access to Medicine Index (AtMI) and the underlying theory of how the Index promotes increasingly socially responsible corporate policies and practices over time. The analysis identified several limitations of 2022 AtMI. These included: data quality concerns about incomplete and reliable data; a lack of clarity about how data are translated into company scores for each indicator; the low standards against which companies are assessed; and the narrow scope of corporate conduct covered by the Index. While noting some improvement in company performance particularly in relation to AtMI indicators assessing access to medicine policies (but also some practices), we also observed a lack of hard evidence that the Index has actually improved access to medicines and other products in low- and middle-income countries (LMICs) in any significant way. We also pointed to how the Index may inadvertently undermine efforts to regulate pharmaceutical companies and thus paradoxically work against the public interest. This analysis is available [here](#).

Soon after publishing our analysis, the Access to Medicines Foundation (AtMF) published its ninth iteration of the AtMI in November 2024^[1] based on a modified and updated methodology. This Addendum assesses the differences between the 2022 and 2024 Index methodology and comments on whether the limitations of the AtMI identified in our initial analysis of the 2022 report remain valid. Here, we first describe how the 2024 Index compares to 2022 Index. In doing so, we conclude that the 2024 Index has been modestly improved by the introduction of new ‘patient reach’ indicators which has strengthened the assessment of whether companies are transparent about their methods for calculating and reporting improvements in patient reach. Further, the revisions made to some of the existing indicators have mostly resulted in a minimal or marginal strengthening of the standards against which companies are assessed, although in a few instances the bar appears to have been actually lowered. More importantly, the fundamental concerns and problems identified with the 2022 Index remain with the 2024 Index.

[1] This addendum has been written in reference to the Access to Medicine Index 2024 (Access to Medicine Foundation, 2024), the Access to Medicine Index 2024 Methodology (Access to Medicine Foundation, 2024.), and the Access to Medicine Index 2022 (Access to Medicine Foundation, 2022).

Changes to the selection of companies, products, diseases, and countries

The 2024 AtMI continues to rank only the 20 largest research-based pharmaceutical companies globally by the same criteria as in 2022 (market capitalization, revenue, and the relevance of their product portfolios and pipelines to the diseases and countries included in the Index). This group of companies remains unchanged from the 2022 Index. The eight product types covered in the 2022 AtMI are also unchanged in the 2024 iteration and include medicines, microbiocides (specifically topical microbiocides to prevent HIV), preventative vaccines, diagnostics designed for use in “resource-limited settings”, vector control products, contraceptives, and platform technologies.

The Index continues to focus on disease, pathogens, or conditions that predominantly affect people living in LMICs. All diseases, pathogens, and conditions in the 2022 AtMI remain in scope for the 2024 Index. However, ‘other endemic treponematoses’ (not covered in the 2022 Index) has now been included in the same single category with Yaws; and all three cardiovascular diseases (stroke, ischaemic heart disease, and hypertensive heart disease) that were included separately in the 2022 Index have now been grouped into a single umbrella category ‘cardiovascular diseases’ with all cardiovascular diseases now included in 2024. This grouping of diseases reduces the total number of categories of diseases, conditions and pathogens in scope from 83 to 81. These include 23 communicable diseases, 20 neglected tropical diseases, 16 non-communicable diseases, 10 reproductive maternal and newborn health conditions, and 12 priority pathogens.

Countries covered in the 2024 Index were selected based on the same criteria as in 2022: countries’ level of income, level of development and scale and scope of inequality. However in addition, countries included in the 2022 Index that no longer qualify for inclusion under these criteria (e.g., higher income level) were maintained in the 2024 Index to facilitate longitudinal analysis and to prevent frequent switching out of countries. 113 LMICs met these inclusion criteria for the 2024 Index, an increase from 108 in the 2022 Index with the addition of Jamaica, Jordan, Lebanon, Marshall Islands, and St Lucia.

Index methodology review process

The methodology review process appears to have been largely unchanged although it was stated that indicators which had a cluster of high scores in 2022 were taken as a signal that the standards against which company performance should be assessed for those indicators may need to be raised.

The same proportionate mix of stakeholders involved in the process remain unchanged: 21% 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. However, it was reported that the proportion of stakeholders representing LMICs had increased and that gender parity in the consultations had been achieved.

Dedicated discussions and roundtables on the topic of ‘patient reach’ were organised to inform the modification of existing indicators and development of new indicators. And for the 2022 Index, an Expert Review Committee with a similar mix of backgrounds and institutional affiliations (including WHO, industry, consumer organizations, academia, investors, NGOs, and governmental institutions) was convened to oversee revisions of the 2024 index.

Changes to the evaluation framework, indicators, and metrics

Table One summarises the differences between the 2022 and 2024 Indexes. Red text in the table signifies revisions made to the indicators in 2024 while strike throughs show 2022 indicators that have been merged, removed, or reworded in 2024. The three technical areas and their weightings remain unchanged: Governance of Access (15%), Research and Development (30%), and Product Delivery (55%). However, the number of priority topics has increased from 14 to 15 and the number of indicators has increased from 31 to 32.

Table One: Comparison between 2022 and 2024 evaluation framework, Indicators and metrics

Technical area	Priority topic	Indicator		2022 (%)	2024 (%)
Governance of Access 15%	Governance & Strategy	Governance structures & incentives (GA1)	Retained	2.14	1.8
		Access-to-medicine strategy <i>and outcomes</i> (GA2)	Merged	2.14	3
		Public disclosure of access to medicine outcomes (GA3) Merged into GA2	Merged	2.14	
	Responsible Business Practices	Responsible promotional <i>business</i> practices (GA4)	Modified	2.14	1.8
		<i>Ethics, risks and compliance</i> Controls (GA5)	Modified	2.14	1.8
		Incidence of breaches (GA6)	Modified	2.14	1.8
		Trade policy: IP and access to medicine (GA7)	Modified	2.14	1.8
	<i>Measuring and Reporting Patient Reach</i>	<i>Measuring and reporting patient reach (G8)</i>	New		3
Research & Development (R&D) 30%	Product Development	R&D pipeline: Prioritised diseases (RD1A)	Retained	6.75	5.75
		R&D Pipeline: Other diseases (RD1B)	Retained	4.50	4.5
	Access Planning	Planning for access: Structured Framework (RD2)	Modified	2.25	2.25
		Planning for access: Project-specific plans for prioritised diseases (RD3a)	Retained	5.25	6
		Planning for access: Project-specific plans for other diseases (RD3b)	Modified	5.25	6
	Product Development	Disclosure of resources dedicated to R&D (RD4)	Retained	3.00	3

	Building R&D Capacity	Capacity building in R&D (RD6)	Retained	3.00	2.5
Product Delivery 55%	Registration	Registration <i>performance</i> (PR1)	Modified	5.00	5
	Product Donations	Access strategies: Ad hoc donations (PP2a)	Modified	2.00	1
		Access strategies: Long-term donation programmes (PP2b)	Retained	4.00	3
	Equitable Access Strategies and outcomes	Access Strategies: Supranational products (PP3)	Modified	6.50	6.5
		Access <i>Strategy quality</i> : Healthcare practitioner-administered products (PP4a)	Modified	6.50	3.25
		Access <i>Strategy outcomes</i> : Healthcare practitioner-administered products (PP4b)	New		3.25
		Access <i>Strategy quality</i> : Self-administered products (PP5a)	Modified	6.50	3.25
		Access <i>Strategy outcomes</i> : Self-administered products (PP5b)	New		3.25
	Intellectual Property (IP) Strategy	Patent filing & enforcement (PPL1)	Retained	2.00	1.5
		Patent status disclosure (PPL2)	Retained	1.50	1.5
		IP sharing (PPL3)	Retained	1.50	1.5
	Licensing Quality	<i>Quality and geographic coverage of access-oriented quality</i> -licensing (PPL4)	Merged	2.50	4.5
		Licensing: Geographic scope (PPL5)	Merged		
		Ensuring continuous supply (PQ1)	Modified	3.00	4
	Quality and Supply	Reporting substandard and falsified medicines (PQ2)	Retained	3.00	2
		Capacity building in supply chains - <i>chain management</i> (PCB2)	Retained	3.00	2.5
Local Manufacturing	Capacity building in manufacturing (PCB1)	Retained	3.00	2.5	
Health System Strengthening	Health systems strengthening (PCB3)	Retained	3.00	2.5	
Inclusive Business Models	Inclusive business models (PBM1)	Modified	2.00	4	

Fourteen of the 31 indicators from the 2022 Index remain unchanged in the 2024 AtMI. The most significant positive change in the 2024 Index is a modest increase in focus on assessing whether companies transparently measure and report outcomes of each company's access to medicine strategies and plans. This has been done by placing a greater emphasis on the concept of 'patient reach' which refers to assessing the actual number of people that have managed to access a company's products. A new indicator 'Measuring and reporting patient reach' (G8) evaluates "the approaches to measuring and reporting patient reach that are being employed by companies". The other significant change is the splitting of two of the 2022 product delivery indicators into two components so as to add two indicators on the outcomes of access strategies for healthcare practitioner-administered products (PP4b) and for self-administered products (PP5b). However, these new 'patient reach' indicators do not appear to score companies on the ambition of their access goals, quality of their approach to measuring patient reach, or actual progress on improving this outcome (see appendix below for further details). Further, 'patient reach' alone is a weak indicator of equity of access or affordability.

Several other indicators have been merged or modified as shown in Table One. In our assessment, some of these changes have resulted in a modest or marginal increase in the standards against which companies are assessed. However, some of the changes appear to have resulted in no significant change in the standards, and in a few instances such as with indicator GA7, the bar that has been set for companies looks to have been lowered (see appendix below).

When it comes to the weighting of indicators, there have only been minor adjustments. The most heavily weighted indicators continue to be included under the priority topics 'Product Development' and 'Equitable Access Strategies', as well as 'Access Planning' and 'Registration'. The lowest weightings continue to be given to 'IP Strategy' and 'Responsible Business Practice' indicators. Additionally, the indicator on 'Ad hoc Donations' has (appropriately) been reduced in weight from 2% to 1%, although arguably this indicator should be removed entirely from the Index.

The approach to scoring is unchanged. As in 2022, companies are scored out of five for each indicator based on specific criteria. Each indicator is weighted before being combined to give an overall score out of five for each technical area. These scores are then combined to give a final composite score out of five.

In summary, while the increased focus on assessing transparency of company measurement and reporting on patient reach in the 2024 AtMI methodology is a positive development, many of the indicators of company performance used in the Index remain relatively weak or soft.

Changes to the Scope and Wider Impact of AtMI

As with the 2022 Index, the scope of 2024 Index remains narrow, leaving many important dimensions of corporate conduct and behaviour with impacts on health (direct and indirect) unassessed. These include for example, corporate financial transparency and conduct in terms of corporate tax abuse, as well as various forms of corporate political activity. As such we remain concerned that the Index may do more to benefit the twenty biggest companies by helping to reinforce their dominance of the sector and prop up their image as socially responsible actors than to benefit people and governments in LMICs.

Furthermore, the 2024 Index reports an overall decrease in performance across the 20 companies compared to 2022. While this is partly due to the strengthening of the Index (as described above), companies also performed worse in areas where indicator standards have not been raised including indicators related to access-oriented licensing and product development for priority diseases.

While it is notable that the AtMF uses some strong language to publicly criticise companies for not scoring more highly, as we elaborate in our detailed analysis of the 2022 Index, the assumption that the Index is an effective instrument for changing company policies and behaviours to improve access to medicines in LMICs is at the very least questionable. And because it fails to assess whether companies engage in anti-social or positively harmful behaviour in relation to, for example financial or political conduct, the concerns we raised about the 2022 Index potentially causing more harm than good remain valid for the 2024 Index.

Appendix: Detailed description and assessment of revisions made in the 2024 AtMI

The Table below provides our assessment of the revisions made in the 2024 iteration of the AtMI. This includes merged, modified and new indicators. **Green** type indicates elements that have been integrated or merged into a single 2024 indicator from another now removed indicator included in 2022; **blue** type indicates significantly new elements in a 2024 indicator compared to 2022 (this does not include rewording with no substantive change in meaning or detail); **orange** type indicates wording in the 2022 Index to show how an element of an indicator has been substantively modified in 2024; and **red** type indicates an entirely new indicator in 2024.

Governance of Access

GA2: Access-to-medicine strategy and outcomes (Merged with GA3)

Indicator

The company has an access-to-medicine strategy which it demonstrates is integrated within its corporate strategy and extends across the company's portfolio and pipeline, for diseases within scope of the Index. **As part of the company's access-to-medicine strategy, it establishes and publicly shares progress on time-bound, measurable objectives, goals and targets related to improving access to medicine in countries within scope of the Index, as well as associated outcomes (e.g. increased proportion of people with more knowledge about diseases, symptoms or treatments or number of patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; and/ or availability of medicines at outlets, or number of health professionals trained).**

Scoring guidelines

5 The company has a clear access-to-medicine strategy with evidence of integration with the corporate strategy. The strategy is applied across the company's portfolio and pipeline, within the Index scope. **As part of its access-to-medicine strategy, the company publicly and clearly discloses its commitments to access to medicine, alongside company-specific measurable goals, objectives and targets. The associated outcomes for all initiatives related to improving access to medicine are clearly reported (or the company plans to report outcomes when available). This is done regularly, and to facilitate accountability and transparency, is centrally available directly on its website.**

4 The company has an access-to-medicine strategy that is integrated with its corporate strategy and applies to all or some of its portfolio and pipeline. The company publicly discloses its commitments to access to medicine, **including at least one company-specific target, goal or objective. While not all of the goals may be measurable, the company demonstrates an effort towards specificity and measurability. The company reports on the associated outcomes, although the reporting may not be regular or fully centralised.**

3 The company has an access-to-medicine strategy that is integrated with its corporate strategy and applies to all or some of its portfolio and pipeline. **As part of its access-to-medicine strategy, the company publicly discloses its commitments to access to medicine, as well targets, goals, objectives and outcomes (or plans to report outcomes when available), but not for all initiatives in which it is involved. Reporting may not be centralised or updated regularly.**

2 The company has an access-to-medicine strategy with a business rationale which applies to all or some of its portfolio and pipeline. **As part of its access-to-medicine strategy, the company publicly discloses its commitments to access to medicine, as well as access to medicine targets, goals, objectives and outcomes (or plans to report outcomes when available), but not for all initiatives in which it is involved. Reporting may not be centralised or updated regularly.**

1 The company has made commitments to improve access to medicine but does not have an access-to-medicine strategy, although it may be in the process of implementing one.

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

In 2024 a useful process indicator that encourages companies to publicly disclose their commitments, goals and outcomes with respect to improving access to medicines (GA3 in the 2022 Index) has been merged with a fairly weak input indicator of the existence of a strategy to improve access to medicines in LMICs (GA1). The quality and relevance of the strategy to LMICs is still not assessed nor the level of ambition of the company's commitments, goals, objectives and targets. Merging these two indicators does not appear to significantly change the standard companies are measured against.

GA4: Responsible promotional practices (Modified)

Indicator

The company incentivises responsible business practices by **taking steps** to decouple bonuses for sales agents (including sales representative employees and third parties) from sales volume targets only, **evidencing that sales targets are not set at the individual level and that sales target bonuses represent a minimal portion of overall compensation**. The company has a **clear public policy to ensure ethical interactions with healthcare professionals (HCPs) which has provisions specifying the legitimate need for the interaction and limiting transfers of value** (include payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary benefits directed at HCPs) in countries in scope of the Index. Additionally, the company publicly discloses information about such transfers of value in countries in scope of the Index, where this is permitted by law. **Companies should have a process in place to determine the legitimate need for HCP interactions and to ensure fair market value at both payment per interaction level and cumulative/overall payments per HCP.**

Scoring guidelines

5 The company demonstrates that they have no sales targets set at the individual level. Bonuses for sales agents are decoupled from sales volume targets only, **and sales target bonuses represent a minimal proportion of overall compensation**. It has a **public policy to ensure ethical interactions with HCPs [2022: a policy to limit transfer of value to HCPs]** and voluntarily discloses information regarding its approach to, or actual, transfers of value to HCPs in all countries in scope of the Index, and not only when required by law, regulation or trade association.

4 The company demonstrates that they have no sales targets set at the individual level. Bonuses for sales agents are decoupled from sales volume targets only, **and sales target bonuses represent less than half of overall compensation**. It has a **public policy to ensure ethical interactions with HCPs [2022: a policy to limit transfer of value to HCPs]** and discloses information regarding its approach to, or actual, transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

OR

The company demonstrates that they have some sales targets set at the individual level. **Bonuses for sales agents are decoupled from sales volume targets only, and sales target bonuses represent less than half of overall compensation**. It has a **public policy to ensure ethical interactions with HCPs [2022: a policy to limit transfer of value to HCPs]** and voluntarily discloses information regarding its approach to, or actual, transfers of value to HCPs in some countries in scope of the Index, and not only when required by law, regulation or trade association.

3 The company demonstrates that they have some sales targets set at the individual level, and bonuses for sales agents are decoupled from sales volume targets only. It has a **public policy to ensure ethical interactions with HCPs [2022: a policy to limit transfer of value to HCPs]** and discloses information regarding its approach to, or actual, transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association. **[2022: criteria for scoring 3 or 4 were combined]**

2 The company demonstrates that they have some sales targets set at the individual level **[2022: Sales agent incentives are driven exclusively by sales volume targets and targets are set at the individual level]** and bonuses for sales agents are decoupled from sales volume targets only. It has a **public policy to ensure ethical interactions with HCPs [2022: a policy to limit transfer of value to HCPs]**, but the policy does not fully align with the standards set by the Index. It discloses information regarding its approach to, or actual, transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

1 The company does not decouple bonuses for sales agents from sales volume targets, i.e. incentives for sales agents are driven (almost) exclusively by sales volume targets. **The company has a statement on payments to HCPs but does not provide evidence of a public policy to ensure ethical interactions with HCPs that align with the standards set by the Index [2022: It has no policy to limit transfers of values to HCP]**. It discloses information regarding transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association.

0 The company does not decouple bonuses for sales agents from sales volume targets, i.e. incentives for sales agents are driven (almost) exclusively by sales volume targets. The company does not have a statement on payments to HCPs nor does it provide evidence of a public policy to ensure ethical interactions with HCPs that align with the standards set by the Index. It only refers to adhering to voluntary disclosure codes on payments to HCPs. It discloses information regarding transfers of value to HCPs in countries in scope of the Index, but only when required by law, regulation or trade association [2022: 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].

AtMF appears to have somewhat strengthened this potentially useful indicator in 2024 to discourage companies from linking financial rewards for sales agents from the volume of medicines they sell and encouraging companies to have clear public policy on ethical interaction with healthcare professionals including specifying the legitimate need for the interaction and limiting transfers of value.

Beyond the 2022 requirements to score a 5, companies must now provide evidence that sales target bonuses represent a minimal proportion of overall compensation, have a public policy to ensure ethical interactions with HCPs, and specifies that the company must voluntarily disclose information regarding its approach to, or actual, transfers of value to HCPs in all countries in scope of the Index, and not only when required by law, regulation or trade association”.

However, the scoring standard for this indicator could be set higher and be more transparent. This could include specifying what must be covered in a public policy on “ethical interactions” with HCPs and potentially also requiring companies to commit to, and provide evidence of, ceasing to “transfer value to HCPs” entirely. Additionally, a company should not be able to score 5 for simply disclosing its approach to transfers of value to HCPs but rather must provide evidence of their actual transfers of value to HCPs.

GA5: Ethics, risks and compliance Controls-(modified)

Indicator

The company has one or more policies in place to mitigate the risk of non-compliance in its operations in LMICs – including by affiliated third parties – covering areas such as ethical marketing, anti-corruption and clinical trials. The company also has country- or region-specific procedures in place to operationalise the policies, taking into account country- or region-specific risks. In addition, the company has a policy or framework in place to guide and promote ethical decision-making among employees. The Index looks for procedures such as fraud-specific risk assessment, country or region risk-based assessments and processes to ensure third-party compliance.

Scoring guidelines

5 The company demonstrates that it has robust controls in place to mitigate the risk of non-compliance in its operations in countries in scope of the Index, which include the following components:

- (a) one or more policies on ethical marketing, anti-corruption and clinical trial standards;
 - (b) formal processes in place to ensure third-party compliance with ethical marketing, anti-corruption and clinical trial standards [2022: ALSO that it takes enforcement action for non-compliance (by third parties) in countries in scope of the Index];
 - (c) fraud-specific risk assessment;
 - (d) country or region risk-based assessment;
 - (e) policy or framework that guides and promotes ethical decision-making among employees.
- [2022: additional component: a live/continuous monitoring system for compliance (other than Auditing)]

4 The company has four of the above-mentioned elements in place that align with the standards set by the Index.

3 The company has at least three of the above-mentioned elements in place that align with the standards set by the Index.

2 The company has at least two of the above-mentioned elements in place that align with the standards set by the Index.

1 The company has at least one of the above-mentioned elements in place that align with the standards set by the Index.

0 The company has no policies or procedures in place which are designed to mitigate risk of non-compliance in its operations in LMICs and, has no framework to guide ethical decision making

This indicator aimed at discouraging unethical or corrupt practices does not appear to have significantly changed and may have in fact been weakened. AtMF explains the wording of this indicator has been updated to “improve company understanding of the information required and to look at ethical decision- making policies/frameworks.”

To score a 5 on this Indicator in the 2024 AtMI a company is no longer required to demonstrate “that it takes enforcement action for non-compliance (by third parties) in countries in scope of the Index” or have “a live/continuous monitoring system for compliance (other than auditing)” in the areas of ethical marketing, anti-corruption, and clinical trials. However, companies are now required to have a “policy or framework that guides and promotes ethical decision-making among employees” but the 2024 Index does not appear to assess the adequacy, quality or effectiveness of this policy or the other outlined controls to mitigate non-compliance.

GA6: Incidence of breaches (modified)

Indicator

The company has not been found to be the subject of negative legal rulings or settled legal cases for unethical marketing practices, corrupt practices, anti-competitive practices, or misconduct in clinical trials during the past two years. In the event of such a ruling or settlement, there is publicly available evidence that the company has taken remedial actions (including cooperation with authorities) and steps designed to ensure the breach does not occur in future.

Scoring guidelines

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

[2022: 3 The company has not been the subject of any criminal or civil infractions in countries within the scope of the Index, but it has been the subject of one breach of a code of practice in one of the countries within the scope of the Index.]

2 The company has been the subject of at least one negative ruling or settlement [2022: more than one breach of code of practice] in a country[ies] within the scope of the Index over the period of analysis. There is publicly available evidence of the company taking either robust remedial actions and/or steps designed to ensure the breach does not reoccur.

0 The company has been the subject of at least one negative ruling or settlement in a country within the scope of the Index over the period of analysis. There is no evidence of the company taking robust remedial actions or steps designed to ensure the breach does not reoccur.

Little change has been made to this indicator monitoring breaches of codes, regulations or laws. In 2024 companies are simply required to also make public evidence that the company has taken remedial actions in the event of a legal settlement or ruling.

It remains the case that 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.

GA7: Trade policy: IP and access to medicine (modified)

Indicator

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 international framework on IP (i.e., the Doha Declaration on the TRIPS Agreement and Public Health). This is evidenced by the company having a publicly available IP policy or statement which discloses explicit support for, and is in line with, the principles embodied within the Doha Declaration on TRIPS and Public Health. [additionally in 2022: this is evidenced by an absence of IP-related anti-competitive practices in relation to access to medicine in countries in scope. These include *Patenting in Least Developed Countries, lobbying against the usage of TRIPS flexibilities by country governments within the Index scope (including through trade associations), lobbying for strengthening of IP standards beyond TRIPS in countries within the scope of the Index, evergreening]

Scoring guidelines

5 The company has a publicly available statement or policy on IP and access to medicine. The policy/statement discloses explicit support for, and is in line with, the Doha Declaration, with no reservations expressed on any of the provisions of TRIPS flexibilities. [Additionally in 2022: 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 has a publicly available statement or policy on IP and access to medicine. The policy/statement discloses explicit support for, and is in line with, the Doha Declaration, though reservations can be expressed on some of the provisions of TRIPS flexibilities.

3 The company has a publicly available statement or policy on IP and access to medicine. The policy/statement discloses a degree/measure of support for, and is partially in line with, the Doha Declaration and/or the use of the provisions of TRIPS flexibilities. [Additionally in 2022: However, it has been involved in one IP-related anti-competitive practice via industry associations.]

1 The company has a publicly available policy or statement on IP and access to medicine, but this is not supportive of, or in line with, the Doha Declaration and/or the use of provisions of the TRIPS flexibilities. [Instead in 2022: The company has been involved in more than one IP-related anti-competitive practice* via industry associations.]

0 The company has no publicly available statement or policy on IP and access to medicine. [Instead in 2022: the company has been directly involved in anti-competitive IP-related practices.]

An indicator to measure company compliance with the principles of the Doha Declaration, including supporting countries in the appropriate use of TRIPS flexibilities is valuable, however this already weak indicator appears to set a potentially lower bar in 2024. In the latest Index, this indicator requires an access conducive IP policy (that confirms explicit support for the Doha Declaration, with no reservations on any of the provisions of TRIPS flexibilities), but it no longer attempts to assess in any way (albeit imperfectly) a company's actual IP-related anti-competitive practices in relation to access to medicines.

It remains true that the barriers to access presented by TRIPs as well as the practical and political difficulties in using TRIPs flexibilities makes this an even weaker indicator than it should be.

GA8: Measuring and reporting patient reach (new)

Indicator

The indicator measures whether a company has a process in place for measuring patient reach that:

- a) Is publicly available in terms of underlying methodology (equation/metrics/assumptions/ limitations);
- b) extends across the company's portfolio, for diseases within scope of the Index;
- c) covers all countries within scope of the Index, where the company's products are sold;
- d) regularly reports resulting patient reach numbers publicly;
- e) incorporates clear goals and objectives to measure and improve patient reach and associated health outcomes over time, and can demonstrate such improvements.

Scoring guidelines

5 The company has a process in place for measuring patient reach which: is publicly available in terms of underlying methodology (equation/metrics/assumptions/limitations); extends across the company's portfolio, for diseases within scope of the Index; covers all countries within scope of the Index, where the company's products are sold; regularly reports resulting patient reach numbers publicly; incorporates clear goals and objectives to measure and improve* patient reach and associated health outcomes over time, and can demonstrate such improvements.

4-1 The company has a process in place for measuring patient reach that meets a number of the following criteria: a) is publicly available in terms of underlying methodology (equation/metrics/assumptions/limitations); b) extends across the company's portfolio, for diseases within scope of the Index; c) covers all countries within scope of the Index, where the company's products are sold; d) regularly reports resulting patient reach numbers publicly; e) incorporates clear goals and objectives to measure and improve* patient reach and associated health outcomes over time and can demonstrate such improvements.

0 The company does not provide evidence (publicly or directly reported to the Index) of having a process in place for measuring patient reach.

* Improvement in patient reach does not necessarily mean an increase in patients receiving a product (for example, where the goal of a product is elimination or eradication of a disease)

This is a new and useful indicator assessing whether a company has processes in place to measure and report on patient reach and also aims to encourage companies to show evidence that they are increasing patient reach over time.

However, it does not appear to score companies on the quality of a company's approach to measuring patient reach. This is important since if measured poorly, or presented non-transparently, patient reach data can give a misleading impression of improved access to medicines. Patient reach does not necessarily provide information on equity of access or whether products effectively reach patients in need for the whole treatment duration and not those who don't need it e.g. inappropriate use of antibiotics).

A company's level of ambition of its goals nor its actual progress on improving patient reach are assessed.

Further, patient reach alone is an insufficient indicator of access to medicines given it does not assess affordability.

Lastly, this indicator only covers countries where a company's products are currently registered for sale (usually UMCs) and therefore does not capture the huge unmet need for medicines in many especially LICs where companies are at least five times less likely to register their products.

Research and Development

RD2: Planning for access: **Structured Framework (modified)**

Indicator

The company ensures it plans for equitable access for all products it develops successfully (both in-house and collaboratively) for people in LMICs and demonstrates a systematic approach to access for all R&D projects, which is applied from Phase II of clinical development onwards. The company makes public commitments addressing its systematic approach to access planning for LMICs

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) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations. Access plans are initiated no later than Phase II of development. [The company makes public commitments addressing its systematic approach to access planning for LMICs.](#)

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) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations. [Access plans are initiated no later than Phase II of development.](#)

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

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

1 The company has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.

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

The description of this relatively weak indicator has been made somewhat clearer in 2024. The standards set in the scoring system are marginally higher with the additional requirement for a score of 5 in 2024 being that the company makes “public commitments addressing its systematic approach to access planning (for pipeline candidates from Phase II onwards) in LMICs”. To score a 4 a company must also now ensure “access plans are initiated no later than Phase II of development”.

It remains unclear how the quality of companies’ access plans are considered in the scoring system.

RD3B: Planning for access: Project-specific plans for other diseases (modified)

Indicator

The company ensures that all its R&D projects targeting diseases in scope of the Index (beyond those identified as R&D priorities by WHO and Policy Cures Research) are supported by detailed plans to improve access to products in countries within scope of the Index.

Scoring guidelines

5-1 Scaled across all companies. The extent to which a company engages in access planning for its late-stage R&D projects [targeting other diseases in scope of the Index beyond those identified as R&D priorities by WHO and Impact Global Health \(i.e. those included under indicator RD1b\)](#) [2022: [only targeting diseases that meet externally defined priorities identified by Policy Cures Research and/or WHO](#)]. This is determined by:

- the proportion of late-stage candidates with access plans in place;
- the quality of access plans;
- the extent of the geographic reach of access plans.

[2022: access plans assessed “on breadth and depth”]

0 The company provides no evidence of access plans for any late-stage R&D projects that [target other diseases in scope of the Index beyond the R&D priorities identified by WHO and Impact Global Health \(i.e. those included under indicator RD1b\)](#) [2022: [that meet externally defined priorities within the scope of the Index. Nor does it provide evidence of any partnerships with access-oriented organisations for these projects.](#)]

This indicator now aims to assess advanced access planning for all in scope products not prioritised by WHO and Policy Cures Research (starting from Phase II), beyond those that address an R&D priority gap (as was the focus in the 2022 Index). The scoring framework is slightly more transparent in 2024, although the details provided as to what level of commitment or quality of strategy is needed to score highly on this indicator remain insufficient.

Product Delivery

PR1: Registration (modified)

Indicator

The company broadly files to register its most recently launched* products that target diseases in scope of the Index, in countries with the highest disease burden.** [The company provides evidence of engaging with mechanisms to facilitate registration, such as WHO Collaborative Registration Procedure, where applicable](#)

Scoring guidelines

5 The company registers its products, in a majority of countries in scope of the Index and in a majority of countries with the highest disease burden** and engages in mechanisms to facilitate registration of its products in LMICs.

4-1 Scaled across companies. The number of countries in which the company registers its products*** and the proportion of these which have high disease burdens.** Whether a company engages in mechanisms to facilitate registration of its products in LMICs.

[to score 4-1 scaled across companies in 2022: Number of newer products (those that were first approved to be marketed in the last 5 years anywhere globally, that targets diseases within scope) 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 (those that were first approved to be marketed within the last 5 to 20 years anywhere globally, that targets diseases within scope) that are filed for registration in number of countries with the highest disease burden and in a number of countries in scope of the Index.]

0 The company provides no evidence of filing to register any of its products in scope that target diseases in the Index scope in any countries in scope.

* Most recently launched' refers to the date that the product was first approved to be marketed anywhere globally. The Index analyses information for up to ten of the company's most recently launched products, depending on the size of the company's portfolio

** The ten countries in scope with the highest DALY rate per disease

*** For analysis, the number of countries where the product is registered is weighted according to the length of time the product has been on the market.

This process indicator monitors if companies are filing to register new products rapidly in LMICs, an essential first step in ensuring access. The description of this indicator is somewhat more detailed and the single significant change to the scoring framework is the requirement that a company engages in mechanisms to facilitate registration of its products in LMICs such as WHO Collaborative Registration Procedure.

PP2a: Access strategies: Ad hoc donations (modified)

Indicator

The company has policies and supply processes in place to ensure ad hoc donations (in line with WHO guidelines) are carried out rapidly in response to expressed need. Efforts are made - in house and/or via partner organisations - to monitor delivery of donations to ensure that they reach the patient.

Scoring guidelines

5 The company has policies and supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company publicly commits to adhering to the most recent WHO guidelines on medicine donations. Efforts are made [2022: polices or processes in place]- in-house and/or via partner organisations - to monitor delivery of donations to ensure that they reach the patient.

4 The company has policies and supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company either has no commitment or commits to adhering to the most recent WHO guidelines on medicine donations, but these commitments are not public. Efforts are made - in-house and/or via partner organisations - to monitor delivery of donations to ensure that they reach the patient.

[In 2022 the was no option to score 4. To score 2.5 in 2022: The company has policies/agreements/supply processes in place to ensure all of its ad hoc donations are carried out rapidly in response to expressed needs. However, neither the company nor its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user, being the patient.]

0 The company does not have policies or supply processes in place to ensure ad-hoc donations are carried out rapidly in response to expressed need. The company does not commit, publicly or otherwise, to align with the WHO guidelines for medicine donations. No efforts are made - in-house and/or via partner organisations - to monitor delivery of donations to ensure that they reach the patient

The indicator description is somewhat more detailed in 2024. It is unclear whether the scoring for this indicator sets a higher bar in 2024. While companies are now required to commit to adhering to WHO guidelines on medicine donations to score a 5, they are only required to make “efforts” to monitor delivery of donations to ensure that they reach the patient, rather than have policies and processes in place to do this. Further, the extent or quality of these “efforts” do not appear to be assessed.

PP3: Access strategies: Supranational products (modified)

Indicator

The company applies access strategies to its supranationally procured products (those for which international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist) and extends those strategies to countries which do not qualify for the procurement agreements [2022: AND to those countries graduating from development assistance]. This is evidenced by:

- a) an access strategy to supply the product through a supranational procurement agreement;
- b) an access strategy for a country outside of the procurement agreement that demonstrates how relevant payer(s)' ability to pay is considered, and how additional strategies improve the affordability and availability of the product for the different segments of the country's population across the full income pyramid. The company's strategy demonstrates goals aimed at improving patients' health outcomes and tracks the progress (number of patients reached or elimination/eradication targets achieved) of the access strategy. This is evidenced by: i) methods to define the total eligible patient population; ii) evidence of patient reach during the period of analysis; iii) evidence of how the strategy has progressed, and future plans for advancing the strategy.

Scoring guidelines

5 For all its supranationally procured products selected for analysis, the company meets all following criteria:

- a) Evidence of an access strategy to supply the product through a supranational procurement agreement, including:
 - i) evidence of the access terms of the supranational agreement including pricing;
 - ii) evidence of the outcomes and impact of the agreement including the number of patients reached during the period of analysis.
- b) Evidence of an access strategy in a country that does not qualify for supranational procurement agreements, where:
 - i) it applies the same pricing terms of the supranational agreement and/or provides details of a pricing strategy that considers the ability to pay of all relevant payers in the country;
 - ii) it applies additional strategies (e.g. patient assistance programmes, donations, voluntary licensing, and technology transfer) to complement pricing strategies to increase reach among patients across the income pyramid;
 - iii) it reports the outcomes of the strategy and demonstrates that:
 - (a) it sets clear measurable access strategy goals aiming to increase sustainable access across the income pyramid;
 - (b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
 - (c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;
 - (d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

[In 2022 to score 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 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.]

4-1 For its supranationally procured products selected for analysis, the extent to which the company meets the following criteria:

- a) Evidence of an access strategy to supply the product through a supranational procurement agreement, including:
 - i) evidence of the access terms of the supranational agreement including pricing;
 - ii) evidence of the outcomes and impact of the agreement including the number of patients reached during the period of analysis.

- b) Evidence of an access strategy in a country that does not qualify for supranational procurement, where:
- i) it applies the same pricing terms of the supranational agreement and/or provides details of a pricing strategy that considers the ability to pay of all relevant payers in the country;
 - ii) it applies additional strategies* to complement pricing strategies to increase reach among patients across the income pyramid;
 - iii) it reports the outcomes of the strategy and demonstrates that:
 - (a) it sets clear measurable access strategy goals aiming to increase sustainable access across the income pyramid;
 - (b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
 - (c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;
 - (d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

[In 2022 to score 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 For its supranationally procured products selected for analysis, the company meets none of the above listed criteria. NS Companies without products in scope that are supranationally procured receive a neutral score.

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.

The main modification to this indicator is the inclusion of an assessment of whether a company sets access strategy goals and provides evidence of the methods used to calculate targets and to measure patient reach and health outcomes. The ambition of goals and quality of methods is not scored.

The scoring guidelines are though clearer in 2024, differentiating between criteria for access strategies to supply the product through a supranational procurement agreement and access strategies for countries that does not qualify for supranational procurement.

In 2022 a maximum of only five products were evaluated per company however this detail is not specified for the 2024 Index. It does appear though that companies are only required to provide evidence of an access strategy in just one country that does not qualify for supranational procurement, allowing cherry picking of their most comprehensive and effective access strategies.

PP4a: ~~Access Strategies~~ Strategy quality: Healthcare practitioner-administered products (modified)

Indicator

The company takes into consideration both the relevant payer(s)' ability to pay and the demographic characteristics of a country to determine its access strategy, aiming to [improve the affordability and availability of its healthcare practitioner-administered products](#) and increase reach among patients across the income pyramid.

This is evidenced by:

- a) an access strategy that demonstrates how the relevant payer(s)' ability to pay for the different segments of the population is considered and any additional strategies (e.g. patient assistance programmes, donations, voluntary licensing, technology transfer etc.) to complement pricing strategies;
- b) initiatives to strengthen health systems and [build capacity to ensure the continuum of care for the product](#) [in 2022: to improve the availability of the products.]

[In 2022 evidence of how the approach has increased the patient number since the product was introduced and plans to increase patient numbers for the following X years were also included here. Assessment of patient reach is now in a stand-alone outcomes indicator PP4b]

Scoring guidelines:

5 For all its healthcare practitioner-administered products selected for analysis, the company meets all the following criteria for all three country income classifications:

- a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price;
- b) it applies additional strategies to complement pricing strategies to increase reach among patients across the income pyramid;
- c) it implements health system strengthening initiatives to facilitate the continuum of care for the product. [in 2022: to improve the availability of the products.]

[In 2022 to score 5 a company was also required to fulfil additional criteria of providing evidence of increased or planned increases in the number of patients reached- this is now assessed in a stand-alone outcomes indicator PP4b]

4-1 For its healthcare practitioner-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income classifications:

- a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price;
- b) it applies additional strategies to complement pricing strategies to increase reach among patients across the income pyramid;
- c) it implements health system strengthening initiatives to facilitate the continuum of care for the product. [in 2022: to improve the availability of the products.]

[In 2022 assessment of evidence of increased or planned increases in the number of patients reached was included here- this is now assessed in a stand-alone outcomes indicator PP4b]

0 For its healthcare practitioner-administered products selected for analysis, the company meets none of the above listed criteria.

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

This indicator evaluates the quality of a company’s access strategy for practitioner-administered products across the income spectrum. Assessment of the outcome (including patient reach) of the access plan has been removed from this indicator in 2024 and included as a more robust stand-alone indicator PP4b (below). There is otherwise little material change to the way this indicator attempts to measure access plan quality.

In 2022 access strategies for a maximum of just five products were evaluated per company in one country per income classification (lower-income, lower middle-income, upper middle-income), however this detail is not specified for the 2024 Index.

PP4b: Access strategy outcomes: Healthcare practitioner-administered products (new)

Indicator

The company demonstrates it has a process in place to monitor the performance of the access strategy for its health practitioner-administered products aimed at reaching patients across the income pyramid. The company’s strategy demonstrates goals aimed at improving patients’ health outcomes and tracks the progress* of the access strategy to ensure that goals are achieved. This is evidenced by:

- a) methods to define the total eligible patient population and patient reach;
- b) evidence of patient reach during the period of analysis;
- c) evidence of how the strategy has progressed, and future plans for advancing the strategy [In 2022 this criterion was previously included in what is now indicator PP4a]

Scoring guidelines

5 For all its healthcare practitioner-administered products selected for analysis, the company meets all the following criteria in all three country income classifications:

- a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid;
- b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
- c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;
- d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

[In 2022 this criterion was previously included in what is now indicator PP4a]

4-1 For its healthcare practitioner-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income classifications:

- a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid;
- b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
- c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach;
- d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy. [In 2022 this criterion was previously included in what is now indicator PP4a]

0 For its healthcare practitioner-administered products selected for analysis, the company meets none of the above listed criteria.

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

A stand-alone indicator that assesses whether a company has a process for **monitoring the performance of the** healthcare practitioner-administered products' access strategies is an improvement on the 2022 Index.

However, as for GA8, this indicator does not appear to score companies according to the quality of a company's approach to measuring patient reach (which, if measured poorly, or presented non-transparently can give a very misleading impression of improved access to medicines). See comment on GA8 for further details.

The extent of a company's actual progress on improving patient reach is also not scored.

Further, patient reach alone is an insufficient indicator of equity of access to medicine or affordability.

If the method remains unchanged since 2022, this indicator also only assesses each company's approach to measuring and reporting patient reach as outcomes of their access plans for a small selected group of healthcare practitioner-administered products in just one country from each income classification (LIC, LMIC and UMIC).

As for other indicators the scoring guidelines provide insufficient detail for use by independent researchers.

PP5a: Access Strategy **quality**ies: Self-administered products (modified)

Indicator

The company takes into consideration both the relevant payer(s)' ability to pay and the demographic* characteristics of a country to determine its access strategy, **aiming to improve the affordability and availability of its self-administered products** and increase reach among patients across the income pyramid. This is evidenced by an access strategy that demonstrates how all the relevant payer(s)' ability to pay for the different segments of the population is considered and any additional strategies to complement pricing strategies.

[In 2022 evidence of how the approach has increased the patient number since the product was introduced and plans to increase patient numbers for the following X years were also included here. Assessment of patient reach is now in a stand-alone outcomes indicator PP5b]

Scoring guidelines

5 For all its self-administered products selected for analysis, the company meets all the following criteria for all three country income classifications:

- a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price;
- b) it applies additional strategies to complement pricing strategies to increase reach among patients across the income pyramid.

[In 2022 to score 5 a company was also required to fulfil additional criteria of providing evidence of increased or planned increases in the number of patients reached- this is now assessed in a stand-alone outcomes indicator PP45b]

4-1 For its self-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income classifications:

- a) it applies equitable pricing strategies that take into account the ability to pay of all relevant payers within the country, providing evidence that demographic and economic factors are considered when setting the price;
- b) it applies additional strategies to complement pricing strategies to increase reach among patients across the income pyramid.

[In 2022 assessment of evidence of increased or planned increases in the number of patients reached was included here- this is now assessed in a stand-alone outcomes indicator PP5b]

0 For its self-administered products selected for analysis, the company meets none of the above listed criteria

This indicator evaluates how companies support access to self-administered products across the income spectrum. Assessment of the outcomes of each company's self-administered products access plan has been removed from this indicator in 2024 and included as a more robust stand-alone indicator PP5b (below).

In 2022 access strategies for a maximum of only five products were evaluated per company in one country per income group (lower-income, lower middle-income, upper middle-income), however this detail is not clearly specified for the 2024 Index.

PP5b: Access strategy outcomes: self-administered products (new)

Indicator

The company demonstrates it has a process in place to monitor the performance of the access strategy for its self-administered products aimed at reaching patients across the income pyramid. The company's strategy demonstrates goals aimed at improving patients' health outcomes and tracks the progress (e.g. number of patients reached or elimination/eradication targets achieved) of the access strategy to ensure that goals are achieved. This is evidenced by:

- a) methods to define the total eligible patient population (defined as the patients that have been diagnosed or identified by a healthcare professional as suitable recipients of the product based on the licensed indication) and patient reach.
- b) evidence of patient reach during the period of analysis [In 2022 this criterion was previously included in what is now indicator PP5a]
- c) evidence of how the strategy has progressed*, and future plans for advancing the strategy.

Scoring guidelines

5 For all its self-administered products selected for analysis, the company meets all the following criteria in all three country income classifications:

- a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid;
- b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
- c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting number including patient reach; [In 2022 this element was previously included in what is now indicator PP5a and could also just have been a company's "planned increase in numbers reached"]
- d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

4-1 For its self-administered products selected for analysis, the extent to which the company meets the following criteria across the three country income classification:

- a) it sets clear, measurable access strategy goals aiming to increase sustainable access across the income pyramid;
- b) it provides evidence of the methods used to calculate the strategy's targets and the resulting numbers including the total eligible patient population and the target patient population;
- c) it provides evidence of the methods used to measure the outcomes of the strategy and the resulting numbers including patient reach; [In 2022 this element was previously included in what is now indicator PP5a and could also just have been a company's "planned increase in numbers reached"]
- d) it provides evidence that the strategy has progressed, and future plans for advancing the strategy.

0 For its self-administered products selected for analysis, the company meets none of the above listed criteria.

See comment on PP4b.

PPL4: Quality and geographic coverage of access-oriented licensing (merged with PPL5)

Indicator

The company grants access-oriented, transparent, non-exclusive voluntary licences which include clauses that facilitate affordability and supply of quality products. The company includes a broad range of countries within the geographic scope of its licences, from a range of country income classifications.

Scoring guidelines

5-1 Scaled across companies. The extent to which a company engages in access-oriented non-exclusive voluntary licensing and the quality of these licence(s) as determined by: • the extent to which the licensing agreement(s) includes access-oriented clauses* to facilitate access and whether these terms are transparent and publicly disclosed. • the extent of the geographic reach of the licensing agreement(s).

[In 2022 scoring was clearer:

5 The company has at least one NEVL (non-exclusive voluntary licensing) 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, with relevant products in its portfolio to pursue a VL.

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

2022 Indicators PPL4: Access-oriented licensing' and 'PPL5: Licensing: Geographic scope' have been merged into this single PPL4 indicator in the 2024 AtMI.

The scoring for this indicator has been revised to a scaling approach where presumably companies are scored relative to each other (between 5 and 1) on the "extent to which a company engages in access-oriented non-exclusive voluntary licensing and the quality of these licences", now including the extent of geographic reach. This is a less transparent scoring approach. It is difficult to assess whether this merged indicator raises or in fact lowers the bar for access-oriented licensing.

In 2022 access strategies for a maximum of only five products were evaluated per company in one country per income group (lower-income, lower middle-income, upper middle-income), however this detail is not clearly specified for the 2024 Index.

PQ1: Ensuring continuous supply (modified)

Indicator

The company has mechanisms in place to **improve supply chain** efficiency and takes informed action to ensure uninterrupted supply. The company uses the following mechanisms to make products available in sufficient quantities in a timely manner in LMICs:

- a) The company has a system in place and works with relevant stakeholders (e.g., government agencies, distributors, hospitals, warehouses, wholesalers, or other relevant networks) to communicate about issues that may affect the supply chain.
- b) The company manages a buffer stock of relevant, finished products.
- c) The company works with several active pharmaceutical ingredient (API) suppliers, holds API buffer stocks and/or produces in-house APIs.
- d) The company works to enhance local **[2022: third party]** supply capacities and strengthen supply chains.*
- e) The company transfers technology (e.g., for API, vaccine adjuvant and/or drug product) to manufacturers to improve manufacturing capacity and availability in LMICs* **and/or manufactures relevant products in LMICs**

Scoring guidelines

5 The company has elements (a) through (e) in place and provides an example of implementing these activities to improve supply of a product addressing a disease in scope of the Index in a country in scope.

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

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

Ensuring continuous supply and preventing the risk of stock-outs means patients who need essential medicines can continue to access high-quality products. AtMF report that for this indicator they now also “collect additional data on company efforts to support manufacturing capacity in LMICs” however it is not clear how this is reflected in the indicator itself with the only revision compared to 2022 the addition to criteria e) “and/or manufactures relevant products in LMICs”. The scoring guidelines remain essentially unchanged. Further, to score 5 a company only needs to show evidence of implementing the described elements to ensure continuous supply for one product in one country, setting a low bar.

PBM1: Inclusive business models (modified)

Indicator

The company develops and implements inclusive business models that aim to provide its products to populations in LMICs **that have been under-served or unserved [2022: at the base of the income pyramid in countries within scope of the Index]**, by existing business models. These models work in partnership to address access issues and have long-term plans for scalability and to achieve a sustainable source of revenue in the long term. **[In 2022: For all models, the company discloses resources invested into the model and there is evidence of, or projections for financial sustainability.]** Outcomes of these models are measured over time.

Scoring guidelines

5 The company develops and implements inclusive business model(s) with evidence of long-term aims for scalability. These **models are comprehensive, addressing multiple access barriers for under-served or unserved populations.** There is evidence that the company is aiming for a sustainable source of revenue through the model in the long-term **[2022: and has scaled up one or more existing inclusive business models.]**

[in 2022 a company could score 4 if it had 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 develops and implements inclusive business model(s), **but these address a less comprehensive range of access barriers of under-served or unserved populations, lack evidence of long-term plans for generating a sustainable source of revenue** or lack evidence of long-term plans for scalability **[2022: but has not scaled up any existing inclusive business models during the analysis period.]**

2 The company does not develop or implement inclusive business model(s) but engages in strategies or targeted initiatives that aim to specifically address the access needs of under-served or unserved populations.

0 There is no evidence of inclusive business model(s), strategies or targeted initiatives designed to address the access needs of under-served or unserved populations

AtMF states this indicator has been modified to expand the target population addressed (from “populations at the base of the income pyramid and /or vulnerable populations that face additional barriers to access” to “populations in LMICs that have been under-served or unserved, by existing business models”) and to focus analysis on models offering company products.

To score 5 for this indicator in 2024 companies were required to show evidence of model comprehensiveness in addressing multiple access barriers for under-served or unserved populations which sets a somewhat higher bar for this indicator (this was not required to score 5 in 2022). However, in 2024 a company is only required to show “evidence of long-term aims for scalability” instead of evidence of having actually scaled up one or more inclusive business model as was required for a score of 5 in the 2022 Index.

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ABOUT UNU-IIGH

The UNU International Institute for Global Health (UNU-IIGH) in Kuala Lumpur, Malaysia, operates as the designated UN think tank specialising in global health. With a mandate to facilitate the translation of research evidence into policies and tangible actions, UNU-IIGH serves as a hub connecting UN member states, academia, agencies, and programmes.

Established through a statute adopted by the United Nations University Council in December 2005, the institute plays a pivotal role in addressing inequalities in global health. UNU-IIGH contributes to the formulation, implementation, and assessment of health programmes.

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