The changing story of access to medicines

The 2024 Access to Medicine Index shows that some manufacturers are increasingly prioritising LMICs, but broader interest in equitable access is waning. Udani Samarasekera reports.

A decade ago, access to medicines was a different story. Governments were willing to use compulsory licensing to produce generic versions of drugs without approval from the patent holders. Meanwhile, pharmaceutical companies offered some access to their products through philanthropic donations. But, according to the 2024 Access to Medicine Index, released on Nov 19, a noticeable shift has happened in how the pharmaceutical industry approaches access to medicines, with several large firms now prioritising low-income and middle-income countries (LMICs) in their business strategies.

Despite this development, however, other findings in the 2024 Index are less favourable for access to medicines. The Index reveals that companies favour high-income settings for clinical trials, which limits access to new treatments in LMICs. Firms also prefer specific countries for technology transfer and too few have voluntary licensing agreements for their patented products. "There are two very specific, proven ways in which companies can directly contribute to improving local availability, which is licensing and technology transfers, and these tools are available to them, and we do need to see more expansion, and companies leveraging those opportunities to really partner up with the right manufacturers to be able to make this happen", explained Claudia Martínez, Director of Research at the Access to Medicine Foundation, which produces the biennial Access to Medicine Index.

Experts are not surprised by many of the findings in the 2024 Index. Despite calls for equitable access to medicines and technology transfer to LMICs after the COVID-19 pandemic, they think the international community's interest in this area is waning. Actions to strengthen African manufacturers and provide incentives to drug companies

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to expand their partner countries are needed, researchers say. They highlight problems with voluntary licensing too. Some health advocates are calling for governments to use compulsory licensing to improve access to life-saving products for their populations.

The Access to Medicine Index has been published every 2 years since 2008 to measure the performance of the 20 largest research-based pharmaceutical companies on access to medicines in more than 100 LMICs. In the 2024 Index, 81 diseases, conditions, and pathogens that disproportionately affect LMICs are covered, including malaria, preterm birth complications, and clarithromycin-resistant *Helicobacter pylori*. To measure company performance, the Access to Medicine Foundation uses 32 indicators relating to governance of access, research and development, and product delivery. Companies tracked include GSK, Sanofi, and AstraZeneca. Although the methodology for the Index is tweaked every 2 years after input from different stakeholders, several indicators have remained stable, allowing progress to be tracked over time.

The latest Index found that five pharmaceutical companies are now implementing so-called inclusive business models. "These are exactly developed with the needs of low-income populations in mind. These are models trying to be sustainable financially but also be rooted on partnerships" with local organisations and ministries of health, explained Martínez. All the models involve companies selling or supplying some of their products or their entire portfolio through affordability strategies adapted to specific settings. Most of the strategies aim to supply products for non-communicable diseases that have no traditionally been supplied to LMICs. "So it is interesting", Jayasree Iyer, CEO of the Access to Medicine Foundation, told *The Lancet*. "We are cautiously excited, but we still need to see the outcomes and the tracking of the actual patient reach for these specific models", she noted.

Claire Wagner at the non-profit Bill & Melinda Gates Medical Research Institute, which partners with industry, commented that "integrating patient reach into strategic planning and evaluation is not easy" but if industry and its partners can get better at doing so, it will result in "greater collective impact in global health".

Suerie Moon, Co-Director of the Global Health Centre at the Geneva Graduate Institute, commended the Access to Medicine Foundation for getting data for the Index from pharmaceutical companies, but she would like firms to share more information about their business strategies to assess their equity implications. "It would be very useful to have information about pricing and affordability", she noted.

Another key finding in the 2024 Index is that only 297 (43%) of 685 clinical trials analysed were done in LMICs. Although the Index argues that doing more trials in LMICs can lead to faster product registration and availability in those countries, it is "not a panacea to increase access

as, for any given drug, this will only concern a few countries and even there affordable access is not automatically assured", commented paediatrician Tido von Schoen-Angerer, who was the Executive Director of the Médecins Sans Frontières *Access* Campaign from 2006 to 2012. "We still need companies' commitment to register their medicines and to make them affordable across LMICs", he said.

The Index also revealed that only two new non-exclusive voluntary licensing (NEVL) agreements were issued between June, 2022, and May, 2024, the period of analysis, with a third afterwards. However, the Medicine Patent Pool currently lists at least ten patented products in companies' portfolios as priorities for voluntary licensing, including lenacapavir (Gilead) for HIV and nersivemab (AstraZeneca and Sanofi) for respiratory syncytial virus. So "there is untapped potential for companies to engage more", noted Martínez.

Voluntary or compulsory licensing to generic producers is the key driver for affordability in LMICs, noted von Schoen-Angerer. But voluntary licensing agreements have not always materialised, he says, citing Gilead's "disappointing" decision for a restrictive bilateral licensing system for HIV prevention drug lenacapavir.

Risdiplam to treat spinal muscular atrophy is also "a striking example of lack of affordability and need for generic availability", von Schoen-Angerer said. "Roche has registered the drug in more than 100 countries but markets risdiplam at £7900 per bottle in the UK and at US$7400 in India. It has only 2163 patients on compassionate-use programmes across 59 countries, 23 of these in LMICs, thus leaving many behind", he explained. Yet Roche has denied requests for voluntary licensing. Roche told *The Lancet*: "Our aspiration is to enable sustainable broad and rapid access to Evrysdi (risdiplam) around the world. We are actively collaborating with local governments on sustainable access and funding solutions", adding that its programme "remains the largest and most inclusive compassionate use programme in spinal muscular atrophy".

Other experts highlight problems with a focus on voluntary licensing. Ellen 't Hoen, founder and first Executive Director of the Medicine Patent Pool and now at Medicines Law & Policy, a coalition working on access to medicines, said "the weakness of relying on voluntary licensing lies in the fact that the companies hold all the cards. They hold the patents and the know-how. While they were willing to license their intellectual property for infectious diseases such as HIV and [hepatitis] C, this is not the case for products to treat non-communicable diseases such as cancer, diabetes, and cardiovascular disease."

NEVL agreements also need to be paired with technology transfers to local manufacturers to allow long-term, sustainable access to products, highlighted the Index. But "aside from South Africa, sub-Saharan Africa is still very much overlooked", said Martínez. Companies are favouring Brazil, India, and China for their partnerships.

Part of the problem might be a reduction in global interest in technology transfers after the COVID-19 pandemic, thinks Moon. "There were a lot of announcements and attention to technology transfer initiatives for vaccines in the wake of COVID…a lot of that initial enthusiasm in terms of real projects, initiatives on the ground that will deliver something concrete seems to have dissipated in my view", she said.

Ken Shadlen, Professor of International Development at the London School of Economics and Political Science, is not surprised by the Index's findings on technology transfers. Big pharmaceutical firms are "going to strike agreements with companies that they know are going to reliably be able to make the product and that they feel comfortable working with. They're often reluctant to get engaged with new companies and there aren't that many companies on the African continent that most pharmaceutical firms have a lot of experience in engaging with", he said.

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He thinks strengthening local firms so they are more likely to be regarded as good partners is crucial, and highlighted the African Vaccine Manufacturing Accelerator of Gavi, the Vaccine Alliance as an example of work in this area. Drug companies need incentives to consider new partners too. For example, global purchasers of vaccines or medicines, such as Gavi, could require firms to have broad production networks or consider this factor when evaluating bids, Shadlen explained.

To improve access to medicines, experts think governments should be more outspoken about the need for voluntary licences and technology transfer. Some support stronger action. "There is a lot of lip-service paid to voluntary agreements as we see today at the negotiations for the pandemic accord at the WHO. But this ignores the fact that companies today are not willing to offer voluntary licence agreements for most of their products or only enter into agreements for a limited list of countries and diseases. Non-voluntary measures by governments can help unblock this", said 't Hoen.

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For **debates around licensing of lenacapavir** see **World Report** *Lancet* 2024; **404:** 1797–98