
**WORKSHOP REPORT**

# Expanding access to high-quality generic medicines in low- and middle-income countries

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On 6 April 2022, the Access to Medicine Foundation convened a workshop to discuss current and future roles and responsibilities of generic medicine manufacturers in improving access to essential health products for people living in low- and middle-income countries (LMICs). This was an opportunity to explore what companies are currently doing to expand access, to share insights about the evolving role of generic medicine manufacturers in global health, and to consider expectations for improving access to medicine.

Participants from eight multinational generic medicine manufacturers joined the virtual workshop, which was chaired by the Foundation's Chief Executive Officer Jayasree K. Iyer. Other participants included experts from global health organisations, procurement agencies, and government bodies.

The generic medicine industry has long played an important role in making essential medicines available and accessible – and the COVID-19 pandemic has highlighted just how critical that role is. Generic medicine manufacturers ensured existing medicines remained available in LMICs, despite disruptions to global supply chains. They stepped in to manufacture the generic medicines (e.g. dexamethasone) that were used for the treatment of COVID-19 when other treatments had not yet been developed. Furthermore, in a sign of how the global health landscape is changing, generic medicine manufacturers have worked with R&D-based pharmaceutical companies to rapidly create generic versions of patented COVID-19 vaccines and treatments for distribution in LMICs.

## Exploring opportunities for the generic industry to tackle global health challenges

In a wide-ranging discussion, the workshop explored how generic medicine manufacturers can leverage their expertise to tackle today's multiple global health challenges. To open the workshop, three representatives from the generics industry were invited to speak, before the floor was opened to participants. The speakers were:

- Amalia Adler-Waxman, Vice President Global Head, Environment, Social & Governance, Teva Pharmaceuticals
- Vinay Singh, Vice President Business Development Emerging Markets, Sun Pharma
- Erika Satterwhite, Head of Global Policy, Viatris

The workshop was held under the Chatham House Rule, and this meeting report summarises the outcomes of the discussion. The report captures different points of view, while showcasing a range of solutions to resolving access issues.

## About this report

The outcomes of the workshop are summarised in the following sections:

1. Defining the changing roles of generic medicine manufacturers in scaling up access
2. Identifying viable business models to expand access
3. Toolkit of approaches for expanding access in LMICs

As part of the Foundation's Strategic Direction for 2022-2026, we are expanding the range of companies and healthcare sectors that we aim to mobilise in the fight against healthcare inequality, and this will include the generic medicines industry. Informed by discussions in this workshop, as well as by conversations with a range of experts and stakeholders, the Foundation is developing an assessment framework that will outline the generics industry's roles and responsibilities in expanding access to high-quality generic medicines.

For more information or to discuss the contents of this report, please get in touch with Claudia Martínez via cmartinez@accesstomedicinefoundation.org.

### About the Access to Medicine Foundation

The Access to Medicine Foundation is an independent, non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access to medicine. The Foundation is funded by the UK and Dutch Governments, the Bill & Melinda Gates Foundation, the Leona M. and Harry B. Helmsley Charitable Trust, AXA Investment Managers, and the Wellcome Trust.

## 1. Defining the changing roles of generic medicine manufacturers in scaling up access

Workshop participants discussed the roles and responsibilities generic medicine manufacturers have in ensuring their products reach more people living in LMICs.

- Producing affordable medicines at scale: By their very nature, generic medicine manufacturers have a central role in expanding access to medicine by producing drugs in high volumes, at a lower cost to patients and procurers than the originator product. This has been the conventional lens through which the generics industry's role in access to medicine has been viewed.
- The evolving role of generic medicine manufacturers in access: Generic medicine manufacturers are starting to expand that business model of 'high-volume / low-cost', finding new mechanisms to reach more people with their products. For example, issuing sustainability-linked bonds can tie financial performance to achievements in access to medicine; taking up voluntary licences of on-patent drugs can increase the reach of essential new medicines within the countries these licences cover; and engaging in adaptive R&D can lead to products better suited to needs of patients living in LMICs. Alongside this, there is a growing recognition of the importance of local manufacturing, supply chain strengthening and capacity building, as well as access strategies that take ability-to-pay and other socio-economic factors into account. Discussions during the workshop highlighted the steps some generic medicine manufacturers are actively taking to improve access to their products in LMICs, as explored below.
- Fulfilling key roles and responsibilities: The exact extent to which generic medicine manufacturers have a responsibility to consider access to medicine in LMICs – beyond affordability – is an ongoing conversation. However, there is a broad consensus that generic medicine manufacturers have an opportunity to actively expand access to their essential health products in LMICs and ensure a continuous supply of high-quality generic medicines and biosimilars.

## 2. Identifying viable business models to expand access

Speakers and participants had an open conversation about how to find commercially viable business models that balance affordability considerations with the need for sustainable availability and product quality. The workshop explored the issue of healthy market shaping and the roles of different stakeholders in ensuring effective ecosystems, in order for essential medicines to reach more patients in LMICs.

*"At the end of the day, if we want to ensure sustainable access, it has to have a sustainable business behind it."*

*"We collectively need to think about: how do we create a thriving market of those kinds of instruments that allow us to launch products fast, at the right kind of prices, and accelerate their uptake?"*

- Question assumptions about markets in LMICs: Companies can explore the feasibility of an expansion into countries that some may assume would not have profitable markets. Participants talked about taking a 'leap of faith', especially when launching a product in a country where the original brand-name product never launched – but this leap of faith can

also be backed up by market research and pilot initiatives to ascertain business potential and financial sustainability.

- Develop networks and relationships to understand local needs: Developing on-the-ground partnerships and relationships, for example with hospitals and clinics, can help generic medicine manufacturers understand the level of demand, raise awareness of particular medicines, and – more generally – build trust in generic medicines as high-quality products. Engaging with governmental agencies, civil society organisations, purchasers, hospitals and other relevant stakeholders can improve companies' understanding of local requirements and inform public-sector tender applications.
    - ⇒ One participant shared a potential solution that can help achieve these goals: start small, build capacity, work with regulatory authorities, and understand the market in a particular country before scaling up. This means developing in-country capacity by manufacturing simpler, low-cost products before widening manufacturing to include more complex outputs.
    - ⇒ One participant highlighted how social responsibility programmes can offer generic medicine manufacturers key insights into how to develop viable business models in LMICs. Learning from these programmes can help companies identify and overcome local barriers to access, understand the commercial feasibility of operating in LMICs and make the case for investment in those markets.

*"Having a local presence has really helped us, it's given us a platform through which we can quickly introduce new products into the market, and we can understand what the needs are through our strong networks with local hospitals and local government institutions."*

- Apply lessons learned from the ecosystems around HIV, TB and malaria: Over recent decades, international multistakeholder efforts to tackle HIV, tuberculosis (TB) and malaria have led to the development of ecosystems specifically focused on ensuring patients in LMICs have access to treatments for those diseases. As part of this, there has been extensive funding from the global health community, with key initiatives including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Global Drug Facility (GDF) for tuberculosis. In the workshop, participants shared views and insights on what lessons can be learnt from the progress in HIV, TB and malaria, and how – or whether – they can be applied more widely to expand access to essential health products in LMICs.
    - ⇒ For companies, the international pooled procurement mechanisms, advance market commitments and market-shaping facilities built to tackle HIV, TB and malaria have helped to ensure clarity about demand for products, and greater certainty about achieving a return on investment. The companies therefore see the commercial case for manufacturing those products and making them available in LMIC markets.
    - ⇒ One participant pointed out that, for many diseases, and especially for non-communicable diseases (NCDs), similar international frameworks and ecosystems are unlikely to be established on the same scale. Companies should not solely rely on international donor programmes to sustain access, and should be proactive about pursuing access to essential products outside of these frameworks, while making use of insights gained from working within them.
    - ⇒ Through participation in these disease-specific systems, generic medicine manufacturers have gained valuable experiences in LMICs that they can apply for

different disease areas. For example, companies have gained experience in registration processes and working with local partners, and gained insight into how health systems function in LMICs.

⇒ Supranational procurement agencies can help to pool demand and coordinate supply, providing greater certainty about the market for particular drugs – including those produced by generic medicine manufacturers.[1]

*"Patients living with HIV, TB and malaria have benefitted tremendously from focused global attention…. [we need to] build on the learnings from that ecosystem."*

*"We don't see enormous appetite for donors to come in and establishing a global procurement fund for NCD medicine... it is going to be very much more about countries developing these ecosystems. If there is going to be money going in from the public sector, it will be supporting countries to establish ecosystems and to have a much clearer and much simpler pathway."*

- Look for solutions around payment: It was shared as a common concern among generic medicine manufacturers that payments for products procured by some lower-income countries' governments may be delayed or incomplete. If this happens, the continuous supply of medicines may be interrupted until the debt is cleared, with negative effects for patients – and companies may become reluctant to enter into new contracts or introduce new products into those countries. To pre-empt and reduce this risk, generic medicine manufacturers and other stakeholders can seek different ways of working. For example, generic medicine manufacturers can make use of international procurement organisations, or work more closely with national governments on contracts that take into consideration more flexible payment schemes and payment plans that work for the countries involved.

## 3. Toolkit of approaches for expanding access in LMICs

Building on the discussion around generic medicine manufacturers' role in access to medicine, several speakers and participants shared experiences and insights about specific approaches that had been – or could be – taken. They delved into both the challenges and opportunities of particular strategies, and discussed practical ways in which they can be made a reality.

- Invest in local manufacturing to ensure continuous supply: Local manufacturing of essential medicines and vaccines, and wider investment in supply chain security, can help safeguard local availability and ensure that those who need products can access them rapidly – a topic that was explored in depth during the Access to Medicine Foundation's April 2022 workshop on Global Health Security. This is particularly true during times of crisis, and companies and other global health stakeholders are taking lessons from the disruption COVID-19 caused to global supply chains. To ensure sustainable continuity of supply, generic medicine manufacturers can develop or scale up local manufacturing capacity in LMICs, either directly or by working in partnership with local manufacturers.

[1] Global and regional organisations involved in procurement for a range of products targeting different diseases include United Nations Children's Fund (UNICEF); United Nations Population Fund (UNFPA); Pan American Health Organization (PAHO) Strategic Fund; Southern African Development Community (SADC); and Common Market for Eastern and Southern Africa (COMESA).

*"Incentivising local manufacturing… I think is a really powerful instrument. COVID-19 demonstrated very clearly to people that global markets are great in good times, and they tend not to work so well when they're particularly put under stress."*

- Consider working with international procurers: There can be positive effects of partnering early on with procurement agencies – such as global heath bodies, regional initiatives and national governments – as well as with implementing partners on the ground. For a new product launch, determining supply logistics early on can help smooth out the process and ensure the product reaches the people who need it.
- Seize licensing opportunities: Participating in voluntary licences issued by the patent-holder (i.e. a research-based pharmaceutical company) is one way to increase the supply of essential patented drugs, and make them more widely available and affordable in LMICs. Generic medicine manufacturers can also seize opportunities where the patent holder has issued a non-assert declaration (NAD). Not all generic medicine manufacturers are currently set up to engage in voluntary licensing; but when such companies do step in to improve access to new, patented drugs, those innovative products are more likely to reach patients living in LMICs, and are more likely to be marketed at an affordable price point.
    - ⇒ In the workshop, participants also raised important issues around transparency, and a need for greater tracking of whether and how manufacturers are fulfilling licensing agreements and the outcomes of licences after they are issued. For example, did the licensee actually file the product for registration and make it available in low-income countries included within the terms of the licence, or did it only focus on middle-income markets that are typically more lucrative?

*"How that licence is implemented by different manufacturers can vary quite widely… fundamentally what it [the licence] provides are certain rights, and how those rights are then exercised is critical to the extent to which that licence will actually result in access at the end of the day."*

- Ensure product affordability: Participants in the workshop emphasised the importance of using pricing strategies to make their products affordable in LMICs, identifying gaps where patients are missing out on essential medicines and where the need is greatest. For example, affordability is a particular problem in low-income countries where people usually pay for care out of their own pockets. It is also a problem for products for non-communicable diseases, including diabetes - with many people with diabetes in LMICs currently unable to afford insulin.
- Explore strategies to overcome registration challenges: Filing for registration is an important first step in making any medicine available in a country, but many products are not filed in LMICs – including some of the older but essential medicines, like antibiotics. Participants touched on some of the commercial reasons why companies may not prioritise registration in LMICs, such as a lack of clarity around local regulatory requirements and capacity from regulatory authorities to assess dossiers. For example, launching a biosimilar product can require resource-intensive clinical trials as part of the regulatory process. However, the discussion also explored some of the ways in which generic medicine manufacturers can actively work to find solutions. Suggestions included:

⇒ Alongside other global health stakeholders, generic medicine manufacturers can explore ways to streamline registration processes in LMICs, e.g. by applying for WHO pre-qualification, or by using collaborative registration procedures (for more examples, see footnote).[2]

⇒ Generic medicine manufacturers can leverage their local presence in LMIC markets and work with regulatory agencies to understand regulatory needs.

⇒ Another strategy suggested during the workshop was to prioritise registration in established LMIC markets first, and then move on to other less-established markets.

- When the originator product was never introduced in a market, explore different approaches: One of the challenges generic medicine manufacturers can face is that in many LMICs, the originator product was neither registered nor structurally introduced by the originating company. This means the generic medicines, when introduced by companies in LMICs, are not yet fully integrated into the continuum of care. To overcome this hurdle, generic medicine manufacturers can explore public-private partnerships, and work with local implementation partners, national governments, and organisations that can help with capacity building – e.g. around ensuring proper storage, and training nurses and pharmacists about how and when to use this product. This can reduce the financial burden of launching the new product, and makes sure it is properly and safely introduced into the continuum of care.
- Engage in adaptive R&D: Generic medicine manufacturers can address global health R&D priorities by adapting products to local contexts and the needs of populations in LMICs. This could include, for example, developing paediatric formulations that are easier to administer to young patients. While not all generic medicine manufacturers currently engage in adaptive R&D, some companies take on this role. This is an area with the potential for game-changing developments that could ensure more people in LMICs have access to medicine.

*"Through active partnerships we can take the most innovative ideas from around the world and use our development capabilities to create targeted products that bridge the gaps in access for LMICs."*

- Contribute to local capacity-building in LMICs: Generic medicine manufacturers can play an important role in building up the skills and knowledge of personnel involved in the manufacture or distribution of their products, and healthcare professionals who administer or prescribe their products. For example, companies with antibiotics in their portfolios have a clear role to play in educating healthcare workers on antimicrobial resistance and stewardship, thereby also protecting the longer-term effectiveness of their product. As discussed above, forming public-private partnerships with implementing organisations can also ensure a product is successfully introduced into a new market.

[2] To facilitate authority assessments, generic medicine manufacturers can engage more systematically with mechanisms designed to facilitate product registration in low- and middle-income countries. They can also seek approval from Stringent Regulatory Authorities (SRAs) recognised by the World Health Organization. Such mechanisms might include: The World Health Organization's (WHO) prequalification system; The WHO Collaborative Registration Procedure, The African Medicines Regulatory Harmonization (AMRH) programme; The African Medicines Agency (AMA); or the European Medicines Agency (EU-M4all, or article 58)

## Three key takeaways

Generic medicine manufacturers have a central – yet evolving – role in the global health landscape and are well-placed to seize opportunities to make their products more available and accessible in LMICs. This workshop explored the role of the generics industry in improving access to essential health products in low- and middle-income countries (LMICs), both today and in the future.

The Access to Medicine Foundation is now expanding its work to mobilise generic medicine manufacturers to ensure greater access to generic medicines in LMICs. The Foundation will engage companies that hold dominant positions in key regional markets, including some of the largest players in the generic sector, to monitor companies' actions in access, identify opportunities to bridge key access gaps, and capture best practices. Points raised during the workshop will help to inform the development of this new research programme. The three key takeaways from the workshop are:

1. Generic medicine manufacturers have more opportunities in ensuring access to medicine, beyond their conventional role. By manufacturing drugs at high volumes and selling them for relatively low costs, the generics industry inherently expands access to medicine. However, simply producing a generic product does not guarantee access to that product in LMICs – and this is especially the case when it comes to low-income countries. As indicated by participants in the workshop, generic medicine manufacturers increasingly acknowledge and embrace the proactive role they can take in expanding access to medicine globally, beyond the traditional high-volume / low-cost business model.

2. Viable business models that build in access to medicine can, and should, be developed. Generic medicine manufacturers can develop business models with long-term sustainability of access at their core, reconciling the need for commercial viability with approaches that result in greater access to generics and biosimilars in LMICs. Over recent decades, multistakeholder efforts to ensure universal access to treatments for diseases including HIV, TB and malaria have led to valuable insights, some of which can be used to inform strategies more widely; but viable business models can also be identified and implemented in disease areas that have not received such international attention and funding. Workshop participants highlighted a range of approaches to expanding access sustainably, including engaging in public-private partnerships to participate in regional procurement initiatives and build local capacity. There are ways to explore whether a new approach is viable, such as by starting small and scaling up; in other cases, companies can take a 'leap of faith'.

3. Generic medicine manufacturers can build on their strengths to overcome challenges specific to LMICs. Particular challenges exist in LMICs that can deter generic medicine manufacturers, such as registration hurdles and lower commercial market potential. One common challenge is that, when the original brand-name product was not introduced or made widely accessible in many LMICs, launching the generic version in those countries can be a more uncertain prospect – as the drug is not yet integrated into the continuum of care, and demand can be harder to predict. To overcome such challenges and provide equitable access to their products, companies can capitalise on their at-scale manufacturing expertise and adaptive R&D capacities, while also developing new approaches to support broad access and affordability. For example, they can enter into partnerships to better understand demand for the product, and therefore align supply; they can leverage collaborative registration procedures; and they can adapt products to better suit the needs of patients living in LMICs.