

SESSION KEY TAKEAWAYS

Solving for global therapeutics access: The evolving role of generics and biosimilars manufacturers and partners in equitable supply

On 24 May 2023, the Access to Medicine Foundation and the World Economic Forum (WEF) organised a dialogue to discuss the role of the generics and biosimilars industry in ensuring equitable access to medicines globally, along the side lines of the 76th World Health Assembly (WHA) in Geneva.

Almost 60 high-level participants joined this interactive discussion including CEOs and experts involved in developing and/or producing medicines, policymakers from government, non-profit implementing organizations and regulators. Several leading manufacturers based in low- and middle- income countries (LMICs) also attended and articulated their readiness to join forces to address the problem of access and build health system resilience to withstand future shocks.

The participants shared insights and solutions towards strengthening equitable supply of a wide range of essential medicines in LMICs.

1. The Foundation & WEF calls to action

Before we reconvene (date and time TBD; before the next WHA), we invite you to review the following outputs of the 2023 meeting as each party's commitment to equity in access to medicines.

As you view the below, **we invite you to share any case examples** with Claudia Martinez via Cmartinez@accesstomedicinefoundation.org for featured inclusion in a future meeting.

1.1 For public sector (government, policymakers, civil society, and non-governmental agencies)

- Invest in domestic resources in manufacturing and the supply of essential medicines.
- Establish cross-country or regional collaborations to facilitate private investments and operations, harmonized regulatory pathways, manufacturing, registration, purchasing, and coordinated procurement processes and data sharing.
- Publicly describe and promote clear pathways for manufacturers to conduct business domestically and engage in voluntary licenses to expand access to innovative products.
- Advocate for and collaborate with partners including generic and biosimilar manufacturers to solve downstream access issues.

1.2 For private sector (manufacturers)

- Build and support Active Pharmaceutical Ingredient manufacturing in Africa.
- Increase the use of voluntary licensing to enable access to innovative and generic medicines earlier in the development process.
- Deploy alternative financing and shared value partnerships to de-risk commercialisation of products.
- Engage in early deployment of end-to-end solutions for co-development between manufacturers and the public sector.

1.3 For investors and donors

- Work directly with end-users to understand their needs.

- Expand suite of financial instruments to facilitate capacity building for producers of essential medicines.

1.4 For procurers

- Pursue regional tools (e.g. coordinated procurement or offtake agreements) that reduce product price and dually enhance local manufacturer capacity.
- Reward price and assure quality, but also diversity in manufacturers/suppliers for tenders.

1.5 For regulatory authorities

- Work with regional entities (e.g. Africa Centres for Disease Control and Prevention, African Medicines Regulatory Harmonization, African Medicines Agency (AMA)) to harmonize regulatory and registration processes to enable business opportunities and public health impact.
- Support regulatory agencies such as AMA to ensure access to quality-assured medicines.
- Advance regulatory preparedness to combat ongoing as well as future disease control, including epidemics, pandemics, and global emergencies.

2. High-level themes

In addition to the above action items, key high-level themes from the discussion are described below.

2.1 Expanding the local manufacturing pool

Many participants, including representatives from medicine manufacturing companies, highlighted that local manufacturing in LMICs is required not only to meet future demand but to establish resilience in terms of *where* products are made. Regional manufacturing specifically would enable a wider pool of producers to prevent shortages and stockouts due to reliance on only international suppliers. There have been effective investments in some domestic markets to support this, however the importance of ensuring opportunities to more manufacturers via offtake agreements and coordinated or pooled procurement approaches with data sharing were discussed. Moreover, additional opportunities to ensure the use of technology transfers, broad voluntary licensing for innovative medicines, and greater harmonised regulation is critical for expanding local manufacturing.

2.2 Building domestic health system and regulatory capacity

Attendees emphasised the need for enhanced health system and regulatory capacity in LMICs, including regional harmonization. Examples demonstrating the need for regional registration harmonization and safety databases were provided as well.

Legal and regulatory preparedness for future pandemic and global emergencies must be established, with clear contracts. Working with regional entities to define future regulatory pathways was suggested. An example of a cross-country collaboration wherein one country's laboratory prequalification is contractually accepted in another was provided as an effective intermediary or established approach. Another example of a continental free trade area was noted as an enabling mechanism to advance regional markets.

For biosimilars, a greater focus on including the training of healthcare professionals (e.g. the use of diagnostics in different healthcare settings), is necessary in LMICs. Training good manufacturing practice (GMP) inspectors was also stated as a strategy for building domestic capacity.

2.3 Ensuring equitable access to quality assured products

Enabling access to quality assured generic and biosimilar medicines was mentioned as a priority by multiple attendees. The availability of low-quality generic medicines, including falsified or substandard medicines, remains a prominent concern in LMICs. Strengthening regulatory systems and quality assurance regimes as well as local manufacturing capabilities were discussed as solutions towards addressing this issue. For example, tenders should not be based on price alone; price and quality matter equally in access. In addition, further capacity strengthening of supply chains for quality medicines is important.

2.4 Increasing political willpower

Addressing inequitable access to medicines is a conversation that cannot be limited to any single disease or department. This should belong to a “Universal Cost of Care” discussion and is thus not a solution for only one country, but a global solution tailored to local needs. The conversation should be embedded in the solidarity agenda and with parliamentarians from different countries involved to advocate for better access.

2.5 Action vs. ideology

It was noted that ideological commitments to equity are distinct from equitable market-based solutions built to last, and that market dynamics are led by the people who buy. To address large gaps in access to essential medicines, tactical solutions (e.g. coordinated and pooled procurement, tech transfer) need to be deployed systematically and intentionally. Participants also discussed the need to dispel certain myths associated with the pharmaceutical industry. For example, manufacturers noted that – with the right investments, infrastructure, human capital, partnerships etc.– biologics *can* be produced in low-income settings. We should not wait for the next pandemic to ramp up investments in local capacity in regions that are not traditionally high-volume producers of pharmaceutical products. This will be enabled by partnerships with multinationals and other entities to accelerate new infrastructure and human capital advances.