MEETING REPORT

ENABLING MANUFACTURING OF INNOVATIVE AND ESSENTIAL MEDICINES ON THE AFRICAN CONTINENT

On the sidelines of the 78th World Health Assembly, Geneva

– 20 May 2025 – The Access to Medicine Foundation and Vizuri Health Dynamics convened a closed roundtable session alongside the 78th World Health Assembly in Geneva, titled “Enabling the Manufacturing of Innovative and Essential Medicines in Africa". The event brought together regulators, manufacturers and senior executives from the health sector for a strategic dialogue focused on identifying and advancing actionable solutions to support the sustainable manufacturing of both innovative and generic medicines on the African continent.

AIM OF THE EVENT

The session explored practical approaches, including policy and financing instruments, that can drive and scale up local production efforts and offered a valuable platform for stakeholders to reflect on progress, share successes and explore new opportunities for collaboration.

Discussions were anchored around three guiding questions

- What type of strategic partnerships are critical to creating an enabling environment that can accelerate the production of medicines in Africa, including innovative medicines?
- How can we use the lessons learnt around partnerships and market positions to call for actionable measures to increase regional manufacturing?
- What policy and regulatory mechanisms are currently in place, or evolving, that can support local manufacturing in Africa through, for example, capacity building, technology transfer, infrastructure development, quality assurance, concessions and procurement?

PARTICIPANTS

Following the Chatham House Rule, participants’ opinions and contributions to discussions during the session are kept anonymous. Joining us during the session to lend their expertise and offer insights were:

- Alexandra Scott, Global Environment & Technology Foundation (GETF)
- Ann-Marie Hosang-Archer, Vizuri Health Dynamics

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- Aubrey Clark, US Pharmacopeia (USP)
- Boitumelo Semete-Makokotlela, South African Health Products Regulatory Authority (SAHPRA)
- Boniface Njenga, Gates Foundation
- Chimwemwe Chamdimba, African Medicines Regulatory Harmonization (AMRH), African Union Development Agency (AUDA-NEPAD)
- Claudia Martinez, Access to Medicine Foundation
- Cyntia Genolet, The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Abebe Genetu Bayih, Africa Centres for Disease Control and Prevention (CDC)
- Emily Kane, USP
- Esteban Burrone, Medicines Patent Pool (MPP)
- Farrah Losper, Biovac Institute
- George Jagoe, Medicines for Malaria Venture (MVV)
- Hiiti Sillo, World Health Organization (WHO)
- Iain Barton, Vizuri Health Dynamics
- Jayasree Iyer, Access to Medicine Foundation
- Joseph Serutoke, United Nations Development Programme (UNDP)
- Judith Kallenberg, GSK
- Komal Kalha, IFPMA
- Mae Shieh, Drugs for Neglected Diseases initiative (DNDi)
- Marian Wentworth, Management Sciences for Health (MSH)
- Mariatou Tala Jallow, Vizuri Health Dynamics
- Marriane Mouly, DNDi
- Matt Tyson, Vizuri Health Dynamics
- Michael Ruffo, PATH
- Navin Choubey, Revital Healthcare (EPZ) Limited
- Olawale Ajose, Market Access Africa
- Paul Lalvani, Empower School of Health
- Perrer Tosso, USP
- Petro Terblanche, Afrigen Biologics and Vaccines
- Pierre Hugo, MVV
- Priya Agrawal, Merck & Co., Inc. (MSD)
- Pujan Vaghjiani, Tasa Pharma
- Ralf Retter, Federal Ministry for Economic Cooperation and Development, Germany (BMZ)
- Rob Lloyd, Eli Lilly and Company
- Robert Matiru, Unitaid
- Sadhavi Chauhan, Access to Medicine Foundation
- Susan Lin, PATH

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6 KEY THEMES IDENTIFIED FOR PROMOTING LOCAL PRODUCTION

1. Strategic partnerships and multi-stakeholder collaboration
2. Demand creation and market-shaping
3. Regulatory strengthening and harmonisation
4. Enforcement, capacity and legal frameworks
5. Effective procurement
6. Technical capacity and investment

Strategic partnerships and multi-stakeholder collaboration

- There is a strong need for multi-stakeholder collaboration on policy, strategy and investment to avoid fragmented efforts and a scenario where *"everybody is doing everything everywhere"*.
- Effective partnerships are emerging among regulators, regional economic communities, manufacturers and institutions like the Africa Centres for Disease Control and Prevention (Africa CDC) and the African Medicines Agency (AMA), including the establishment of a pooled procurement mechanism.
- Local manufacturing efforts require short- to medium-term flexibility, with stakeholders – such as regulators, procurement agencies and manufacturers – taking on enabling roles beyond their traditional mandates. For example, regulators are developing policies that allow them to act not only as enforcers, but also as supporters and facilitators of African manufacturers. At the same time, Africa CDC is investing in specific manufacturers while also building a pooled procurement mechanism that will eventually pre-qualify and purchase from a wider group. Meanwhile, manufacturers are balancing the demands of running a focused business with the need to take on advocacy roles.

Demand creation and market-shaping

- Clarity of demand is essential for the commercial viability of African manufacturers. Pooled procurement mechanisms, such as those being developed by Africa CDC and the AMA, were highlighted as key enablers. These mechanisms are expected to prioritise locally manufactured products through preferential procurement policies.
- Manufacturers should assess their product pipelines to identify high-demand molecules suited to African markets, creating opportunities for early partnerships, voluntary licensing (VL) and demand generation activities.

- A participant from research-based pharmaceutical company noted that demand creation and market-shaping activities are critical for the long-term sustainability of local manufacturing in Africa. However, there is no clear mandate on who should fund these efforts. The maturity of

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the market and the need for activities such as training healthcare workers and building diagnostic capacity typically influence research-based companies' decisions on which manufacturers to engage with.

- Africa-based local manufacturers emphasised that improved regulation should go beyond facilitating market entry for global companies and also include mechanisms for technology transfer, co-development and the retention of local investment.

Regulatory strengthening and harmonisation

- Strengthening regulatory systems is vital to building trust in locally manufactured products among health professionals and patients. However, some attendees warned that over-reliance on harmonised mechanisms could undermine local ownership and innovation.
- Greater awareness is needed among African manufacturers about AMA initiatives and how to take advantage of these opportunities.
- Regulatory convergence (i.e., the alignment of standards without requiring identical regulations) was seen as more practical and supportive of local production than full harmonisation.
- Some national regulatory authorities (NRAs) are implementing policies to streamline regional standards and reduce registration timelines: for example, by committing to a 90-day product registration goal.
- Positive feedback was shared on initiatives like the African Medicines Regulatory Harmonisation (AMRH) and the AMA, including the creation of centralised product listings and priority product approval guidelines. One attendee from an R&D-based pharmaceutical company remarked: *"AMA has had a proactive strategy, has been highly efficient and has been brilliant to partner with."*
- Feedback is being gathered from local manufacturers on the usability and effectiveness of centralised registration systems developed under AMA, especially in relation to priority product approvals.

Enforcement, capacity and legal frameworks

- Strong regulators with empowered enforcement create a level playing field and protect investments in both intellectual property (IP) and manufacturing capacity.
- Enforcement capacity is improving. Some NRAs are implementing commercial penalties and the blacklisting of companies in violation of regulations, enforced at the national, regional and continental levels. These efforts are supported by memoranda of understanding (MoUs) that enable cross-border post-market surveillance for substandard and falsified products.
- Yet, some NRAs still lack legal independence to initiate enforcement or legal actions, limiting the effectiveness of regulatory systems.

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Effective procurement

- Participants called on global procurers to recognise Maturity Level 3 (ML3) regulatory standards in African countries when making procurement decisions, supporting the credibility and autonomy of local NRAs.
- Participants emphasised that tenders should go beyond price and quality by requiring suppliers to contribute to market creation and long-term sustainability of technology transfer efforts. One suggestion involved breaking voluntary licensing (VL) into phased steps, for example starting with a "second brand," to allow earlier market entry and gradual technology transfer while building demand and brand recognition.

Technical capacity and investment

- Manufacturers entering in-licensing agreements face significant technical and financial challenges, including costly infrastructure, limited technical expertise and restricted access to capital.
- Participants called for stronger support through concessional financing, technical assistance and public-private partnerships to address these structural barriers.

LOOKING AHEAD

The Access to Medicine Foundation remains committed to tracking how companies are working to improve the availability of essential medicines in low- and middle-income countries (LMICs), including through local and regional manufacturing, voluntary licensing, technology transfer, and capacity building, as reflected in the 2024 Access to Medicine Index. The Foundation also runs a dedicated Generic & Biosimilar Medicines Programme, which, assesses this industry's role in expanding access through increased supply, quality assurance, and entry into underserved markets, while exploring opportunities for greater impact through collaboration and local production. We encourage you to continue sharing updates on your initiatives and insights from your organisations with Claudia Martínez, Director of Research at the Access to Medicine Foundation, at cmartinez@accesstomedicinefoundation.org.

Vizuri Health Dynamics continues its engagement with manufacturers and stakeholders to accelerate regional manufacturing in Africa. Looking ahead, the African Health and Medicine and Technology Conference (AHMTEC) 2025, hosted by the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) and Vizuri Health Dynamics, will provide another important opportunity to assess progress and define future action. AHMTEC 2025 will be held in Accra, Ghana from 7-9 October 2025 and early-bird registrations are open on www.ahmtec.org Contact Dr Mariatou Tala Jallow, Council Chair, Vizuri for additional information at tala@vizuri.org. We look forward to continuing the conversation and building momentum together.