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Global Council on Inequality, AIDS and Pandemics

Discussion Paper: Leveraging a G20 Alliance on Local and Regional Production to Expand Global Manufacturing of HIV-Related Technologies

This paper was developed for the Global Council on Inequality, AIDS and Pandemics by a working group including the following Council members and experts from UNAIDS, Africa CDC, Instituto Todos pela Saúde and Georgetown University's O'Neill Institute for National and Global Health Law:

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Introduction

The global response to AIDS has made remarkable progress over the past two decades, with over 30 million people now accessing life-saving antiretroviral therapy. However, the AIDS pandemic continues to claim one life every minute, predominantly in low- and middle-income countries (LMICs). This ongoing crisis, coupled with persistent inequities in access to HIV-related health technologies, demands a transformative approach to how, and where, essential medicines and diagnostics are developed, manufactured and distributed.

The Global Alliance for Local and Regional Production, Innovation and Access, proposed by the Brazil G20 Presidency, aims to bring together key stakeholders to accelerate efforts to build capacity within low- and middle-income countries for research and development (R&D) and local/regional production of drugs, vaccines and diagnostics against diseases that are neglected and affect vulnerable populations. This Alliance is a strategic imperative for global health security and economic development in LMICs. It also presents a critical opportunity to efforts to end AIDS as a public health threat by 2030. The inclusion of HIV health technologies in the work of the Alliance will also contribute to local and regional production of health products for neglected diseases, and strengthen health security for future pandemics.

Addressing health security risks and establishing a more equitable and resilient global health ecosystem

The global HIV response faces several interconnected challenges that underscore the need for a new approach. African countries, despite bearing the highest burden of HIV, import 80-90% of medicines and 99% of vaccines. For example, less than 1% of HIV commodities procured by the United States global AIDS response initiative, PEPFAR, are produced by African manufacturers.[1] [2] This overreliance on intercontinental and fragmented supply chains was starkly exposed during the COVID-19 pandemic, when many LMICs struggled to procure essential HIV medicines due to disruptions in global trade.[3] A similar lack of influence and direct say in manufacturing, value and supply chain for its products also characterizes the market for neglected diseases. These experiences reinforced political will in Africa to strengthen local manufacturing capacity. The African Union has identified over-reliance on imported health technologies as a top health security concern. Africa CDC's New Public Health Order calls for achieving a secure supply of priority vaccines, therapeutics and diagnostics through greater investment in local research, development and manufacturing capacities.[4]

[1] Pharmaceutical imports in Africa include up to 80% of the antiretroviral drugs (ARVs) used to treat HIV/AIDS, according to trade data. https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines.
[2] US Department of State. (2022) PEPFAR sets bold manufacturing targets for Africa. https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/.
[3] The Joint United Nations Programme on HIV and AIDS (UNAIDS). (2020) The impact of the COVID-19 response on the supply chain, availability and cost of generic antiretroviral medicines for HIV in low- and middle-income countries. https://www.unaids.org/en/resources/documents/2020/covid19-supply-chain-availability-cost-generic-arv
[4] Africa CDC. A new deal for African health security. 11 October 2023 (https://africacdc.org/news-item/a-new-deal-for-african-health-security/).

Moreover, the current HIV response is overly dependent on a few funders and institutions, raising concerns about long-term sustainability. Breakthrough HIV medicines and technologies are not reaching vulnerable populations quickly enough, prolonging inequities in access to optimal care and prevention. Upper-middle-income countries that fall outside the mandates of Unitaid, the Medicines Patent Pool and other international initiatives continue to pay high prices for well-established antiretroviral formulations. For example, drugs used for second-line HIV treatment are nearly nine times the price of drugs for first-line treatment in upper-middle income countries.[5] The limited local production of HIV-related health technologies also represents a missed opportunity for economic growth and development in LMICs. The annual market for generic antiretroviral medicines in LMICs is estimated at US$2.5 billion, yet much of this economic activity occurs outside the regions most affected by HIV.

Other regions face similar challenges. Southeast Asia has faced disruptions in the availability of some essential medicines including those needed to treat infectious diseases. Costs of medicines claimed to be 'non-commercially viable' to manufacture can be very high. The Association of Southeast Asian Nations recently completed a feasibility study for the establishment of a new mechanism to improve drug security and self-reliance in the region.[6]

By establishing a broad Alliance in support of local and regional manufacturing, the G20 can help ensure a more equitable and resilient global health ecosystem. Supporting local and regional manufacturing efforts in the Global South contributes to countries' health technological sovereignty, reducing dependence on foreign manufacturers. This diversification of production capabilities is crucial for building resilience against future global health threats. Countries in the Global North are themselves pursuing decentralized and regional manufacturing, through established policy goals to "near-shore" or "friend-shore" strategic industries, including pharmaceutical manufacturing, and mitigate risks associated with the current status quo.[7] [8]

HIV-related health technologies as a foundation for end-to-end ecosystems

Expanding local manufacturing capacities for health technologies can help contribute to broader sustainable economic growth. Local manufacturing creates high-skilled jobs, fosters innovation within ecosystems, and can lead to technology spillovers into other sectors. The substantial market for HIV-related health technologies can serve as a foundation for developing end-to-end ecosystems for innovation, production and distribution. Current spending on antiretroviral medicines in sub-Saharan Africa is estimated at US$ 1.6 billion annually, with about 55% of the

[5] Aidsmap, Second-line treatment nearly nine times more expensive than first-line in upper-middle income countries, Rosalie Hayes, 9 August 2022.
[6] The ASEAN Secretariat. Situational Analysis and Feasibility of Regional Collaboration to Improve ASEAN Drug Security and Self-Reliance (ADSSR). 2023.
[7] The United States-Abraham Accords Cooperation and Security Act Establishing an "Abraham Accords" FDA Bureau in the Middle East. See also Medical and Pharmaceutical Friend-Shoring Is Bipartisan Common Sense, Newsweek, 06 Feb 2024.
[8] European Parliament Directorate-General for External Policies, Policy Department, Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy.

total funded by domestic resources.[9] Local capacities built to supply this market can be leveraged to address neglected diseases and prepare for future pandemics.

The Alliance can promote specific and concrete technology transfer and capacity building linked to specific projects, serving as a platform for discussions and negotiations between technology holders and potential manufacturers. By supporting local production of, for example, pediatric ARV formulations and new technologies like long-acting injectable PrEP, the Alliance can address critical gaps in the current HIV response. It can also facilitate the exchange of resources, technology, and knowledge on shared challenges, such as scaling up manufacturing of existing ARVs and novel HIV technologies.

Furthermore, the Alliance can provide a platform for support and assistance to Member States in creating national and regional ecosystems that facilitate sustainable, quality local production. This includes recommendations and coordination in issues such as establishing policy coherence, robust regulatory systems, and public health-oriented management of intellectual property rights.

The Alliance can help facilitate capacity building and knowledge transfer for new health technologies with complex manufacturing requirements, and it can play a critical role in consolidating the fragmented markets for neglected diseases. The use of existing pooled procurement mechanisms, wherein financial resources of multiple purchasing groups are pooled together, can potentially help guarantee markets and establish predictable demand for local manufacturers.

Coordinated and pooled procurement is a proven strategy for both improved access to medicines and supporting industry. The Gulf Health Council established pooled procurement in the 1970s and it has since helped secure equity among countries, support local industry, and reduce the cost of procurement[10]. Similarly, in the Americas, the Strategic Fund of the Pan American Health Organization (PAHO) pools demand and centralizes procurement of essential health commodities, and in combination with relevant technical advice and expertise, helps its member states secure access to essential medicines and products[11]. The African Union recently announced a decision to establish a pooled procurement mechanism creating a potential $50 billion market for medical products for drugs and vaccines for different diseases.[12]

Furthermore, Global players such as PEPFAR have already made commitments to support such local production initiatives by committing to purchase HIV medicines and diagnostics made by local manufacturers.[13] [14] However, integrated follow-up on these commitments has been slow. A strong Alliance can help advocate for and

[9] UNAIDS financial estimates, 2024.
[10] Cecile Mace, 2022, POOLED PROCUREMENT OF INSULIN AND ASSOCIATED SUPPLIES, Analysis of Mechanisms and their Applicability for Small State Countries or Countries with Limited Needs.
[11] Ibid.
[12] Africa CDC. 2024. Africa CDC Spearheads Bold Move to Secure Africa's Health Future by Creating a 50 billion Dollar Medical Market. https://africacdc.org/news-item/africa-cdc-spearheads-bold-move-to-secure-africas-health-future-by-creating-a-50-billion-dollar-medical-market/
[13] The Global Fund (2022). The Global Fund's contribution to local production of health products. https://www.theglobalfund.org/media/12104/thematic_local-production_overview_en.pdf
[14] US Department of State. (2022) PEPFAR sets bold manufacturing targets for Africa. https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/

ensure that existing global procurement structures support regional and local manufacturing.

Transforming global health and strengthening pandemic preparedness and response

The establishment of a G20 Alliance for Local and Regional Production, Innovation and Access represents a critical opportunity to transform the global health landscape. By bridging coordination and existing gaps in drug manufacturing and innovation initiatives, strengthening responses to neglected diseases, and accelerating progress towards ending AIDS by 2030, the Alliance can drive meaningful progress towards global health equity. Moreover, this initiative is a logical and necessary response to evolving global dynamics, ensuring that LMICs are included in the strengthening of strategic health technology production sectors. The expansion of local and regional production of HIV-related health products will not only save lives and improve health equity but also position the world to better prepare and respond to future pandemics.

The G20 has a unique opportunity to lead this transformative effort. We call on G20 leaders to formally establish the Alliance with a broad mandate and resources, set ambitious targets for increasing the proportion of HIV-related health technologies for LMICs that are locally produced, create mechanisms to facilitate technology transfer and capacity building between G20 countries and LMICs, and invest in strengthening regulatory systems and policy frameworks in LMICs to support sustainable local production. A broad Alliance can and should start with clear and concrete objectives, from where it can grow organically.

By taking these steps, the G20 can catalyze a new era of equitable access to health technologies, drive economic development in LMICs, and strengthen global health security for all.

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