



Discussion Paper on Advancing African Regional Manufacturing of Vaccines and Other Medical Countermeasures

The demand for greater capacity to manufacture vaccines, diagnostics, therapeutics, and other medical countermeasures (MCMs) locally on the African continent is not new. Even before the COVID-19 pandemic, Africa, which comprises 17% of the entire global population, was importing 99% of its necessary vaccines and between 70% and 90% of its other pharmaceutical and medical consumables. Furthermore, many African countries are reliant on donor grants or allocation cycles that are often time limited, disease-specific (often prioritizing diseases that are trending in global health discourses), or commonly vertical or siloed in application.

At the same juncture, Africa has the highest incidence of mortality caused by infectious diseases and annually reports that millions of people (mostly children) are under-immunized or receive zero doses of any vaccines altogether. Despite this, the continent has remained subject to global market trends, profit-making, and investment opportunities that privilege new medical consumables over gaps in coverage or improved health outcomes. This extends beyond vaccines, to other MCMs such as diagnostics and therapeutics.

COVID-19 exposed the fragility of the global health system and a need for countries and regions to ensure a minimum level of supply security for health products. While COVID-19 Vaccines Global Access (COVAX) made vaccines available to lower-income countries within just 39 days of high-income countries first receiving them, the wealthiest countries claimed the vast majority of the supply and even offered third and fourth booster shots to citizens before hundreds of millions of people in low- and middle-income countries (LMICs), particularly in Africa, received their first shot. The implications are multifold.

First, African countries do not have adequate supply of MCMs to prevent, detect, or treat diseases that primarily affect LMICs, especially when only low volumes of medical consumables are needed, such as for neglected tropical diseases (NTDs). African countries can neither adequately address health challenges unique to Africa nor equally benefit from economic opportunities and human capital growth; worse, this limits African countries' ability to plan and prepare for whatever may come next.

Second, to prepare for a Disease X,¹ Africa needs to develop the kinds of medical countermeasures that are needed all over the world, such as vaccines for diphtheria, measles,

¹ Disease X represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease.

and cholera. Such an undertaking should center on a multi-disease, multi-tool, end-to-end platform for coordinating the rapid development and the equitable access (available, acceptable, and affordable) to MCMs for African-focused needs and gaps, and for contributing to the global market of medical consumables. Further, the best approach to tackling current and future pandemics is to have steady production of routine MCMs for greater ease of adaptation when responding to new public health threats; this also helps ensure that provision of routine countermeasures is not undercut by pressures to redistribute health budgets.

At present, companies actively involved in vaccine production initiatives are consolidated in just five African countries (South Africa, Morocco, Tunisia, Egypt, and Senegal). Only a few conduct value-adding upstream manufacturing activities, and research and development activities on the continent have been limited, with a narrow disease focus. To date, there is not one manufacturer on the African continent that can produce vaccines, and the sector and demand lags significantly in comparison to manufactured therapeutics and diagnostics.

Both the African Union (AU) and the Africa Centre for Disease Control and Prevention (Africa CDC) have stipulated that if the continent scales its manufacturing ecosystem, it has the potential to improve access, quality, availability, and affordability of pharmaceutical products, in addition to the increased economic benefits through sustainability, competitiveness, and self-reliance of the industry. Localizing vaccine manufacturing could also reduce reliance on foreign aid and supply; mitigate risks of supply chain disruption and priority vaccine access; and generate substantial economic impact through job creation, increased investments, and increased intracontinental trade.

Thought leadership to advance the agenda has been largely driven by the AU and the Africa CDC. In 2021, the collaboration jointly launched the Partnership for African Vaccine Manufacturing (PAVM) Framework for Action. The framework aims to offer a blueprint for how to accelerate local manufacturing in a coordinated way to realize its bold vision of meeting up to 60 percent of its vaccine demand particularly for routine vaccines through regional manufacturing. In September 2022, as a part of the launch of the “New Public Health Order,” AU and Africa CDC called on Gavi and UNICEF to purchase at least 30% of all vaccines from African manufacturers.

Beyond agreeing to this call to action, Gavi produced a white paper requested by the German G7 Presidency that mapped out the opportunities for the continent and recommendations on the potential role Gavi could play and has undertaken an extensive process over the last year to design a regional manufacturing Advanced Market Commitment (AMC). Citing its expertise and capacity to aid in market shaping, co-financing, and knowledge transfer, Gavi is proposing to support building facilities that are capable of reliably producing high-quality vaccines that comply with globally recognised standards, such as Good Manufacturing Practice, Good Clinical Practice, and Good Clinical Laboratory Practice. The AMC would focus on addressing the demand and market shaping barriers that have historically rendered entry into the market for investors and manufacturers immensely challenging.

Going forward, the challenge is not “IF” or “WHY” scaled-up manufacturing is needed or advantageous but HOW, by WHEN, and by WHOM to ensure sustainably realizing this agenda for all Africans.

The ACTION Global Health Advocacy Partnership conducted a desk review of resources and interviews with key informants deeply involved in efforts supporting or advancing Africa’s regional capacity for medical countermeasure manufacturing. When reflecting

on this information and resources, we have laid out our thoughts on six important areas for discussion around future advocacy and priorities.

1. How do we put a “commitment to health equity” at the forefront?

At the root of this agenda is the fundamental call for health equity for communities in Africa. Equity should be prioritized in all aspects of the new pandemic prevention, preparedness, and response (PPPR) and global health architecture, starting from the earliest stages by ensuring equitable access and participation to the means of research, development, and innovation. This will be a central aspect to ensure proper adaptation and, thus, optimal delivery and use of technologies and innovations to local contexts. Development assistance organizations² and other potential investors must keep equitable access — accessible, available, affordable, and acceptable — to vaccines, diagnostics, and therapeutics as the core tenet in their involvement in supporting or advancing the agenda for regional manufacturing. Realizing the human right to health, achieving regional and global health (and health-sensitive) targets, and ensuring health security must be put before profits. This requires donor countries and development assistance organizations to systematically design their funding to guarantee this equity, and in order to deliver on a commitment to equity, they should support countries to conduct a full stocktaking of their present manufacturing capacity and the gaps they face.

2. Which medical countermeasures should be considered when it comes to market opportunities for Africa?

COVID-19 vaccine nationalism, where countries pushed to get first access to the vaccines and hoarded key inputs for vaccine production, galvanized interest in advancing regional manufacturing capacity, but vaccine equity and localization of markets for vaccines is not the sole need or opportunity for manufacturing in Africa. Development assistance organisations should champion and support processes that explicitly explore a broad suite of medical consumables (diagnostics, treatments and therapeutics, protective equipment, vaccines, prophylaxes, etc.) that leverage investments that build capacity and infrastructure to expand the commodity portfolio beyond vaccines.

3. How do we ensure alignment of vision to avoid duplicative or competing processes?

Development assistance organizations should play a proactive role in supporting an aligned vision for an Africa-wide free market for MCM manufacturing that encompasses a full suite of factors. This includes looking at the entire MCM manufacturing landscape; aligning with current global and regional frameworks and efforts, particularly regulatory; providing a whole-of-Africa market and current capacity and infrastructure assessment; and identification of strategic areas of opportunities. Additionally, the vision should consider and propose, in partnership with the African Union and Africa CDC, a range of recommended policy changes and resource

² This includes multilateral development institutions, global initiatives and bilateral organizations such as USAID, FCDO, Gavi, Global Fund, World Bank etc.

mobilization solutions that contribute to the realization of an entire MCM manufacturing ecosystem.

4. Where can we expand opportunities for greater country ownership?

In order to ensure sustainability and abate inequality (within and between countries), nation-led accountability and country ownership must be nurtured as the starting point of the local manufacturing agenda in line with or in reinforcement of an aligned regional vision. Development assistance providers should support interested countries by taking into consideration the fundamental interests of the country, a clearly articulate political will, and a locally driven assessment of technical capacity — in terms of human capital, “know-how,” trade barriers, and infrastructure — as well as market demand, production costs, and financing gaps from end-to end. This process requires engagement with all relevant government ministries and private sector, as well as local CSOs to ensure accountability.

5. How do we ensure transparency and comprehensive stakeholder engagement?

Planning for scaled-up local manufacturing capacity must allow adequate time for robust stakeholder involvement and integration (and the full capitalization) of externally funded assets within a regionally and nationally defined road map. Countries receiving external funding should make publicly available a realistic timeline of ongoing processes from the start of any planning or assertion of support and clearly communicate to all key stakeholders the process, timeline, and means of engagement.

Development assistance organizations should also systematically collaborate and ensure that all African countries — regardless of eligibility for support — are able to acquire vaccines in a timely, efficient, and affordable manner.

6. How can civil society and affected communities be key partners?

Civil society and affected communities must be considered primary development partners for design, delivery, and advocacy of these initiatives. Civil society and communities play a critical role in providing evidence-based rationale for demand and assessment of current capacities and need and holding governments to account on their commitments. Additionally, civil society and communities could have a role in community engagement and increasing demand and access for vaccines, as well as quelling disinformation. Development assistance organisations must foster meaningful involvement, communication, and coordination with CSOs throughout efforts to support scaled up regional capacity for medical countermeasure manufacturing.