Establishing Health Biotech and Enhancing Local Manufacturing of Pharmaceuticals in Sub-Saharan Africa

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Abstract
Although many nations in Sub-Saharan Africa (SSA) have recently recorded impressive economic growth, and several countries could attain middle-income status in the next decade, there is no or little concurrent advance in health biotech with little capabilities for manufacturing of medicines, medical supplies, and health commodities in the region. They import majority of medicines, medical supplies, and health commodities used in national programs including immunization, family planning, tuberculosis, HIV, and malaria that drive health outcomes and population-level impact with supports mainly obtained from high-income countries, multilateral agencies, or philanthropies. Nevertheless, there is a growing global debate that countries should graduate from receiving development assistance which goes to the most important health programs like immunization when nations transition from low-income to middle-income economic status. Since sudden withdrawal of all or partial development assistance could send a shock to the health care and dent the trajectory toward achieving the health Sustainable Development Goal, it is imperative to urgently establish or strengthen health biotech and enhance manufacturing of pharmaceuticals in SSA.

Keywords
health biotech, local manufacturing, pharmaceuticals, Sub-Saharan Africa

Introduction
In 2015, the United Nations transitioned global goals from Millennium Development Goals (MDGs) to Sustainable Development Goals (SDGs). Based on experiences garnered through the implementation of MDGs, ambitious targets for the sustainable development have been set with a signature promise of “no one should be left behind.” The Universal Health Coverage (UHC) covers a diverse range of health targets of the SDGs and should offer a unique opportunity to leverage consistent political commitment across both resource-rich and resource-poor countries. As critical drivers of impact, there should be unhindered access to medicines, medical supplies, and health commodities. This could be attained through establishing health biotech and manufacturing these essential supplies in Sub-Saharan Africa (SSA), the region they are most needed.

Status of Health Biotech and Source of Essential Supplies
Health biotech is a foundational platform for manufacturing medicines, medical supplies, and other health commodities. Although essential, the health biotech sector is underdeveloped in most nations in SSA. Whereas South Africa is leading the way in investment in health biotech in the region, we are yet to see substantial business spin-off and successful local manufacturing of pharmaceuticals. For instance, the Government of South Africa has invested an amount of approximately Rands 1 billion in the period from 2003 to 2011 in the biotech start-ups. In 2015, Ethiopia launched National Strategy and Plan of Action for Pharmaceutical Manufacturing Development and Improving Access. More recently, Rwanda announced a plan to locally manufacture medicines for HIV, tuberculosis (TB), and...
malaria. However, in general, health biotech and local manufacturing could not garner the attention it merits and nations in the region failed to make significant inroads in the sector.

As the investment in health biotech and efforts toward local manufacturing is currently minimal, countries in SSA mainly import vital products including medicines, vaccines, and other health commodities. Such supplies originate and are manufactured in high-income countries and few middle-income countries. Further, the cost of pharmaceuticals used for high-impact interventions including immunization, HIV, TB, and malaria programs in resource-poor countries in SSA is largely covered through multilateral or bilateral support. It should be noted that this support has helped save millions of lives in resource-poor nations in SSA. However, this partnership model between resource-poor and resource-rich countries is not robust enough to encourage investment in health biotech, which in the long term could ensure self-sufficiency of SSA in the sector.

On the bright side, it is evident that the economy of several nations in SSA has been growing fast. For instance, Ethiopia’s gross domestic product has grown by an impressive average of 10% every year for over a decade. Some nations in SSA have already attained middle-income economy status. While the remarkable rally in the economy sector is encouraging, we have not seen contemporaneous investment and corresponding progress in health biotech due partly to the higher level of priority given to infrastructure development including roads, water, and electric power. Health biotech at times is considered a luxury and off-limit to the nations in SSA. Also, even if the average public expenditure on health has substantially increased since Abuja declaration in 2001, most countries in the region fell short of the pledged 15% of annual budget.

**Graduation From Development Assistance**

Currently, an overwhelming bulk of foreign aid to the health sector in low-income countries goes to life-saving supplies including vaccines, antiretrovirals, TB and malaria medicines, and other health commodities. These are considered a backbone of the health sector, and they drive population-level impact. According to the World Health Organization, immunization has averted more than 50 million deaths during the last 50 years. Even with clear rooms for improvement in national immunization programs, vaccines currently save 2.5 million lives annually. Gratefully, resource-rich countries; multilateral agencies like Global Alliance for Vaccines and Immunization (GAVI), International Development Association, and the Global Fund; and philanthropies including Bill and Melinda Gates Foundation have continued to support vital programs that translate into saving millions of lives in resource-poor countries.

There is a growing global debate that middle-income countries should cover expenses for immunization, family planning, and other essential health programs that are currently fully or partially covered through development assistance or global partnerships. While this donor-dominated programmatic landscape in the health sector should eventually morph into domestically led investment, expected withdrawal of external support following countries’ economic transition could send irreversible shock to national health systems. Upon graduation from development assistance, it is virtually impossible for nations in SSA to suddenly bridge the expected chasm in the sector through procuring medicines, vaccines, and health commodities from the current manufacturers using domestic resources.

This prevalent view that middle-income countries should graduate from developmental assistance like Expanded Program for Immunization support could work only if economic development translates into improved health biotech and local manufacturing of pharmaceuticals and eventually ensures self-reliance in the sector. Relatedly, any potential programmatic gaps created due to pulling of external support, which goes to some vital medicines, vaccines, and other health commodities, could be overcome only if there is sufficient upstream investment in capacity development in health biotech, which could lead to regional or local manufacturing of pharmaceuticals. With little or nonexistent capacities for health biotech, the path to meaningful regional or local manufacturing of pharmaceuticals and self-reliance in the sector may take decades. As a consequence, the high-yielding programs like immunization, family planning, and communicable diseases prevention and control could suffer grave consequences. In light of this, I argue that, with a nascent health biotech and little efforts to laying the foundation for regional or local manufacturing of medicines, vaccines and other health commodities, there is a slim chance for graduating nations in SSA to achieve the health SDG and UHC.

The counterargument could be considerable efficiency gains and cost-effectiveness in cases of massive production in high-income countries. Issues related to international trade, patent, and proprietary schemes may favor the continuation of the current model whereby high-income countries are developers and manufacturers of health products and low-income countries, particularly nations in SSA are mostly consumers. Regional or subregional hubs for manufacturing whenever feasible and locally led investment in big countries, however, could be a smart alternative. In this regard, some middle-income countries have shown unprecedented progress in establishing health biotech, and they can serve as a
benchmark. For instance, India is by far the biggest supplier of vaccines to the United Nations International Children’s Emergency Fund. Since the turn of the century, low-cost antiretrovirals manufactured in India have saved millions of lives worldwide. Countries like Cuba and Vietnam have largely attained and sustained self-sufficiency in the provision of locally manufactured medicines, vaccines, and other health commodities and have now sizable contributions to the global market. Bangladesh, a low middle-income nation, fulfils nearly 100% of its domestic medicines demand through local production, and it has made major inroads in developing capabilities to manufacturing essential vaccines in the country. The successes recorded by those middle-income countries could serve as surrogate indicator for concrete possibilities for health biotech outside its traditional origins—high-income countries.

**Recommendations**

Lessons drawn from MDGs implementation have shown that a chorus of support from resource-rich countries resulted in substantially improved health outcomes. In the era of SDGs, I believe that such well-run programs should continue to perform at sufficient quality, scale, and impact. The health programs in this era also require uninterrupted supply of essential medicines and other health commodities. In this regard, I have 2 intertwined recommendations.

The first recommendation is region-initiated, urgent establishment of domestically financed health biotech centers in SSA. A cross-continent political, economic, and scientific communities including the African Union should cultivate collaboration between African nations and with the north and spearhead the establishment of health biotech in the region. Whereas this should be a top-tier priority for all nations in SSA, its depth and breadth could depend on the burden of the diseases, simplicity of the processes, and saving gains on the expected outputs. The efforts should start with intensified research and development and ultimately lead to manufacturing of pharmaceuticals in the region. There should be concurrent investment in building robust regulatory system to safeguard citizens from potentially low-quality products. Further, the architecture of north–south collaboration should shift its focus from developer/producer–consumer relationship to tech transfer and capacity development in establishing regional and national platforms. South–south collaboration in health biotech should focus on developing collective capabilities for supplying products that target shared health challenges.

The second recommendation is that multilateral agencies should transition their role from providing ready solutions for health programs to capacity development for health biotech at regional or subregional levels in SSA. The mode of support from global agencies like GAVI, the Global Fund (GF), and others to nations in SSA should include direct funding to local manufacturing of medicines, vaccines, and health commodities. Newer partnerships like Coalition for Epidemic Preparedness Innovations (CEPIs) could also play a critical role in developing local capacity for vaccine development. CEPI could beef up preparedness for potential outbreaks in SSA through encouraging and incentivizing vaccine development in the region. Another opportune platform is European and Developing Countries Clinical Trials Partnership (EDCTP), a partnership between European countries and countries in SSA. EDCTP has to further its goalpost from capacity development for conduct of trials to capacity development for health biotech and manufacturing in SSA.

Coupled with improved downstream aspects of supply chain management, local manufacturing in SSA could have a game-changing impact on access to essential supplies. Smart metrics should be in place to measure the progress in the health biotech sector as well as its direct contributions toward improving health of the population. I believe that establishing health biotech in SSA could have substantial return on long-term investment and could help the region achieve health SDG and UHC.

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