



Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance

Workshop on the Preliminary Report
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A Project of the Open Society Foundations Public Health Program
Study Undertaken by Nova Worldwide Consulting
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Research Questions and Methodology

Questions

- Whether and to what extent gaps in the availability of financing are constraining the development of pharmaceutical manufacturing* in Africa, especially to address COVID-19?
- Assuming that gaps are identified, what steps or measures might be advocated to address those gaps?

Methodology

- Methodology entailed desk research, stakeholder interviews, questionnaires and small group learning session, relying also on previous research work and experience of Team

*Diagnostics, vaccines and therapeutics (DVT), as well as personal protective equipment (PPE)

Objectives of Today's Workshop

- Present summary of findings of research
- Suggest measures that might change existing dynamic
- Recommend potential avenues for advocacy
- Hear suggestions for changes to Preliminary Report, and/or avenues for future work program

Meta-Gaps

- Financial capital is available on global markets for investment in manufacturing pharmaceutical products, including in Africa. However, to date there has been relatively little capital investment in Africa's pharmaceutical manufacturing sector
- Even though holders of financial capital espouse interest in “impact investing” and environmental, social and governance (ESG) investing, they seek a market or close to market return on investment.
- International donors that are major funding sources rely on stringent GMP compliant, low cost, producers, typically from India or China. Very few manufacturing facilities in Africa are stringent GMP compliant, and local manufacturers lack incentive to invest in upgrading facilities.

Public Health Security

- African governments have not “prioritized” pharmaceutical manufacturing as they have military/defense, power grid and certain other infrastructure
- COVID-19 pandemic starkly illustrates potential scale of risks to national security from lethal pathogens
 - May be foundation for transforming government attitudes toward health sector
- Both national and regional public health security are relevant
 - National security likely to remain first priority, but regional security may closely follow



Main Findings

- Diversity of conditions and contexts within Africa
- Misleading to treat all African countries as sharing the same constraints
- In many countries, there are failures and weaknesses on both the supply side and the demand side
 - supply side: expertise, finance, regulatory, technology
 - demand side: market size, offtake guarantees, tariff protection
- Addressing the constraints requires a 'policy mix' approach (no single solution)

Fundamental Product-Dictated Differences

- The market for developing and manufacturing vaccines to prevent pandemic spread of virus is by nature contingent and traditionally reliant on public funding.
- Industry generally expected to deliver vaccines in developing country markets at or near cost of production, limiting potential interest of “market-based” investors.
- A “sustainable business model” approach that may facilitate financing for private sector development may not translate directly to vaccine sector.
- For low- and middle-income countries external funding sources such as World Bank/IFC, other Development Banks, Foundations likely needed

Pharmaceutical Manufacturers are Dependent on Markets

- Sustaining profitable operation of pharmaceutical manufacturing facility depends on access to and acceptance by purchasers (i.e., demand)
- Various factors constrain demand in Africa
 - In many cases, small national markets (population and/or income)
 - Analogy to problem set of R&D for “neglected diseases”
 - National procurement authorities tend to operate on relatively short cycles, and rely on lowest cost suppliers, often Chinese or Indian producers
 - International donors demand strict GMP compliant suppliers, very few of which are present in Africa

Steps to Address Demand Gaps

- Establishing improved demand structure
 - Reduce impediments to intra-Africa trade in pharmaceutical products
 - Coordinated/harmonized regulatory approvals
 - Reduction of tariffs and related trade barriers
 - Create regional pooled procurement mechanism
 - Persuade international donors to fund upgrade of African manufacturing facility GMP through, e.g., price premiums for locally-produced products
 - Establish regional production centers or hubs for intra-continental supply
 - Focus on cost reduction and efficiencies through shared infrastructure
 - Encourage local production procurement premiums

“Investable” Business Models

- Persuading capital investors toward making investment in African pharmaceutical manufacturing requires presentation of sound business models that are sustainable
 - Grant funding is effective only so long as it lasts unless underlying business is profitable
- “Infant industries” nevertheless may require public incentives, including direct subsidies, tax credits, guaranteed offtake agreements, localization pricing premiums, import restraints
- Investable business models ultimately rely on balance of supply and demand, and reasonable return on investment



Opportunities for Advocacy

- Public Health Security: Advocacy groups and civil society should encourage African governments to view local production of pharmaceuticals as a matter of national and regional public health security, and to provide financial support for localization through subsidies, tax incentives, procurement preferences, advance purchase commitments and other mechanisms
- The "market problem": Advocate toward creating pooled procurement modalities for the African region that aggregate demand. Cost-effective scale production or supply may be improved through establishing regional production hubs or centers that take advantage of collective infrastructure and sources of raw material supply

Opportunities for Advocacy

- Social Returns: Sovereign Wealth Funds, retirement-focused asset managers, insurance organizations and private equity investors, are seeking to make a positive social impact with their investments. These asset holders should be encouraged to view investment in local production of pharmaceutical products in Africa as sound business investments with potentially substantial "social returns"
- Multilateral Financing: Encourage multilateral funding institutions, including World Bank and IFC, African Development Bank (AfDB), Asian Development Bank, and others to invest in long-term public health security in Africa and to take greater risks with capital investments in local manufacturing. Replication of project assessment standards used by commercial lenders does not meaningfully add to pool of available capital

Opportunities for Foundations

Foundations:

- Provide African pharmaceutical industry entrepreneurs with practical assistance in establishing sustainable business plans capable of attracting investors
 - Assist in connecting African businesses with potential joint venture/technology partners
- Provide support for the creation of regional production hubs
- Provide support for the creation of regional pooled procurement and distribution mechanisms
- Support a regional African Vaccine Institute similar to India's Serum Institute, recognizing the existing work of African Vaccine Manufacturing Initiative
- Encourage potential funders of localizing production to make transparent and coordinated the opportunities for funding and potentially create a financing pool to support localization initiatives



Thank You for Participating and Looking Forward to Your Input!

The Nova Worldwide Team