

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

Final Report: Executive Summary

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Frederick M. Abbott

Ryan B. Abbott

Joseph Fortunak

Padmashree Gehl Sampath

David Walwyn

A landscape mapping and analysis of financing for African manufacturing of COVID-19 diagnostics, vaccines, therapeutics and essential PPEs

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

A Project of the Open Society Foundations Public Health Program

Study Undertaken by Nova Worldwide Consulting

Team Members: Frederick Abbott, Ryan Abbott, Joseph Fortunak, Padmashree Gehl Sampath, David Walwyn*

Full report available [here](#)

Executive Summary

Background

At the request of the Open Society Foundations Public Health Program (OSF-PHP), a Team of researchers assembled by Nova Worldwide Consulting undertook to study 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. In this context, pharmaceuticals are understood to include diagnostics, vaccines and treatments (DVT), as well as personal protective equipment (PPE). Assuming that gaps in the availability of or access to financing are acting as a constraint on local production, what steps or measures might be advocated to address those gaps?

The research Team -- Frederick Abbott, Ryan Abbott, Joseph Fortunak, Padmashree Gehl Sampath and David Walwyn -- represent a variety of disciplines and experience, including legal, economic and scientific/technical. The methodology of research for this study entailed preparation of an inception report, desk research, interviews of stakeholders, a small group learning session with a group of experts, preparation and distribution of a questionnaire at the firm level, discussion with civil society advocacy group representatives, as well as reliance on the experience of Team members.

As of the date of this report in March 2021, the reasons for undertaking the study are evident. The global response to the COVID-19 pandemic laid bare the lack of adequate manufacturing facilities for production of vaccines. The COVID-19 response has been evidenced by uneven availability of vaccines among countries and continents, a phenomenon that has been labeled “vaccine nationalism”. For virtually all countries and regions, the risks associated with lack of access to life-saving vaccines has focused the attention of political leaders and the wider public to the importance of having local production facilities available for situations of emergency. The early stages of the pandemic also revealed an inability of nearly all countries to respond to surges

* See About the Team at back of this Executive Summary.

in demand for PPE and of many essential medicines. The world was seen to be critically dependent upon China and India for filling the supply chain for these products.

Well before the COVID-19 pandemic, the potential benefits of increasing local production of pharmaceutical products were identified by the World Health Organization (WHO) and other organizations and groups. The African region is especially reliant on imports of pharmaceutical products. This represents a challenge to public health, and also burdens national budgets with substantial import/export imbalances. There is a growing demand among political leaders, public health officials, civil society advocates and others in Africa for the region to transition to greater self-reliance in the area of pharmaceutical manufacturing.

Findings

Diverse environment

Africa is a diverse region of 54 countries with varying geographies, levels of socio-economic development, health burdens, political systems, infrastructure characteristics, educational systems (including for scientific training), and cultural traditions. The pharmaceutical manufacturing industry is diverse. Smaller producers face different challenges than larger established producers within the region. The conditions for sustainable pharmaceutical manufacturing are different for different types of products. Overall capacity is assuredly inadequate to meet demand by African production alone. This study acknowledges these underlying complexities and the inherent limitations presented for analysis and prescription.

Global financial liquidity

As a broad proposition, there is a great deal of investment capital available in global financial markets, including capital available for African investment as well as COVID-19 relief. In principle that capital is available for investment in local production of pharmaceuticals in Africa. To the extent there are constraints on financing for manufacturing -- whether diagnostics, vaccines or treatments -- this is not because of a global shortage of available capital.

Multilateral institutions, development banks, foundations and other financing institutions

In response to the COVID-19 pandemic, multilateral institutions such as the World Bank and International Finance Corporation, as well as regional development banks, have announced large commitments of funding to support responsive measures. Yet, with rare exception, this support has not to date included financing for local production of pharmaceuticals in Africa. The IFC indicates that financing is available for serious well-planned projects, but that so far it has not seen demand of that type. The African Development Bank (AfDB) is actively exploring potential opportunities for financing in the African pharmaceutical sector, but this work remains in fairly early stages.

Likewise, foundations are financing research and development, advance purchase commitments of vaccines and diagnostics, and other efforts to address COVID-19, but have not so far materially

funded projects to locally produce in Africa. Each of these potential funder groups is in one way or another reassessing this landscape.

Impact and/or ESG investing

In recent years there has been much attention paid by asset managers to the idea of “impact investing” that combines securing reasonable returns while generating social benefits. Similarly, there is considerable focus on environmental, social and governance (ESG) investing. There are many types of asset managers, including private capital managers, sovereign wealth funds, insurance and pension funds, and individual investors. There are public and private asset managers. It is reasonable to think of impact investing and/or ESG investing as a source of financing for local production in Africa, particularly given the attention being given to difficulties arising from lack of access to vaccines. While this may be an attractive idea, as of the date of this report there is little evidence of financing by impact or ESG investors of pharmaceutical manufacturing facilities in Africa.

Market factors

A key question addressed by prospective investors in local pharmaceutical production in Africa is whether such production is sustainable from the standpoint of returning capital and profit, thereby justifying investment. A variety of factors help determine whether a manufacturing facility will be economically sustainable, including the size of the relevant market for the product(s) and the extent of demand. African national markets are disparate. Smaller geographic and lower-income markets present greater challenges for producers. Even in larger and relatively higher income markets like South Africa, the structure of the market, including the major role played by the government in procurement, creates difficulties for some producers.

Significantly, the market for vaccines has traditionally been challenging for producers, whether in high- or low-income countries. Vaccine producers are typically subsidized in one way or another by government. Finance comes from the government budget.

The role of governments in procurement

In a large number of product categories, across a large number of African markets, the government remains the main procurer. In these instances, inconsistent demand due to shortages in public budgets, or procurement practices that do not prioritize local producers creates disincentives for setting up new local production initiatives, and expansion of existing local production into new categories.

Government procurement is usually done through open tendering processes. In addition to facing competition from Chinese, Indian and other producers, existing local manufacturers in some African countries express concern with the relatively short procurement cycles and “all or nothing” contract processes. A local producer that wins a bidding competition may be able to operate its facility at full capacity, but after a few years may lose its contract in a new procurement cycle and see its production fall precipitously, leaving it with expensive excess

manufacturing capacity. This makes it very difficult for African local producers to source investment capital and to engage in longer-term business planning.

Competition from China, India and elsewhere

For African producers there is a general problem of meeting competition from Chinese, Indian and other low-cost generic finished pharmaceutical product (FPP) producers, and producers of APIs. These non-African manufacturers companies employ scale economies, benefit from government support, and often operate at low margins. This makes it very difficult for potential competitors, including in Africa, to succeed in procurement competitions. African public health procurement mechanisms typically seek the lowest-cost/price supplier. In order to compete with Chinese and Indian pharmaceutical manufacturers African producers require local production pricing preferences or other types of support. Because budgets are tightly constrained, African procurement authorities are reluctant to provide these supports. In the absence of additional incentives that cross-subsidize the initial costs of production of pharmaceuticals, and a good selection of product baskets where they can establish internal strengths, African companies will find it difficult to secure and sustain domestic market sales.

Although it represents something of a special case, the COVID-19 pandemic has generated massive subsidies programs in high income countries to support build-out of vaccine manufacturing facilities. All other things being equal, it would be extraordinarily difficult for African governments to provide comparable levels of subsidies and other financial support for vaccine manufacturing in Africa. This may lead to a situation in which there is global capacity, or even overcapacity, for the production of COVID-19 related vaccines that will make it more difficult to justify additional investments or other support, including in Africa.

International donors and stringent GMP

African manufacturers face a relatively unique problem posed, perhaps paradoxically, by the substantial role played by international donor organizations or groups in the procurement and supply of pharmaceutical products. The international donor organizations require that suppliers meet stringent GMP requirements, including those used for WHO prequalification. Very few African producers meet these stringent GMP requirements and are effectively shut out of a large part of the African procurement market. This phenomenon arose largely in response to the HIV-AIDS epidemic and the need for large-scale procurement of low priced generic antiretrovirals and other products. It is conceivable that a similar situation could arise with respect to vaccines or treatments for COVID-19, or other products over the longer-term.

Upgrading pharmaceutical production facilities to meet stringent GMP requirements, and maintaining those facilities, is a costly undertaking. Because African producers are typically supplying local markets and complying with national GMP standards, there is limited incentive to invest in upgrading, particularly if there is no assurance that, having upgraded, they would be awarded contracts by international donor organizations.

Intra-continental constraints

The ability of African local manufacturers to produce and sell at scale depends on identifying markets of comparable scale. Many African countries offer small markets because of population size, income and/or geography. This small-market constraint is compounded by difficulties associated with selling and distributing products across borders. Challenges include the need to register and comply with regulatory requirements in each jurisdiction, relatively weak transport infrastructure, and border measures such as tariffs, that impose additional costs. The recent entry into force of the African Continental Free Trade Agreement may help address some of these constraints. The growing role of the Africa CDC likewise may improve the situation. But, for the present, these constraints limit the market opportunities for African local producers.

Industry and financial stakeholders observed that African leaders regularly announce plans to bolster pharmaceutical manufacturing on the continent, but that there is limited follow-through in terms of implementation, little to no monitoring of success or failure and a lack of data-keeping to draw conclusions on allocation of scarce financial resources in procurement, the functioning of the market, or competition trends.

Firm-level financing constraints

Much of the financing for African local producers comes from private investors who rely on family or other relationships to aggregate capital. While these producers typically do not use ordinary commercial banks as the primary means to finance their operations, there is demand for bank and similar commercial lending, and the lending rates by commercial banks for local pharmaceutical producers is typically at a premium, apparently because of the perceived risks. High rates for commercial loans contribute to difficulties in competing with non-African suppliers.

There is some evidence that multilateral financing institutions also offer higher rates and/or fees when dealing with African local producers.

Government planning, setting of targets, and provision of incentives for local pharmaceutical manufacturing must provide a comprehensive approach over a sustained period of time to be effective. Many support programs do not address root-cause issues that are critical limitations to local production. Preferences for local manufacturers in public sector procurement, for example, are difficult to implement if local producers lack access to hard currency to purchase raw materials, modern equipment, and spare parts to maintain production.

The broader infrastructure environment

This study focused on the role of finance, but the prospects for increasing local production of pharmaceuticals in Africa realistically cannot be viewed through a too-narrow lens. Manufacture of pharmaceutical products is dependent on continuous supply of electricity, availability of water, environmental control infrastructure, and other elements. In addition, the operation of a pharmaceutical manufacturing plant requires trained technical personnel. Pharmaceutical manufacturers in countries like India and China -- where there are a substantial number of producers -- benefit from the presence of an ecosystem of suppliers and service providers, including for the installation and repair of machinery and equipment, software, etc. In addition,

producers in India and China have good access to the intermediate chemical compounds and APIs that are key components of pharmaceutical production. The relative absence of comparable infrastructure and ecosystems in Africa makes the establishment of a cost-effective manufacturing operation more difficult than for some major country competitors.

A substantial part of the explanation for the lack of robust demand for pharmaceutical products must be attributed to a wider cyclical chain of causation, where finance, technology and expertise play a role.

Structural funding issues

Case studies of pharmaceutical production projects (including vaccines) in South Africa illustrate the potential challenges presented by public-private partnership models. While government funding may be necessary to successfully launch a project, a significant continuing ownership role by the government may inhibit subsequent private capital investment. Reliance on continuing financial contributions from the government is risky because it is subject to changing political tides and perspectives. Private investors that perceive greater than ordinary risk from government participation may demand greater than normal returns on capital as a price of participation.

Conflict between industrial policy and public health objectives raise another structural barrier. For example, demands for pricing premiums to sustain local production has in the past met with resistance from public procurement authorities.

Personal protective equipment

Because the manufacture of PPE is often less technology intensive than pharmaceutical manufacturing, and requires more modest upfront capital investment, there has been substantial opportunity for PPE manufacturing in Africa during the COVID-19 pandemic. Governments and the private sector have stepped in to support local PPE manufacturing. Financing does not appear to be a major constraint in this area.

Socio-economic conditions more broadly

The level of demand for pharmaceutical products in a country or region depends in substantial measure on the level of socio-economic development, in addition to the role that each government chooses to play in addressing public health concerns. Improved socio-economic conditions within a country will almost certainly increase the demand for pharmaceutical products. Pursuing policies that improve socio-economic conditions would create better market conditions and support local production of pharmaceuticals in Africa. This study looks specifically at measures that would address pharmaceuticals markets as compared with measures that might more generally improve socio-economic conditions, recognizing that improving socio-economic conditions would improve the prospects for local production of pharmaceuticals.

The functioning of more robust markets is not a straightforward matter of governments and/or the private sector making better decisions regarding pharmaceuticals. It remains a part of a wider set of issues regarding economic and social development.

Primary and secondary objectives

Promoting more robust local production of pharmaceuticals in Africa involves several objectives. The overriding objective is to enhance access to safe and effective medicines for the people of the continent. This study does not seek to resolve what is a long-standing debate regarding whether local production will result in lower prices in part because there is at least an initial cost involved in supporting an industry in the process of development that will not necessarily entail lowering prices, and it is difficult to predict the competitive landscape over the medium to longer term. It should probably not be assumed that localizing production will in the short-term result in the availability of lower-priced pharmaceutical products on the continental African market.

The secondary objectives of localizing production involve economic development and industrial policy goals including increasing employment opportunities, promoting science and technology advancement, improving infrastructure, and reducing balance of payments outflows.

The combination of the primary objective of enhancing access to medicines through greater public health security, and the secondary objective of enhancing various elements of economic development, in principle present a sound basis for addressing gaps in the financing of Africa's pharmaceutical manufacturing sector.

Concluding observation regarding findings

The overall findings of the study are that gaps in financing pose a constraint on the localization of pharmaceutical production in Africa. The gaps are not mainly due to a lack of financial capital in global financial markets that might be deployed for this purpose. The main problems are associated with the market environment in the sense that sustainable business operations require adequate demand, and market demand for pharmaceutical products in Africa is limited by various factors. In addition, comparatively weak infrastructure (recognizing variation among countries) makes it difficult to compete with large efficient foreign suppliers that are bolstered by foreign government support. Potential investors appear to perceive relatively high risks associated with investing in pharmaceutical manufacturing in Africa.

New Approaches

Transforming political engagement

Governments in Africa prioritize certain sectors of their economies in terms of long-term financial support; typically, the military/defense sector, power grid and, to a somewhat lesser extent, agriculture. Although public health occupies in many cases a significant part of the public budget, procurement of supplies is mainly through importation. African governments have not prioritized pharmaceutical manufacturing in terms of providing subsidies, guaranteed offtake agreements,

pricing premiums, trade measure protection and similar support measures. The COVID-19 pandemic may serve as adequate impetus to transform local production of pharmaceuticals into a governmental priority. Government commitment at a high level is required to engage the financial levers that will support localization of production.

The concept of “public health security” could be employed by governments to elevate public perception regarding the importance of preparing for future disease outbreaks. While for each country and government “national” public health security is likely to occupy the top priority, for the African continent secondary attention to “regional” public health security may also be important.

Public health advocacy groups may play a helpful role in this transformation by applying pressure to governments to raise the profile of local production.

Vaccines

The market for developing and manufacturing vaccines to prevent the spread of the pandemic virus is by nature contingent. Because market demand for a particular vaccine may never manifest itself, private investors are unlikely to invest in vaccine manufacturing plants absent government financial support. The development of a sustainable business model from a private investment standpoint almost certainly entails some form of advance purchase or guaranteed offtake commitment, or continuing subsidy, to induce investment. Alternatively, governments may themselves invest in vaccine manufacturing facilities.

Regional pooled procurement commitments would be a useful tool for supporting the construction and operation of vaccine manufacturing in Africa. Funding from multilateral institutions such as the World Bank and other development banks will also be important.

Regional production hubs and pooled procurement

Overcoming the limitations presented by limited infrastructure might be accomplished by concentrating pharmaceutical production in designated areas and investing in surrounding infrastructure for those areas. There may be specific locational advantages for certain types of products. For example, manufacturers of small molecule pharmaceuticals may benefit from proximity to existing petrochemical complexes. Countries such as India and China have created pharmaceutical production zones along these lines.

Within a group of countries seeking to establish a regional arrangement, allocation of industrial opportunities is inevitably challenging. There is no easy answer for solving the allocation challenge, but in the broad framework of the African Union there may be trade-offs available between industrial sectors. Given the scale of the potential market for pharmaceutical products in Africa, there may be space for 3 or 4 regional production hubs located on different parts of the continent.

Just as regional production hubs may help achieve economies of scale and the prospects for competing effectively with non-African producers, establishing regional procurement mechanisms would pool and help to create a source of continuing large-scale demand. This should facilitate reducing prices, again to better compete with non-African producers.

Sustainable business models

Particularly outside the vaccine sector, successfully operating a pharmaceutical manufacturing facility means addressing a market with sufficient demand to generate revenue and profits. Alternatively, or as a supplement, governments may provide direct subsidies, guaranteed offtake agreements, tax credits, local production pricing premiums, and other measures to substitute for market demand. These forms of support are commonly used for “infant industries”, and there should be plans to withdraw such support once a business has achieved sustainability.

African governments could, in addition, consider using tools such as awarding limited periods of market exclusivity to products from African producers that successfully introduce the first locally produced version of a product on the national or continental market.

Both Chinese and Indian pharmaceutical manufacturers have benefited substantially from shipping to export markets. Building sustainable production in Africa may well include plans for exporting, bearing in mind that shipping to the high-income markets requires compliance with stringent GMP. Export opportunities in high-income markets are precisely what impelled the Indian and Chinese manufacturers to introduce stringent GMP within their own countries i.e., to be able to adequately address US and European regulators.

Foreign exchange and the lack of hard currency hampers a good deal of pharmaceutical manufacturing in Africa. Many firms operate at low occupancy rates (a critical factor for success), due to inability to pay for spare parts, repairs, preventive maintenance, and raw materials – all of which are imported. The inability of financial markets to respond rapidly to currency needs for this purpose is a truly critical limiting factor for local production in Africa.

The social impact investor market

African governments should consider a program to encourage sovereign wealth funds and other financial asset managers to invest in local production on the African continent as a way to accomplish important social goals. To facilitate this objective, there should be some type of backstop or guarantee of the social impact investments within reasonable parameters. The African Development Bank may be helpful in establishing mechanisms for this purpose.

At the firm level

Pharmaceutical production ultimately is undertaken by individual firms, each of which will face its own challenges. These range across the spectrum of identifying the products to be produced, the technologies to be employed, the sources of raw materials, the suppliers of equipment and software, securing land and permits, undertaking construction and validation of processes, obtaining regulatory approval for market entry, commencing manufacturing and distribution,

establishing a reputation in the marketplace, and expanding operations. At each phase, there are requirements for financing, both shorter and longer term.

The availability of a dedicated team of finance experts in the pharmaceutical sector, whether under the auspices of the African Development Bank, or another institution, may assist local producers in addressing the various challenges along the way.

In addition, African entrepreneurs should be encouraged to pursue collaborative arrangements with foreign partners that have requisite technologies, experience dealing with regulatory compliance, and potentially financial capacity. As in other regions, foreign partners may find strategic advantage in terms of market support and penetration to joining with locally based African manufacturers. This should provide incentive for collaboration on local production efforts.

Just as the African Development Bank or a similar institution in Africa may assist local entrepreneurs with addressing financing requirements, there should be a dedicated institution to assist with negotiating technology transfer and joint venture arrangements in terms of legal and regulatory expertise.

If the vision of regional production hubs can be realized, there may be possibilities for incorporating associated centers of technical expertise that could provide assistance for multiple producers.

Opportunities for advocacy

There is substantial room for advocacy by civil society to move Africa toward greater self-sufficiency in the production of pharmaceutical products. At the high level of political commitment, government authorities should be persuaded to prioritize local production of pharmaceuticals as a matter of public health security, engaging the financial levers to support such a commitment. At the level of industrial policy, the African Union should be encouraged to engage in concrete planning for regional pharmaceutical production hubs, and associated infrastructure and centers of technical expertise. Whether in conjunction with that, or separately, procurement authorities should be encouraged to form regional pooled procurement mechanisms to aggregate demand, allow for more effective bargaining with suppliers, and support regional hub manufacturers.

Support for effective implementation of the African Continental Free Trade Area in terms of reducing barriers to intra-Africa trade in pharmaceutical products would improve the market situation. Similarly, continuing support for efforts to integrate the African regional regulatory structure for pharmaceutical products would accelerate access to medicines. Establishment of a library of available drug master files for reference by manufacturers would significantly lower barriers to manufacturer market entry.

Governments should be encouraged to support the establishment of joint ventures with foreign technology partners that can facilitate the establishment of local manufacturing facilities.

Advocacy groups should encourage global asset managers, including private investors, insurance and pension funds, and sovereign wealth funds to view local production of pharmaceuticals in Africa as social impact investment, and encourage the African Development Bank and other financial institutions to provide some forms of backstops or guarantees for these investments to offset risk. An African Development Bank program for guaranteeing commercial debt would more generally aid in lowering the cost of capital, particularly for smaller pharmaceutical manufacturers.

Foundations should be encouraged to develop a transparent platform which could provide information to African manufacturers with respect to opportunities for financing and expertise for pursuing their objectives.

For more information on Open Society Foundation's support for this project, and work to advance manufacturing of essential medicines and health technology, please contact Rosalind McKenna on <rosalind.mckenna@opensocietyfoundations.org>

About the Team

Frederick M Abbott is President of Nova Worldwide Consulting. He is the Edward Ball Eminent Scholar Prof. of Law at Florida State University College of Law. As a specialist in law and economics with a focus on transfer of technology, public health, trade, intellectual property and competition, he has undertaken a number of studies for the World Health Organization (and others) regarding the legal and policy frameworks conducive to establishing successful pharmaceutical production with the objective of promoting equitable access to healthcare. His published work and a complete curriculum vitae can be found at <https://frederickabbott.com>.

Ryan Abbott is Professor of Law and Health Sciences at the University of Surrey School of Law, and Adjunct Assistant Professor of Medicine at the David Geffen School of Medicine at UCLA. He has published widely on issues associated with life sciences in leading legal, medical, and scientific books and journals, and his research has been featured prominently in the media including in the New York Times, Wall Street Journal, and Financial Times. Professor Abbott has worked as an expert for, among others, the United Kingdom Parliament, the European Commission, the World Health Organization, and the World Intellectual Property Organization.

Joseph Fortunak is a Professor of Chemistry and Pharmaceutical Sciences at Howard University in Washington, DC. He teaches postgraduate programs in drug manufacturing and regulatory sciences in Africa including the University of Ibadan School of Pharmacy, Center for Drug Discovery and Development. Professor Fortunak has worked with many generic companies in India, China, and several African countries in addition to consultancies with WHO, USAID, USP, GFATM, and UNIDO. He previously was the Global Head of Chemical Development at Abbott Labs.

Padmashree Gehl Sampath is Senior Advisor of the Global Access in Action Program, Berkman Klein Center for Internet and Society, Harvard University, and an adjunct professor of Social Sciences, University of Aalborg Denmark. She has a wide body of work on trade, technology and development issues. Prior to joining Harvard University, she has led several programs at international agencies focused on innovation and local production in the pharmaceutical sector and its impact on access to medicines. More information on her and her recent work is available at: www.rights2100.org

David Walwyn is a Professor in the Graduate School of Technology Management at the University of Pretoria. His research interests cover sustainability transitions, renewable energy, science and innovation policy, research management and industry localisation. He currently teaches two courses in engineering economics and three courses in energy value chains. He has published widely in the area of science and technology policy, research management, health sciences and biotechnology; further details are available on ResearchGate. He has also consulted on many policy projects relating to innovation policy and supported university technology transfer through techno-economic feasibility studies.