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

Final Report

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

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Nova Worldwide Consulting®

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 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 manufactures 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>

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DVTs	Diagnostics, vaccines and therapeutics
OSF	Open Society Foundations
PHP	Public Health Program
PPE	personal protective equipment

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1. Background to the Assignment

1.1 Introduction

Recognizing that the COVID-19 pandemic provides a decisive moment for the Open Society Foundations (OSF) to push for change that is structural, impact-focused, and aligned with its long-term economic and social justice aims, the foundation is seeking to use this opportunity to mobilize people, politics and movements to promote equitable and affordable access to life-saving diagnostics, vaccines and therapeutics (DVTs) for COVID-19, as well as those needed in future health crises.

More specifically, the OSF's Public Health Program (PHP) wishes to support the urgent need for increased manufacturing capacity in Africa, Asia and Latin America, both to respond to the pandemic and, over the longer term, to increase research and manufacturing power in the Global South. As part of this focus, the OSF-PHP has engaged Nova to undertake a landscape mapping of financing for DVT and essential personal protective equipment (PPE) manufacturing in Africa, and to provide a set of recommendations as to how the constraints to financing can be mitigated so as to promote the development of the DVT manufacturing in Africa.

1.2 Scope of the Assignment

The mapping provides an analysis on how funds are structured (including co-financing requirements), what guidelines are used for their utilization, and what blockages or barriers may exist in accessing financing. The mapping also identifies areas where civil society advocacy and influence could result in more successful technology transfer and rapid scale-up of manufacturing capacity to enhance equitable access to DVTs and essential PPE/health technologies.

The project has been undertaken in eight phases between September 2020 and March 2021 as detailed below and shown in Figure 1, resulting in the following outputs:

- an Inception Report for consideration by OSF-PHP and the attendees of the Learning Event (Phase 1). The input from the Learning Event has been summarized in Appendix A.
- a detailed review of the literature, resulting in a baseline perspective on how to transform government policy for the local production of pharmaceuticals (Phase 2 and covered in Section 2)
- a mapping of financing for DVT and PPE in Africa based on secondary data sources (Phase 3 and covered in Section 3)
- a qualitative perspective of the DVT manufacturing sector based on a series of scoping interviews with key stakeholders and individuals with prior knowledge of the sector (Phase 4 and covered in Section 4). The interviewee list is attached in Appendix B.
- a detailed sector analysis based on interviews and a semi-quantitative questionnaire to stakeholders in connection with the core problem statement (local DVT and PPE

manufacturing is constrained by limited availability and the high cost of finance) (Phase 5 and covered in Sections 5 and 6)

- a report on two case studies in the sector (Biovac and Ketlaphela) (Phase 6 and covered in Section 7)
- a list of opportunities and recommendations for civil society advocacy groups and others to address the financial constraints and hence unlock pharmaceutical industrialization (Phase 7)
- a list of opportunities and recommendations for consideration by diverse stakeholder groups based on the perceived opportunities identified in this Report (Phase 8).

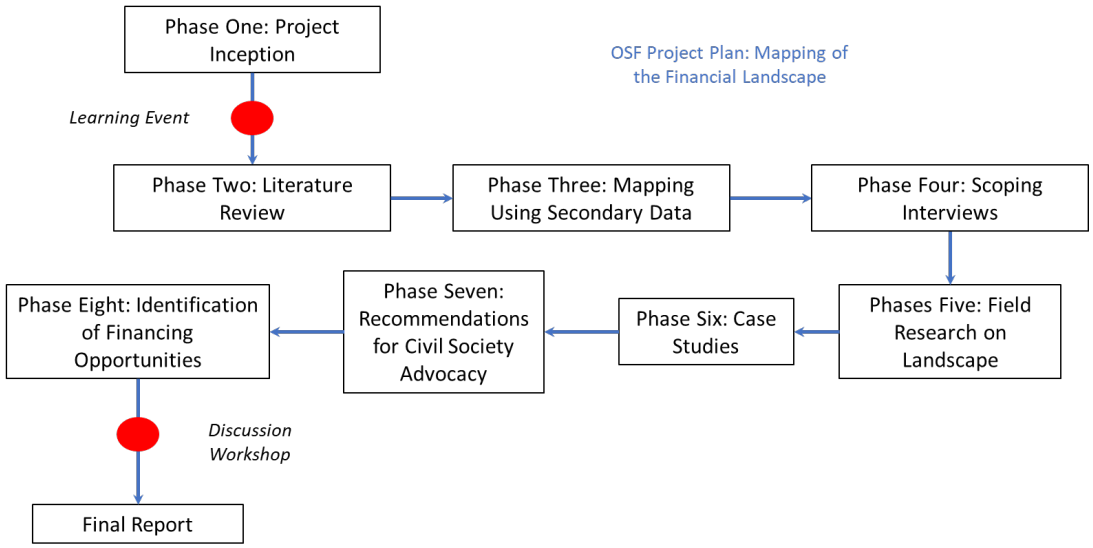

Figure 1. Overall phasing of the project

1.3 Structure of the Report

As noted at the outset, this study was conducted through a number of different modalities, including desk research, small group meetings, interviews, case studies and survey. The results of the study are presented in sections identified by the principal Team author(s).

The first section following this introduction, principally authored by Fred Abbott, includes an introductory essay regarding potential transformation that may be brought about by reframing pharmaceutical production as a regional or national public health security matter, and the potential value of improved regional integration, each in the context of financing.

Section 3 contains the results of the mapping undertaken by Ryan Abbott, including a typology of financial institutions relevant to financing local production in Africa. Following that, in Section 4, is a summary of interviews conducted by Fred Abbott as lead interviewer.

Section 5, principally authored by Padmashree Gehl Sampath with inputs from Joseph Fortunak, looks at how finance and local production interact, what the relative differences are between global companies, large companies from the Global South, such as India, and African companies today. This section also contains a discussion on how business plans in the pharmaceutical sector tackle risks and uncertainties, with an analysis of the additional categories of risks that can and do materialize in a low-income context. Here, the discussion focuses on the relative dependencies between finance, technology, upgrading, product choice and market access, and how those factors inter-weave complicatedly dictating access to capital and investment decisions at the field level. The section highlights critical findings informed form the field, on how the different stages of production interact with finance, and what informs the decisions of firms. The resulting impact on the high costs of capital are also discussed.

Section 6 principally authored by Joseph Fortunak, with inputs from Padmashree Gehl Sampath, summarizes the size of the African Pharmaceutical market, discusses the diversity of the market, and outlines the current state of local pharmaceutical manufacturing. This section also contains a discussion of the technology requirements, existing capacity, timelines for implementation, and needs for capitalization of local production for diagnostics, vaccines, PPE, and therapeutics. This section discusses the critical findings from surveys of local pharmaceutical manufacturers. A series of possible support mechanisms for local manufacturing is also in this section. Straightforward access to capital is also discussed within the framework of the needs of manufactures to operate in an environment that is conductive to solving the "on the ground" problems that so often cause local manufacturing in less developed countries to fail. The needs for financial mechanisms to address the critical factors that limit success by providing novel mechanisms for accessing and utilizing investment are also discussed.

Section 7 principally authored by David Walwyn contains two case studies of South African projects for local pharmaceutical production, namely Ketlaphela and Biovac. The case studies reveal some of the important factors for the success or failure of such projects.

Appendix A contains a synthesis of the main inputs from the learning event. Appendix B identifies individuals interviewed by Team members in the course of carrying out its research.

The report also contains a number of relevant Addenda. The Inception Report (Addendum 1) is followed by the survey questionnaire (Addendum 2), and then a number of reports authored by researchers engaged by the project, including an addendum regarding the role of sovereign wealth funds, an addendum regarding the activities to date of the African Union with respect to financing, an addendum on the specific finance related incentives provided by the Indian government to the pharma sector (1970 until now), and an addendum on specific recent incentives in African countries.

1.4 Definitions of Key Terms

1.4.1 What is meant by "Financing"?

If financing is limited to access to capital for investment, whether in the form of equity investment, debt issuance, commercial bank lending or multilateral institutional financing, there may be gaps, but this is not perceived by stakeholders as the core of the problem. If financing is more broadly understood to include the type of financial assurance that comes from long-term purchasing contracts and/or advance purchase commitments, or even direct subsidization, then financing may be understood as one of the key constraints to expanding local production in Africa.

1.4.2 What is meant by "Local Production"?

In this study, local production is understood in terms of its territorial location (ownership is not considered), with the argument being that local production is supported by stronger logistics infrastructure/networks, and hence has a more positive impact on health security or an improvement in access to DVT and PPE within the host country (WHO, 2011).

1.4.3 What is meant by "Access to Medicines"?

In the report by WHO (2004), 'access to medicines' is defined as encompassing four key areas, namely the rational selection of medicines; adequate financing (for the purchase of medicines); affordable prices; and systems for reliable supply. This list is extended by Kaplan (2011) to include lower prices (and greater affordability); greater availability through the presence of local branded generic medicines; local adaptation of pharmaceutical products by local firms (through incremental innovation efforts of local firms); new forms of innovative medicines and medical products developed by local firms that may/not be tailored to the local population(s); and greater availability through better distribution networks of local firms (e.g., in some LMIC settings, local firms may be able to improve penetration of rural markets).

In this study, 'access to medicines' has been defined as follows, drawing on the recommendations of the WHO Policy Brief (WHO, 2011):

- Strategic selection of essential medical products for local production (appropriateness). Focusing on the medical products that are important for local public health needs, are in short supply and that can be produced locally with some support.
- Pricing of locally-produced medical products that governments and people can afford (affordability). Striking a correct balance between affordability and economic feasibility of production is a challenge. Government support to help local producers of selected essential medicines through appropriate pricing policies can be very important.

- Strict compliance to quality standards by manufacturers and effective national regulatory authorities (quality assurance). No local production of medical products is desirable without quality assurance, and any government incentives have to ensure strict compliance with required quality control systems in accordance with acceptable quality standards.
- Ensure health security; an uninterrupted supply of essential medical products (security of supply). To ensure health security, there must be continuous availability of essential medicines at various levels of the health system. Taking a longer-term strategic perspective, local production is one area that could contribute to greater health security and access.
- Innovation for development of formulations more suitable for local conditions (technological innovation). Innovation capacity is a critical prerequisite not only for R&D leading to new drug discovery, but also for the development of products that are incremental improvements, such as formulations that are more suitable for local conditions.

We also point out that the scope of this study is not limited to access to medicines. Diagnostics, treatments (medicines), vaccines, and PPE are included within the range of our studies; each of these areas is critical for comprehensive healthcare strategies in the context of COVID-19.

2. Transforming Government Policy on Local Production of Pharmaceuticals

2.1 Public Health Security as a Theme for Transformation

There is an important lesson emerging from the COVID-19 pandemic. This is that the security of a national population is vulnerable to attack by an unseen virus just as it is to attack by weapons of war. Yet governments have long prioritized military preparedness as a funding imperative, while they have not similarly prioritized security risks associated with public health vulnerabilities such as inadequate supply of vaccines and treatments to address novel diseases.[1] Likewise, governments have treated the national energy infrastructure and transportation systems as funding priorities entailing special arrangements for long-term financing, again a prioritization that has not encompassed pharmaceutical production readiness.

Governments have various financial levers available to support industrial policy decisions, including direct subsidization, tax incentives, loan guarantees, and guaranteed offtake agreements. The transformation of pharmaceutical production security to a national priority equivalent to that of military preparedness might entail employment of any or all of these financial levers, recognizing that each may create some budgetary pressure. However, government intervention does not necessarily entail a cost to the economy. There are offsetting economic benefits including increased employment, positive trade balance effects, reduced healthcare expenditures resulting from illness, etc., that may encourage the employment of government financial levers to support an industry.[2]

The idea of prioritizing public health security does not mean "public ownership of production". Without going into detail here, there are good reasons to be skeptical toward the potential benefits of government owned and operated manufacturing operations.[3] Just as with the defense sectors of many countries, the government does not need to own and operate the producers, but instead can contract with them. This is not to suggest that publicly owned and operated facilities should not play a role, but this Report does not suggest a preference for government ownership.

[1] The idea of transforming governmental approaches on pandemic preparedness toward treatment as a public health security threat, including changing perspectives on financing, was raised by Dr. Nick Drager at the Learning Group meeting organized by the Team on November 30, 2020, as reflected in the Synthesis attached as Appendix A. Military threats go to the existence of the state and its control over the national territory. Military threats tend to arise externally, while public health threats typically result from personal or locally arising disease factors. An international pandemic is different in that the source is likely external, and in principle may be deliberately perpetrated.

[2] See economic analysis in Andre Kudlinski (2014).

[3] See, e.g., Abbott, Public-Private Partnerships (2018).

Government subsidization or other support for pharmaceutical manufacturing in Africa may be particularly useful to address particular areas of public health where “market failure” is most evident.[4] For example, the COVID-19 pandemic has revealed a manifest lack of capacity for the manufacture of vaccines, in Africa and worldwide, which has resulted in large-scale subsidization toward R&D, production and distribution in countries outside Africa, including the United States and China.[5] At the same time, there is also a huge potential for Africa – with existing capacities and captive supply chains to produce textiles – to produce most types of PPE to supply both the continent as well as for export.

2.1.1 National and regional public health security

Assuming that the COVID-19 pandemic has sufficiently illustrated a need to raise the priority of public health security in the perspectives of governments, there remains a potential tension between the public health security of an individual nation (or sub-region) and the public health security of a region, in this case the continent of Africa. We have witnessed, by way of illustration, growing conflict between the United States, European Union, the United Kingdom and other countries regarding prioritization of supply of vaccines. The phenomenon is sometimes referred to as “vaccine nationalism”.

This raises the question from the standpoint of prioritizing localization of pharmaceutical production in Africa whether security interests from a public health standpoint are national interests or regional interests. Self-evidently, they may be both simultaneously, and they could be viewed on a scale of priority. An individual African national government will presumably favor its own population if for no other reason than the national population constitutes its base of

[4] A fundamental problem well known in public health Is that market forces and disease burdens do not necessarily align the supply of pharmaceuticals with demand. In a range of cases, pharmaceutical products will not be created or supplied because of the absence of a conventional "business case". The problem is common when the question is basic research into the cause of a disease where business enterprises choose not to invest because there may be little return on investment for advances in "pure science". There is no assurance that an expensive research program will successfully identify the cause of a disease. If the discovery is of a natural phenomenon, it may not be patentable and the results of the investment will be shared. From a scientific standpoint that outcome may be beneficial but may not be perceived as such by investors seeking a return when risk factors are taken into account. The problem of so-called neglected diseases is well-known. These are conditions which are primarily affecting individuals in low-income environments. Regardless of the medical need for treatment, demand is limited by lack of financial capacity.
The risks are more limited when the question is whether or not to build a manufacturing facility. In that case a successful outcome in terms of accomplishing the objective is largely predictable because a product exists, but sustainability from a business perspective is a different question. The risk of failure for a manufacturing facility is the lack of demand at a price which covers costs and profit.

[5] We can posit differentiating factors among different types of disease conditions that would make it more or less necessary to subsidize off-take. For example, treatments for chronic conditions might require less financing intervention because of continuing expectations of demand, although this would still be affected by factors such as the general economic environment (e.g., public ability to pay) and the possibility of demand destruction based on introduction of new technologies.

power. And, rather importantly national constitutions typically define the responsibilities of governments as protecting the welfare of the nation and its inhabitants, and not as regional interests.

Addressing the national and regional priorities scale is a "nontrivial" matter when considering localization of pharmaceutical manufacturing. While there may be efficiency gains to creating concentrations of larger pharmaceutical manufacturing facilities in Africa to take advantage of economies of scale, better platforms for investment in quality control, and so forth, the question will remain "where" to situate those platforms. In a crisis, the question of location may become important as a government facing a shortage may decide to prioritize placing goods on the national/local market rather than exporting to other markets. And, we are currently witnessing the EU considering the imposition of export restrictions on vaccines for this reason.

At the same time, it seems clear that establishing duplicative production facilities in many different countries of Africa would be economically infeasible. The question becomes, how could the countries of the continent establish a plan to collectively localize pharmaceutical production while at the same time assuring that the output of the relevant facilities is distributed equitably in the event of a crisis? Is such a concept feasible, or is public health security as a priority limited to national public health security?

This study does not propose to resolve this particularly difficult problem. The issue of allocating the benefits of a regional integration program underlay many of the difficulties in achieving successful implementation that have confronted regional organization efforts for decades. What might be suggested is that it may be more feasible to think in terms of hierarchies of priority, beginning with national interests and moving up to regional interests, which might still be prioritized over more general global interests from a public health security standpoint.

2.2 Fixing Fragmentation Markets through Pooled Procurement

If the problem of financing is viewed through the lens of inadequate market demand and fragmentation in Africa, a part of the solution may involve regional pooled procurement that gives preference to local production.[6] This is not so simple in the sense that pooled procurement presumably would involve product requirements that are sufficiently homogenous across the continent that the "same thing" could be provided throughout the region. This would entail cooperation or coordination among regulatory authorities. In addition, there would either need to be a common budgetary fund envisaged with contributions from countries across the continent, or a mechanism for sales from the pooled procurement authority to the individual country participants. Finally, but not exhaustively, while pooled procurement may create a sufficient "market" such that economies of scale could be achieved by a supplier, there is an

[6]See Abbott and Reichman (2020, 2007).

associated risk that the African market could be dominated by that supplier to the exclusion of continental alternates. The latter may in fact be a foreseeable consequence of a pooled procurement arrangement, and not necessarily adverse from a developmental standpoint. But there would need to be some mechanism for allocating production to different country "champions" or otherwise.

As discussed below, there might be a linkage between the establishment of regional pooled procurement, on one side, and the creation of regional production centers, i.e. matching of supply and demand.

Regional production hubs

Producers of small molecule chemical APIs and formulated products depend on key inputs and infrastructure dependencies. The types of chemical inputs used in the production of small molecule pharmaceuticals are similar to those used in petrochemicals, and there may be infrastructure and economic efficiencies gained by situating pharmaceutical production facilities nearby existing suppliers to petrochemical facilities. Reliable, uninterrupted supply of power is a key component of pharmaceutical production, and for a number of African countries electricity generation is variable. Pharmaceutical manufacturers face common needs for environmentally sound processing and disposal of waste. The governments of China, India (at the central administration level, and in several State-led initiatives) , recognized the potential efficiency and environmental gains from creating designated zones as preferred locations for pharmaceutical manufacturing, the idea being that the industry as a whole would benefit from sharing infrastructure.[7] Another advantage of proximity is the potential for development of local supporting industries, including equipment repair and supply, software developers, and so forth. The development of a globally competitive African pharmaceutical manufacturing sector might be advanced through the creation of geographically designated production hubs intended to supply throughout the continent, including potential links to larger scale pooled procurement as discussed above. As with any proposal for consolidating areas of production, there is the potential for conflict regarding the choice of location. If such regional production hubs were to be part of a broader regional industrial development policy, there might be trade-offs and balancing in terms of location.

2.2.1 "Denationalized" or regional pharmaceutical manufacturing zones

The idea of a "denationalized" pharmaceutical production hub or hubs in Africa may merit some consideration, but it is not clear that the practical obstacles to such a development could be overcome. The basic idea would be to establish a geographic or "virtual" territory that was not under the control of an individual African government, but rather that functioned under the collective control of an entity such as the African Union. In principle, decisions regarding matters such as construction, employment, procurement of inputs and allocation of output could be

[7] WHO, Indian Policies (2017).

made at a regional level rather than a national/local level. And, by way of illustration, the problem of national public health security being in tension with regional public health security could be addressed through such a collective approach. The obstacles include that such a denationalized (or "regionalized") area would need to be governed by a set of laws and institutions, and that is a significant challenge to put in place. Moreover, even a regionalized area would need to be situated "somewhere", and there may be well be economic competition regarding the location of the area.

2.3 The African Continental Free Trade Area

It is early days for the African Continental Free Trade Area (AfCFTA), but the formation of a group that envisages tariff free movement of regionally produced goods across the continent[8] may herald movement toward a more integrated pharmaceutical production and distribution market, as well as further movement toward harmonization or approximation of regulatory requirements.

A detailed analysis of the AfCFTA is beyond the scope of this Report insofar as the AfCFTA is not directed toward financing as such, but to the extent that fragmentation of the African continental market has been identified as a constraint on development of a more robust pharmaceutical production sector, it is important to recognize the potential value of this development. On a cautionary note, regional integration efforts worldwide have an inconsistent history. Once again, implementation defines success or failure.

2.4 Differentiating Financial Requirements

While it is appropriate to ask the general question whether finance is constraining the production of pharmaceuticals in Africa, answering the question will need to take account that financing requirements differ depending upon the products to be manufactured. At a broad level, the different types of production requirements include:

- Packaging and labeling facilities for each type of product
- Formulation facilities for small molecule chemical products
- Active pharmaceutical ingredient (API) facilities for small molecule chemical products
- Fill and finish facilities for vaccines
- Bulk antigen facilities for vaccines, subdivided between various categories
- Diagnostic test strip manufacturing
- Diagnostic reagents and medical device analyzers

[8] See Article 7(1), Protocol on Trade in Goods, AfCFTA.

Personal protective equipment (PPE) and more complex medical devices are not pharmaceutical products as such, and involve different markets and financing requirements.

WHO (and other) studies and have previously suggested that establishing a pharmaceutical industry sector within a developing country might best involve backward integration, with the process starting with simple packaging and labeling, and moving through formulation, and ultimately to API manufacturing in a series of steps.[9] In the current state of technological development where sophisticated contractors are able to create facilities of virtually any type, the backward integration concept may be becoming less relevant. Pharmaceutical production involves a network infrastructure. Unless there is a critical mass of producers within a single country, it may be substantially more expensive to operate.

The headwinds to establishing more robust local production in Africa suggest that there is a need for some type of financial support to the "infant industry" that otherwise has difficulty competing from a strictly competitive market perspective. In principle, financial support can come in many different forms, and this study attempts to identify those various forms. As a predicate, however, there needs to be a political commitment to providing financial support, whether from domestic or foreign sources.

2.4.1 Alternative Financial Instruments

One element of this study involves considering whether alternatives to conventional sources of finance, such as some form of “social impact” bond that would be offered to deep-pocket investors, would help promote local production of pharmaceutical products in Africa. The overall results of this study based on interviews with market participants is that the problem of finance is wider than that of simply choosing a specific investment instrument. This is not to say that some investors might not prefer an instrument denominated with a social objective. Some might. But the overall conclusion of the study Team is that gaps in financing are neither the result of a shortfall of investable capital, nor related to the kinds of financial instruments that could be used. Instead they are related to the question of sufficiently attractive markets for the sale and purchase of pharmaceutical products. In that sense the gaps in financing are largely driven by structural deficiencies in the market, not by an absence of capital that would be available with improved market conditions. If the international investing community perceived the African pharmaceutical manufacturing sector as attractively investable, there are a wide range of capital sources that could be tapped.

Creating attractive markets is almost certainly dependent on government support for the purchase of pharmaceutical products. This could be through increased investment in public health budgets that in turn demand pharmaceutical products, through direct participation in

[9] See, e.g., WHO Think Tank (2015).

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purchasing markets, including through direct subsidization, market protection and/or advance purchase commitments. As alluded to in the introduction to the study, the comparatively low levels of income that typify African countries mean that individual purchasers may not be able to support a robust pharmaceutical production sector until wider problems of economic development are successfully addressed.

One idea is to consider whether governments should approach their pharmaceutical sectors from the standpoint of government-supported incubation to eventual transition to self-standing private sector operation. Thus, for a relevant sector the development of the industry would begin with government financial support such as direct subsidization, advance purchase commitments, tax incentives and/or bidding preferences. Once the industry had developed to a sufficient level, the government could begin backing away from the instruments of financial support. This would be a form of infant industry protection - a well-known form of industrial policy.

The concept of blended finance refers, inter alia, to using a mix of public and private sector money. Investors apparently are reluctant to participate in ventures with joint government management because changes in capital structure and other decisions become constrained by government involvement. This is the lesson of Biovac in South Africa.[10] A blended finance alternative could be devised such that a government invests financial resources in a public-private joint venture, agreeing in advance to step out when certain benchmarks are met. Private investors might be accorded a right to buy out the government on specified terms and conditions; a form of privatization set in advance. If the conditions are not met, the private investor might have the right to put its investment to the government, which in turn must buy it. That would be a form of investment guarantee.

2.4.2 Political Investment

We do not ignore that some governments seeking political influence in Africa may choose to invest in inherently uneconomic projects and may be prepared to write off these investments. Each country and region must decide for itself whether the gains from uneconomic investment outweigh the risks of external influence. This study has not considered in any depth the prospect that some pharmaceutical manufacturing investment might be made without expectation of economic return.

2.4.3 Link between Markets and Finance

A consistent theme of this study is that there is not a global shortage of capital available for investment, including investment in local production of pharmaceutical products in Africa. The problem-set instead is how to make the African pharmaceutical manufacturing sector sufficiently attractive as an economic proposition to induce the holders of that capital to invest. One element

[10] See D. Walwyn, Section 7.2.

is appeal to laudable social goals such as enhancing access to medicines for those who need them. But impact investors and those prioritizing the achievement of social goals are interested in preserving and growing their investments. At a basic level, attracting finance from private sources (or public sources other than the local government), requires the development of a sound business model.

Whether investment is coming from sovereign wealth funds, retirement-focused asset managers, insurance organizations, private equity investors, or other sources of capital, there is a need to demonstrate a sound business proposal.

Sound business models also depend upon all involved parties understanding the critical needs for success. The public sector, financial institutions, and producers strongly benefit from a process of (non-medical) triage in which producers have inputs to defining and prioritizing how to address critical limitations. Several companies interviewed note that it is easy to secure a government promise for land and preferential tax rates. But ready access to foreign exchange is limiting for access to equipment, spare parts, APIs and other raw materials (e.g., glass vials, capsules, even finished packaging). Other notable limitations include improvement of land for access to transport, basic services (fire, security and sewage). Creating pools of finance that are readily accessible for producers to address these bottlenecks is important to promote success.

2.5 Transformation is a Longer-Term Exercise

The question this project seeks to address is whether finance is acting as a constraint on local production in Africa, with a focus on addressing the COVID-19 pandemic. It should be noted that the principal constraints manifested by the pandemic relate to production and availability of vaccines, and that there are limits to the speed at which vaccine manufacturing it can be initiated. It is possible to repurpose existing pharmaceutical manufacturing facilities to engage in "fill and finishing", essentially taking bulk antigen and placing it in vials for distribution and use. in principle this type of repurpose may be accomplished in a matter of months, and already at least one manufacturer in South Africa has been involved in negotiations toward this end. However, filling and finishing is not the main constraint on availability of vaccine supplies. That is instead the manufacturer of bulk antigen. Although there is one vaccine manufacturing facility in Africa (Biovac) that has indicated it may be able to manufacture bulk antigen to address COVID-19, that prospect is uncertain. To establish a "greenfield" bulk antigen producing facility is a multi-year exercise involving highly complex planning and execution. Whether or not financing is a constraint, it is doubtful that building bulk antigen production facilities in Africa will play a meaningful role in addressing COVID-19.[11] It is probably more realistic to consider increasing the production capacity of vaccine manufacturers in Africa as a longer-term exercise to address

[11] One lesson of the COVID-19 pandemic is that predictions regarding the future course of the outbreak, and assumptions associated with those, must be made and understood with due caution.

future requirements than as a near-term fix to addressing shortages of COVID-19 vaccines for Africa.

On the other hand, there may be substantially better opportunity to produce locally in Africa certain existing treatments, such as dexamethasone and ivermectin for which production capability exists and could be scaled-up. It is not apparent that financing constitutes an obstacle to such scaling up, except to the extent that producers must be assured of a market through advance purchase commitment, subsidy or otherwise.

Recommendations

- 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. Public health security can be both a national and regional priority, and advocacy should be directed both toward national and regional authorities.

- Addressing inadequate markets through collective regional modalities: Cost-effective manufacturing of safe and effective pharmaceuticals is dependent on achieving economies of scale. Without achieving such scale economies, it is exceedingly difficult to offer products competitive with those from existing foreign sources. The "market problem" may be addressed by 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. As Africa is making considerable progress in pursuing integration of the regional market, advocacy may be directed toward creating new production and procurement modalities to take advantage of that integration.

- Holders of capital, including 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". So far, the attention of these asset holders has been directed toward environmental sustainability, which is a worthy objective, but advocacy may encourage adding localization of production with corresponding public health security benefits to the social impact portfolio.

3. Landscape Mapping

3.1 Introduction

This mapping section focuses on a selection of funding mechanisms and entities relevant to the financing of COVID-19 Diagnostics, Vaccines, Therapeutics, and Essential PPE manufacturing in Africa. These were chosen based on input from the study team, results from desk research, comments during the learning group meeting, and statements from interviewees. It is not intended to be a fully comprehensive mapping of financing options, but to provide a sense of some of the key institutional players and commitments that have been made in the area. It also incorporates excerpts from three interviews conducted for this project.

The section first provides a general finance typology, although in practice there are not always clear demarcations between various sources of finance (e.g., sovereign wealth funds, central banks, and public development banks), not all potential finance sources appear to be active in funding health-related local African manufacturing. The section then discusses specific potential funding sources in detail. These may generally provide financing for investment in Africa, or they may specifically provide COVID-19 related financing in Africa.

Few entities are publicizing that they are specifically financing health-related African local production, whether in a COVID-related context or otherwise. Still, even if they have not previously funded a DVT or PPE local manufacturing project, some funding sources might fund such a project under the right conditions.

3.2 General Finance Typology

Funding for local manufacturing can come from a wide variety of sources, and through a wide variety of mechanisms. Broadly speaking, financing can be provided directly or indirectly from private or public sources, or from combinations of the two independently or in collaboration (e.g., public-private partnerships). Within the public realm, financing can be made available at the multilateral/international, regional, national, state, or local level, directly by governments or through a variety of intermediaries. Similarly, with respect to private financing, there is significant diversity in funding sources (e.g., angel investment, private equity, venture capital, public stock offerings) and mechanisms (e.g., equity, loans, guarantees, project finance, etc.).

Governments have a variety of ways in which they can intervene in the economy, including via public financial institutions that perform development financing. These bodies are often referred to as public development banks (PDB)—financial institutions that facilitate funding for projects which are expected to generate profit or other positive social outcomes, but for which private financing options may be suboptimal (Eduardo Levy Yeyati, 2004). PDBs seek to ameliorate market failures (e.g., where private capital will not fund any otherwise profitable project due to

resource constraints) and to facilitate industrialization, as well as to address specific social issues (e.g., energy dependency or green energy). They are particularly important in regions with significant economic constraints, such as in many parts of the developing world, where otherwise beneficial projects may not be pursued without long-term, subsidized development bank funding.

In 2018, PDBs invested $2.3 trillion, about 10% of the world's investment (Jiajun Xu, 2020). There are about 450 public development banks worldwide, with total assets of almost $12 trillion (Jiajun Xu, 2020). However, a relatively small number of these banks, fewer than 150 have balance sheets in excess of $3 billion. Most activity in this space centers around a few very large institutions. For example, the PDBs of the EU member countries, including the regional European Investment Bank (EIB) and European Bank for Reconstruction and Development (EBRD), have about $4 trillion in assets. This is about the same amount held by Chinese PDBs.

PDBs generally provide subsidized, medium- to long-term financing. PDBs can be multilateral, national, or subnational with respect to ownership, and can operate with a global (e.g., World Bank), regional (e.g., African Development Bank), national (e.g., Development Bank of South Africa), or local focus. PDBs also have various means of facilitating investment, including direct lending, credit guarantees, subsidized interest rates, equity purchases, and technical assistance. Different banks have different funding methodologies and motivations.

Development banks have government funding but may also raise additional funds in national and international capital markets, and bank loans are often co-financed by the private sector. Development banks in developed regions, such as the European Investment Bank, often fund projects in Africa and other developing regions. Development banks are not without criticism—they may operate with political motivation to support controversial projects, and they can crowd out private capital (Sergio G. Lazzarini, 2012).

African PDBs number around 95, representing about 21% of all PDBs worldwide. However, African PDBs only have about $131 billion in collective assets, representing only about 1.1% of the assets held by PDBs worldwide (Jiajun Xu, 2020).

In Europe, the term development finance institution (DFI) may be used to refer to PDBs as well as a wider range of financial institutions that pursue public policy objectives. This includes banks, but also non-bank institutions that issue guarantees, insurance, or equity investments to carry out state public policy financing—a mix of what can be referred to as international finance corporations, multilateral development banks, national development banks, investment funds, guarantee funds, policy banks, or promotional banks.

Aside from providing funding through PDBs, local, national and regional governments can provide financing through, effectively, subsidies in the form of direct payments, advance purchase

commitments, loan guarantees, prize funds, and tax credits. Governments can also lend directly from national treasuries, or through reserve banks, in addition to doing so through intermediaries such as PDBs. Governments may also provide support through non-direct infrastructure development, such as by improving energy networks, roadways, and workforce upskilling.

Sovereign wealth funds, which are state-owned investment funds, may also be invested in ways that can promote local manufacturing. These may be funds held by central or reserve banks, and states may invest assets from banking management, state savings, or foreign-exchange reserves. A separate Addendum to the report, prepared by Binit Agrawal, considers sovereign wealth funds in greater detail.

There is not a universally accepted typology for understanding the various ways that financing is provided, however the below structure is one way to broadly understand potential funding sources for local manufacturing.

1. National public finance
    a. national government subsidy
        i. various forms: direct payment, tax credit, advance purchase commitment, prize fund
        ii. distinguished from lending by absence of obligation to repay
    b. national government lending
        i. direct from national treasury, including Reserve Bank
        ii. channeled through intermediary lenders
        iii. loan guarantees as alternative by reducing effective interest rate
    c. state and local subsidy
    d. state and local lending
    e. infrastructure support
        i. generally accessible public goods, e.g., improved roadways or electric grid
        ii. specific support, e.g., local environmental control system
    f. Development assistance to foreign countries, e.g., JICA, EIB, IDFC, CIDCA
2. Multilateral finance
    a. lending support to national government
    b. grant support to national government
    c. direct lending to private investor
    d. lending guarantee programs
    e. collective purchasing and distribution, e.g., GAVI, UNICEF, Global Fund
    f. issuance of special-purpose instruments, e.g., social bonds, pandemic bonds, loan syndication

        i. bonds in public and private markets structured with many configurations, reflecting differences in yield or coupon, duration, collateralization, call-ability
3. Foundation or charitable funding
4. Sovereign wealth fund investment
5. Private investment
    a. Personal business investment
        i. including through friends and family, and angel investment
        ii. shareholder equity stakes or loans
    b. Equity fundraising from unrelated third parties
        i. restricted offerings
        ii. publicly traded share offerings
        iii. crowdsourcing
        iv. large-scale private equity
            1. alternative configurations
                a. impact investing - directed toward achievement of specified goal(s)
                b. sustainable and resilient investing (e.g., ESG - environmental, social and governance)
            2. synthetic instruments (mirror or derivative based on criteria)
    c. Borrowing
        i. commercial banks and other lenders
        ii. bond offerings
            1. Including packaging and syndication of loans
    d. Joint venture investors
        i. passive financial contributors
        ii. active co-venturers, e.g., technology partners or distributors
6. Public-private partnership (Abbott, 2018)
    a. "public" in this context often refers to "not-for-profit", such as supported by foundation or government grant, though may be government-owned entity; "private" typically refers to a for-profit enterprise
    b. in the pharmaceutical development context, the private entity is typically contributing some form of technology or technical support, as compared with financial support which comes from the public side
    c. commonly the product developed by a PPP may be subject to differential licensing or other contract conditions, such that low-income markets are

supplied by or through the public entity and high-income markets are supplied by the private entity

d. A public-private partnership is in essence a form of joint venture with the co-venturers having objectives largely other than profitability, for example, providing a public good

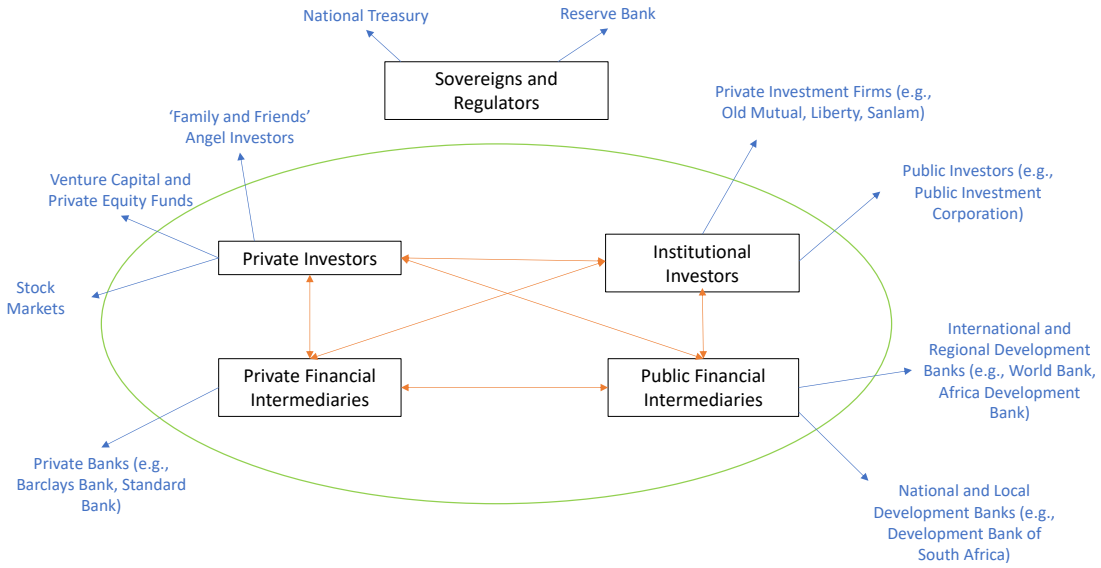

Figure 2. Finance Ecosphere

In the following sections, further details on potential funding sources are provided.

3.3 Development Banks (International and National)

World Bank

The World Bank Group (WBG) refers to five institutions that make leveraged loans to developing countries: the International Bank for Reconstruction and Development (IBRD), the International Development Association (IDA), the International Finance Corporation (IFC), the Multilateral Investment Guarantee Agency (MIGA), and the International Centre for Settlement of Investment Disputes (ICSID) (WBG, 2021). In contrast, the "World Bank" only refers to the IBRD and IDA which provide debt and concessional financing, usually on the basis of sovereign guarantees (WBG, 2021). IDA replenishes its resources every three years by mobilizing donations from donor countries. The IBRD is IDA's parent institution and it relies on sovereign creditworthiness to raise funds from capital markets rather than donor contributions. IDA provides grants or interest-free

concessional loans to low-income countries, whereas IBRD provides ordinary loans (i.e., without tangible interest subsidies), guarantees, risk management products, and advisory services to middle income and certain low-income countries. Since 2018, IDA has started to issue bonds and repay debt from reflows.

In April 2020, WBG announced a new Health Emergency Preparedness and Response Multi-Donor Fund (HEPRF) to complement $160 billion in financing WBG was planning to provide over the next 15 months to support COVID-19 measures. These funds were intended to both provide health-related project financing as well as general economic recovery measures—financing for a broad array of needs. In June 2020, WBG reported it had made nearly $12 billion available throughout Africa to help with the COVID-response through both redeployment of existing resources and new financing for various health, social, and economically focused projects. (WBG, 2020) As of October 15, 2020, a first set of emergency health projects in 34 African countries had been financed with about $750 million in funding.

However, this funding was largely not expected to finance local manufacturing. Mr. Andreas Seiter, Global Lead, Health, Nutrition & Population, World Bank Group, was interviewed together with Dr. Subir Basak, Senior Industry Specialist, International Finance Corporation (IFC). Together, they agreed that WBG has reservations about financing local African production largely due to non-finance challenges. IFC, for example, generally requires WHO certification for pharmaceutical production which African manufacturers tend not to qualify under. If not WHO standards, then IFC at least requires qualification under strict national cGMP and compliance standards, but the organization is skeptical of national compliance standards that do not meet WHO standards. IFC does not want to finance local production that generates unsafe or ineffective products.

IFC has been working with a variety of pharmaceutical and distribution companies, including in Africa, but past projects have failed or taken substantially longer than projected. In addition to issues related to compliance, the fragmented nature of national African markets with diverse procurement and regulatory systems constrains effective regional competition. Also, potential loan recipients tend to have deficiencies with respect to technical capacity, and potential projects may not have adequate infrastructure availability. In addition, IFC tends to fund projects in the $10-20 million range, and looks for even larger projects, and so it does not tend to fund smaller projects in the $2-5 million dollar range. The costs associated with establishing an African manufacturing plants are thus likely to fall under IFC's funding threshold. The organization is finding distribution enterprises to be a more promising funding target than manufacturing enterprises.

Mr. Seiter noted that only two investments had been made or were in preparation for board approval by WBG in Africa health manufacturing. One involved financing a risk facility that reduces health service provider costs not related to pharmaceutical manufacturing. The second

involved leasing of medical equipment. Mr. Seiter was of the view that the non-financial barriers were what was impeding WBG interest in this space, and that if those barriers were adequately addressed the financing would follow. He also noted that WGB had provided technical support with respect to regulatory harmonization for a number of years to Ethiopian regulatory authorities in association with an industrial park, in collaboration with partners including WHO, the African Union, and the Gates Foundation. He believed such efforts were important to make Africa a more efficient regional market for pharmaceutical manufacturing, but also noted that funding for the project was running out and WBG's involvement was planned to end in 2021.

International Finance Corporation

IFC works in partnership with the WBG and also functions as a stand-alone financial institution focused on the private sector. It provides advisory services for businesses and governments, who can also apply directly for COVID-19 related relief.

In March 2020, IFC announced it was making $8 billion available in fast-track financing as part of a $14 billion package being deployed by WBG (IFC, 2020b). This financing has four component – $2 billion for each of:

- the Real Sector Crisis Response Facility, which will support existing clients in industries vulnerable to the pandemic such as mining and agriculture. This will include loans and potentially equity investments.
- the Global Trade Finance Program, which will cover the payment risks of financial institutions so they can provide trade financing to import/export enterprises. This includes support for small and medium-sized companies in global supply chains.
- the Working Capital Solutions program, which will provide funding to emerging-market banks to extend credit to help businesses replenish the pool of day-to-day funds.
- the Global Trade Liquidity Program and the Critical Commodities Finance Program, both of which offer risk-sharing support to local banks so they can continue to finance companies in emerging markets.

Of the $4 billion already committed in financing, about half is expected to benefit populations of the poorest countries and fragile states, such as small businesses in sub-Saharan Africa. IFC has already invested almost $1.1 billion in sub-Saharan Africa through the fast-track COVID-19 facility to shore up private sector trade and liquidity needs. This includes loans of About $300 million to major Kenyan and Nigerian financial institutions, such as Equity Bank in Kenya, and Zenith, Access and FCMB banks in Nigeria. These banks are expected to use the funding to lend to SMEs facing COVID-19-related disruption. (IFC, 2020a)

IFC has historically provided at least some financing for local health-related manufacturing in Africa. In 2011, IFC announced it was providing up to $110 million in debt financing to Hikma

Pharmaceuticals PLC, which was primarily based in the Middle East but which also had African operations (IFC, 2011). In 2015, IFC announced a $4.5 million loan to Goodlife Pharmacy Limited to help it open a chain of 80 pharmacies in Kenya and East Africa (IFC, 2015).

IFC is also helping promote local PPE manufacturing by "hosting learning webinars with health, textile and machinery experts, as well as by providing linkages to potential buyers and suppliers." (Maylie, 2020). Sri Lanka-based Hela Clothing has transitioned to PPE manufacturing, and "IFC supported Hela to reinvent itself as a PPE producer by working with the company to source sewing patterns for surgical masks and by introducing it to manufacturers of nonwoven materials necessary to produce medical masks. IFC is also introducing other prospective buyers of the masks to Hela, which is a member of IFC's Global Trade-Supplier Finance program." (Maylie, 2020).

Multilateral Investment Guarantee Agency (MIGA)

MIGA's promotes cross-border investment in developing countries by providing guarantees (political risk insurance and credit enhancement) to investors and lenders (MIGA, 2020).

In April 2020, MIGA launched a $6.5 billion fast-track facility to help investors and lenders manage COVID-19. As of September 2020, MIGA had provide over $2.6 billion to mitigate the impact of COVID-19 in emerging and developing markets. MIGA's fast-track financing is available to potential clients whose projects demonstrate a clear COVID-19 related development impact.

African Export-Import Bank (AFREXIMBANK)

Afreximbank's vision and mandate is to be 'The Trade Finance Bank for Africa' and to stimulate the expansion and development of African trade (Afreximbank, 2021). It makes programs, instruments and services available to large corporates, governments, financial institutions, and any other entity's project fitting within the Bank's mandate. In particular, the bank supports industrialization and export development, including, it says, with respect to the pharmaceutical industry (Koigi, 2018).

Afreximbank introduced a $3 billion facility, the Pandemic Trade Impact Mitigation Facility (PATIMFA), to provide COVID-19 related relief to African countries. Of this amount, $200 million has been reserved to "support food production as well as the manufacture of, and trade in, medical equipment and supplies." Requests for facilities of $5 million or more will be directly financed by Afreximbank, those of less than $5 million will be handled through local financial institutions (Sodipo, 2020).

West African Development Bank

The West African Development Bank (WADB) has released 120 billion CFA francs in the form of 15 billion CFA franc loans (€23 billion) to each of its eight member states. The bank has undertaken to freeze part of these countries' debt, estimated at 76.6 billion CFA francs (Mayaki, 2020).

New Development Bank

The New Development Bank (NBD) was created by BRICS (Brazil, Russia, India, China, and South Africa) countries in 2014 to finance infrastructure and sustainable projects in BRICS countries as well as other emerging or developing countries. The NBD primarily provides financing through bonds to both public and private bodies (OxfordBusinessGroup, 2020).

In June 2020, NBD announced the creation of a $1.5 billion, 3-year response bond for emergency assistance loans to finance direct COVID-19 related expenses and to provide state support. In September 2020, NBD announced a new $2 billion, 5-year bond, which was created primarily for COVID-19 emergency assistance programs. It also announced that NDB planned to provide $10 billion to help finance COVID-19 related healthcare and social safety expenditures. NBD has also dispersed $1bn to each member country, excluding Russia, with the funds taken out of the bank's $10bn Emerging Assistance Program for 2020. Much of the fast-track COVID-19 financing may be distributed to states to then distribute to public and private sector organizations. NDB has stated that it is prioritizing funding for PPE and developing therapeutic treatments and vaccines.

European Investment Bank

The European Investment Bank is the lending arm of the European Union. It is the largest multilateral financial institution in the world, and offers loans, guarantees, equity investments and advisory services. EIB works to benefit its shareholders, namely EU member states, but it is also active in Africa.

By December 2020, EIB had invested more than 27 billion euros in COVID-19 related projects (EIB, 2020b). In 2019, EIB had provided more than 3 billion euros for public and private African investment. Among other financing opportunities, it has approved financing for a proposed COVID-19 essential API manufacturing in sub-Saharan Africa. EIB proposing to finance 50 million EUR of a total cost of 100 million EUR, to increase local API manufacturing capacity (EIB, 2020a).

U.S. International Development Finance Corporation (DFC)

DFC is the USA's development bank. It partners with the private sector to finance various projects, including related, at least in part, to African health-related projects (DFC, 2020). The bank is providing $50 million of debt financing to the Meridiam Africa Infrastructure Fund, which is investing in a variety of infrastructure projects—from energy to an airport rejuvenation to port development to a university hospital.

Japan International Cooperation Agency

As the organization in charge of Japan's official development assistance, in 2018, JICA provided ¥ 98.5 billion in grants, ¥191.1 billion in Technical Cooperation, and ¥1,266.1 billion in finance and investment cooperation to developing countries—including in Africa (JICA, 2020).

China International Development Cooperation Agency

CIDCA provides foreign aid, identifies major programs, and supervises and evaluates implementation. In May 2020, the Chinese government announced it was planning to provide $2 billion in international COVID-19 related aid over two years, as well as a cooperation mechanism for Chinese hospitals to partner with African hospitals (CIDCA, 2020).

Prior to COVID-19, the Chinese government considered Africa as an important component of its one belt, one road initiative and made numerous strategic investments in the content—including financing for industrial development (CIDCA, 2018).

Industrial Development Corporation

IDC is a South African national development finance institution set up to promote economic growth and industrial development. It funds IDC funds start-up and existing businesses up to a maximum of R1 billion and considers debt of R1 million, and it invests throughout Africa.

IDC funds chemical product and pharmaceutical manufacturing, and has, for example, funded Chemical Process Technologies Pharma (CPT Pharma) to promote their manufacturing processes. IDC has made more than ZAR 3 billion available for COVID-19 related relief in the form of industrial funding and fast-track financing for firms (IDC, 2020).

Trade and Development Bank

The Eastern and Southern African Trade and Development Bank (TDB), is the financial arm of the Common Market for Eastern and Southern Africa (COMESA), and operates in eastern and southern Africa. It provides sovereigns and corporates with import and export financing, structured commodity finance, guarantees and bonds, pre-and-post shipment finance, letters of credit, and receivable-backed and asset financing in all economic sectors.

Development Bank of South Africa

DBSA supports infrastructure development in energy, digital transformation, transport, water, social sector, and, mostly, in municipalities and local-government structures. This involves

supporting the development of basic household necessities such as water, sanitation, electricity and housing, as well as community services.

African Development Bank (AfDB)

The African Development Bank (AfDB) Group's mission is to promote sustainable economic development and social progress in its regional member countries (RMCs). It invests in RMCs, provides policy advice, and technical assistance, including with respect to health-related projects. AfDB raised $3 billion in a three-year bond, the Fight COVID-19 social bond, to provide COVID-19 related relief. It is the largest dollar denominated social bond ever launched in international capital markets to date, and the largest USD benchmark ever issued by AfDB. It also launched a $10 billion COVID-19 Response Facility to assist RMCs with COVID-19 (AFDB, 2020).

CDC

CDC is the UK's DFI. The company has investments in over 1,200 businesses in emerging economies with total net assets of £6.5bn and a portfolio of £4.7bn. CDC invests to alleviate poverty and to make a financial return, which is reinvested in Africa and South Asia.

Arab Bank for Economic Development in Africa (BADEA)

The Arab Bank for Economic Development in Africa (BADEA) has earmarked $100 million to support sub-Saharan African countries in their efforts to prevent and contain the spread of the pandemic (Mayaki, 2020).

Central Bank of Nigeria

Nigeria's central bank is providing $2.7 billion in COVID-19 related funding (Soto, 2020). This is intended to, among other things, provide "credit to indigenous pharmaceutical companies and other healthcare value chain players intending to build or expand capacity." (CBN, 2020). Eligible participants include healthcare product manufacturers, including pharmaceutical drugs and medical equipment, and qualified activities include manufacturing of pharmaceutical drugs and medical equipment as well as medical R&D. Working capital loans are limited to 20% of the average of three years of a borrower's turnover subject to a maximum of N500 (naira) per obligor while a term loan is subject to a maximum of N2 billion.

Standard Charted Bank

A wholly owned subsidiary of Standard Chartered Bank Plc, headquartered in the UK, the Bank financed mask production from the Transgreen O-Care company. The company was making DVDs at the outset of COVID-19, and finding no PPE production in Nigeria, transitioned part of the company to making masks. In December 2020, the company reported it was making 240,000

masks a day and was working toward a 300,000 mask per day production capacity (AfricaCDC, 2020).

3.4 Private Funders and Donor Agencies

Drugs for Neglected Diseases Initiative (DNDi)

DNDi works to coordinate clinical trials, facilitate and accelerate research, and to advocate for accountability.

GAVI

Gavi is co-leading COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. This involves coordinating the COVAX Facility, a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines. Gavi also provides countries with financial health system strengthening and technical assistance.

African Union COVID-19 Response Fund

The African Union COVID-19 Response Fund aims to raise resources to strengthen the African response to COVID-19. Among other objectives, it is supporting pool procurement of diagnostics and other medical commodities. It is also mitigating economic and humanitarian impacts from COVID-19.

Open Society Foundations

OSF is the worlds' largest private funder of independent groups working for justice, democratic governance, and human rights. It provides thousands of grants annually, many now related to COVID-19 relief. Its 2020 budget was $1.2 billion.

Gates Foundation

The Gates Foundation has funded health care projects in Africa, however, there does not appear to be any funding or RFP currently available for African manufacturing. The foundation does "not make grants outside our funding priorities. In general, we directly invite proposals by directly contacting organizations. We do occasionally award grants through published Requests for Proposals (RFPs) or letters of inquiry." (GatesFoundaiton, 2020)

In November 2020, the foundation announced an additional $70 million to global efforts to distribute vaccines to low- and middle-income countries. This includes an additional $50 million to the COVAX Advance Market Commitment of Gavi. That announcement brings the foundation's total commitment to Gavi's COVAX AMC to $156 million.

Rockefeller Foundation

The Rockefeller Foundation Announces New Awards to Strengthen Covid-19 Response in Communities Across Africa and Asia, May 28, 2020.

In May 2020, the Rockefeller Foundation announced three new grants to support organizations that are working in Africa and Asia to leverage data and technology to bolster their COVID-19 response. These grants will enhance data collection through contact tracing, symptom checking, and testing that can generate data that is crucial for ensuring efficient COVID-19 responses across community, country, and regional levels (RockefellerFoundation, 2020).

Notable Private Investments

Private investment of $250 million has recently been made into a new Africa pharmaceuticals company. The founding investors are the private equity firm Development Partners International, UK-based impact investor CDC Group and the European Bank of Reconstruction and Development. The group's initial investment funded the acquisition and combination of Egyptian generic drugs maker Adwia Pharmaceuticals and Celon Laboratories, an Indian oncology and critical care specialist (Reuters, 2020).

3.5 Government and Intergovernmental

European Commission

Horizon 2020 is the EU's funding program for research and innovation, making about 80 billion euros available from 2014 to 2020. It provides funding for, among others, the European & Developing Countries Clinical Trials Partnership (EDCTP), which focuses on infectious diseases research in sub-Saharan Africa. This public-public partnership has funded 24 projects with a total of 11.45 million euros aiming to prevent or manage the spread of COVID-19. In addition, EDCTP and its partners are investing 23 million euros to build research capacity, strengthen regional research networks and establish an African cohort of research scientists (EU, 2020).

Horizon Europe is planned to succeed Horizon 2020 including an additional 100 billion euros in funding.

Government of Zimbabwe

Made $1.3 million available for technical universities to produce PPE. Chinhoyi University of Technology (CUT) was producing 2,500-3,5000 masks a day (TBI, 2020).

Organisation for Economic Co-Operation and Development (OECD)

OECD is an intergovernmental economic organization that stimulates economic progress and world trade. It is funded by member state contributions. OECD maintains a list of research funding initiatives related to COVID-19 (OECD, 2020).

Select US Federal Grants (www.grants.gov)

1. ALIMA USA, Inc. Date: March 2020, Purpose: to strengthen the response capacities of Senegal's Ministry of Health and Social Action and Cameroon's Ministry of Public Health to COVID-19, Amount: $500,000, Topic: Emergency Response, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: New York, New York, Grantee Website: http://www.alimaong.org
2. ThinkWell Institute, Date: October 2020, Purpose: to support strengthening of Mozambique's COVID-19 response and essential health services continuity, Amount: $1,325,687, Topic: Delivery of Solutions to Improve Global Health, Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development
3. Clinton Health Access Initiative Inc, Date: July 2020, Purpose: to support Lagos State's COVID 19 case management through the procurement and installation of up to 50 oxygen kiosks to rescue the high number of severe case of COVID 19 being recorded in health facilities, Amount: $1,419,323, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: Boston, Massachusetts, Grantee Website: http://www.clintonhealthaccess.org
4. eHealth Africa, Date: April 2020, Purpose: to support the Nigeria government through the Nigeria Center for Disease Control to improve its testing capacity for COVID-19 pandemic, Amount: $300,533, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: Washington, District of Columbia, Grantee Website: http://www.ehealthafrica.org
5. Tony Blair Institute for Global Change, Date: April 2020, Purpose: to support improved and efficient strategic coordination for Nigeria's emergency response to COVID-19 outbreak, Amount: $200,000, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: London, Grantee Website: http://institute.global/
6. ALIMA USA, Inc., Date: April 2020, Purpose: to strengthen the response strategies of the Burkina Faso, DRC MoHs to the current outbreak of COVID-19, among other African countries, and to share expertise in epidemic preparedness and response, Amount: $200,000, Topic: Emergency Response, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: New York, New York, Grantee Website: http://www.alimaong.org

7. Medpharm Holdings Africa, Date: April 2020, Purpose: to support Ethiopia's response to the COVID-19 pandemic by leveraging public private partnerships to ramp up and strengthen capacity for testing and diagnostics, Amount: $1,098,930, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: Addis Ababa, Addis Ababa, Grantee Website: http://www.icladdis.com
8. United Nations Development Programme, Date: July 2020, Purpose: to support the Government of Uganda to expand its testing capabilities to meet the need for COVID-19 case finding and strengthen contact tracing, Amount: $357,179, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: New York, New York, Grantee Website: http://www.undp.org/content/undp/en/home.html
9. Rwanda Biomedical Centre, Date: July 2020, Purpose: to support the Economic Task Force of the Rwandan government to ensure an effective response to COVID-19 across recovery and normalization phases, Amount: $500,000, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: Kigali, Kigali City, Grantee Website: www.rbc.gov.rw
10. Health Systems Consult Limited, Date: June 2020, Purpose: to support the coordination and mobilization of civil society's response to COVID-19 to mitigate community transmission and minimize the health, social and economic impact at the subnational and community level, Amount: $117,246, Topic: Global Health and Development Public Awareness and Analysis, Regions Served: GLOBAL|AFRICA, Program: Global Development, Grantee Location: Abuja, Grantee Website: http://www.hscgroup.org

UNCTAD

UNCTAD is a UN Agency that works with developing countries to help them, among other things, attract investment, promote entrepreneurship, and limit exposure to financial volatility and debt. It provide technical cooperation products specifically in the context of COVID-19, and it is working with WHO, local producers, foreign investors, and developing country governments to scale up local manufacturing (UNCTAD, 2020a). UNCTAD only provides technical cooperation to members states and regional organizations (UNCTAD, 2020b).

Christophe Spennemann, Legal Officer and Officer-in-Charge, UNCTAD, was interviewed as part of this project. Mr. Spennemann is in charge of the IP Unit and advises developing countries on IP and development implications, including in the area of pharmaceuticals and access to medicines. He has experience visiting east African countries to learn about their local production policies and to provide training, though his work did not specifically focus on financing. In his experience, achieving adequate quality standards and having robust drug regulatory authority enforcement was a challenge. In fact, manufacturers argued that some of their own governments were skeptical of locally manufactured pharmaceuticals and would prefer Chinese or Indian

generic products. This resulted in regulatory barriers that made regional sales of local products challenging, which in turn made achieving economies of scale problematic.

Manufacturers need financing to upgrade their production facilities and ultimately product quality, but they struggled to obtain financing from commercial banks which considered such projects risky. Mr. Spennemann suggested that banks were overall hesitant to lend to pharmaceutical manufacturers, and that if they were prepared to lend that the interest rates they wanted to charge (8-10%) were too high for the manufacturers. He noted the Ethiopian development bank had a program which made capital available to local producers at preferential rates, but that the bank did not make such loans available to the pharmaceutical industry. However, this might be a model that would facilitate local pharma manufacturing. The funds for the Ethiopian PDB came originally from EIB.

Mr. Spennemann believed that PDBs are a promising source of needed capital for local manufacturing, but this should be done together with upgrades to drug regulatory agencies and greater regional harmonization to create larger markets and make a better up-front business case for investment.

3.6 Conclusions and Recommendations

The key insights from this mapping are that:

- A very substantial amount of capital is available for investment in Africa. However, relatively little capital appears to be directed to local manufacturing of DVT and PPE.
- A wide variety of institutions are making capital available for COVID-19 related relief, but without significant focus on local manufacturing.
- Information about the availability of financing for African health-related manufacturing is not easily accessible.

It is recommended that:

- Stakeholders advocate for local DVT and PPE manufacturing as a policy priority for PDBs and other public financing sources.
- The pandemic is an opportunity to change how developed and developing countries think about the importance of African local manufacturing.
- Create information portals to collect, validate, and disseminate information about the availability of financing.

4. Interview Synthesis

A series of interviews were conducted with stakeholders with direct and indirect involvement in the South African pharmaceutical sector to further determine the extent to which gaps in the availability of finance may be hindering more robust development of local production. This included stakeholders from Foundations, Asset Managers, an international technology transfer organization, the private pharmaceutical industry, and government (among those listed in Appendix B).

The information obtained through these interviews, and the perspectives expressed by the interviewees, was largely consistent.

1. The main limitation facing local pharmaceutical producers in Africa is not a lack of available sources of capital, but rather structural limitations that make it difficult to develop sustainable manufacturing businesses.
2. Much of African pharmaceutical procurement is funded by international donors. The donors require compliance with stringent GMP and they seek the lowest prices. With some exceptions, African local producers do not meet stringent GMP standards, and it would be very costly to upgrade facilities to meet that objective. Because there would yet be uncertainty as to whether contracts based on international donor funding would be secured, there is limited incentive for African manufacturers to upgrade.
3. In some countries, the dominant role of government in procurement of pharmaceuticals, and associated budgetary limitations, make it difficult for manufacturers to build and develop facilities that confront wide variations in volume demand depending on whether procurement contracts are awarded and their typically limited duration.
4. Government procurement authorities seek the lowest available prices. These are commonly offered by Chinese and Indian producers, and it is very difficult for local manufacturers to compete with these foreign exporters on price. Detailed studies have indicated that the benefits to an economy from maintaining a robust pharmaceutical sector would outweigh the additional government budgetary costs from providing preferences to locally produced pharmaceuticals (up to a fairly significant premium), but governments and their procurement authorities have been unwilling to establish sufficient pricing preferences for local producers.
5. There are a substantial number of regulatory, infrastructure and trade barriers to moving pharmaceutical products between the countries of Africa, making it difficult for producers to achieve economies of scale through exporting within the region.
6. Some Foundations have seen substantially greater interest in localizing production in Africa from stakeholders, including governments, particularly as a consequence of the COVID-19 pandemic. Up to this point, the Foundations have concentrated their efforts on push and pull financing mechanisms to facilitate the availability of and access to vaccines, diagnostics and therapeutics, including by investment in R&D. Though there is growing

interest, there are not yet concrete plans to encourage local production through financing. Financing through grant funding is probably not a sustainable approach to development of robust local pharmaceutical manufacturing because grant funding inevitably runs out, and businesses must be sustainable to continue operating.

7. The idea of creating improved regional platforms for production and distribution have been discussed.
8. Governments in Africa have adopted a significant number of plans and pronouncements regarding encouraging local production, but these plans have not been implemented. The focus moving forward should be on implementation.
9. There may be merit to the route of encouraging joint ventures between foreign technology holders and local manufacturers, inter alia, to encourage the establishment of stringent GMP compliant facilities.
10. There is existing manufacturing capacity in South Africa for products that may be effective in helping to treat COVID-19, including dexamethasone, fluvoxamine and ivermectin.

Some recommendations that might be derived from the interview results summarized above are given in the text box that follows.

Recommendations

- Advocacy should encourage participation of Foundations in providing financial support for localizing production in Africa. This could include linking advance purchase commitments to local manufacturing in some manner.
- Advocacy should assist with overcoming the reluctance of African governments to support local production that may entail higher procurement prices but have substantial positive economic welfare benefits.
- Foundations could be helpful in redirecting governments in Africa to pursue sustainable business models for local production rather than relying on unsustainable grant funding.
- There is interest within some Foundations on the prospect for regional production hubs. This is an area where support may be sought for future development of projects.
- Pursue removal of obstacles to the intra-regional supply of pharmaceutical products, including through facilitating harmonized regulatory approvals, so as to encourage regional production.
- Reform pharmaceutical procurement processes to allow for longer-term supply security for manufacturers to enable successful business operations.
- Support localization in phases beginning with increasing formulation manufacturing capacity.
- Seek modalities to balance the dominant role of government in procurement with greater private sector health system involvement.
- Encourage local South Africa companies to develop investable pharmaceutical manufacturing plans for consideration by domestic asset managers.
- Local manufacturers in South Africa should explore opportunities for manufacturing drugs shown to be useful in treating COVID-19, including dexamethasone, fluvoxamine and ivermectin.
- South Africa should be encouraged to reform its pharmaceutical procurement system to provide preferences to local production, and to reduce the impact of the “all or nothing” tendering system that places the preponderant financial burden on the suppliers.
- African local manufacturers might pursue joint ventures with foreign partners involving technology transfer and training as a means of upgrading to stringent GMP and/or becoming more price competitive.
- Regarding public health security, it may be useful to look at industries in Africa which are ready to scale, such as for PPE stockpiling.
- Advocacy should support a regional African vaccine Institute similar to India’s Serum Institute.
- Encourage Foundations and other potential funders of localizing production to make transparent and coordinated the opportunities for funding and potentially create a financing pool to support localization initiatives.

5. Making Pharmaceutical Investments Viable in Africa;

What Current Local Production Experiences Tell Us[12]

5.1 Local Production and Finance: Context Setting

As opposed to new drug discovery that relies on R&D investments, local production traditionally refers to efforts that support companies to *produce drugs and vaccines of assured quality* (in accordance with current GMP standards), to serve *local needs*, at *competitive* prices. This kind of pharmaceutical production begins with the promotion of large-scale investments into plant and production facilities. As a next step, to produce drugs at competitive prices, local firms need to overcome the capital costs associated with setting up such capacity (investment), and of continuing operations (production). In other words, the local producer needs to be able to build a working facility, access raw materials and labor cheaply, and manufacture drugs at a scale large enough to recover initial investments, in order that it can be priced competitively.

Sourcing ingredients reliably, training and retaining skilled personnel, and manufacturing drugs at scale were never easy undertakings. It is true, however, that this is far more difficult today than ever before.[13] Regulatory agencies emphasize that the requirements of GMP are constantly evolving, thus today's expectations are higher than those in years past.[14] Internationalization of the pharmaceutical sector implies that new firms in African markets do not operate in a national market that is protected, as was the case when several developing countries such as India, China, Brazil, Argentina and Bangladesh sought to build local pharmaceutical sectors in the 1970s and the 1980s. Today, new firms seeking to produce pharmaceutical products must compete with established multinationals on the one hand, and large international firms from India, China and other developing countries that supply to much of the Africa market.[15] The incumbent companies

[12] The author acknowledges research assistance from Nanditta Batra for Indian incentives in the pharmaceutical sector (see Addenda), and Misthura Otubu on researching policy initiatives in Nigeria and Ghana.

[13] See Fisher, Okediji and Gehl Sampath, Fostering Local Production of Pharmaceuticals in Developing Countries, 2021.

[14] World Health Organization: HEALTH PRODUCT AND POLICY STANDARDS – GOOD MANUFACTURING PRACTICE. https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/gmp

[15] A recent UNAIDS report estimates that more than 80 percent of Anti-Retroviral drugs (ARVs) used on the continent are imported from outside, with 70 percent of all pharmaceutical and medical products market being served by foreign imports. See UNAIDS, 21 COUNTRY PROFILES: AN INTRODUCTION TO LOCAL PHARMACEUTICAL PRODUCTION OPPORTUNITIES IN AFRICA (2018), 6, https://developmentreimagined.com/portfolio-posts/portfolio-04-3-2/. The same discrepancies are mirrored at the country level in many, if not most SSA countries. A 2020 news report shows that with 38 pharmaceutical manufacturing companies (27 active[15]) in Ghana, about 30% of pharmaceutical products consumed in Ghana are currently produced locally with the remaining 70% being imported mostly from China & India. See Citi Newsroom, 'Ghana Export-Import Bank collaborates with indigenous pharmaceutical companies for exportable products'. (October 27, 2020) https://citinewsroom.com/2020/10/ghana-export-import-banks-collaborates-with-indigenous-pharmaceutical-companies-for-exportable-

have several advantages, including: 1) established production facilities; 2) experience in regulated markets; 3) large profit margins; 4) established reputation; 5) prior knowledge of markets and distribution channels; and 6) established domestic supply chains that offer access to all production components in an easy and accessible manner. In stark contrast, African firms function in industrial environments that are highly constrained, with a low-skilled work force (especially a low number of highly educated and experienced professionals), a weak emphasis on technology absorption capacity, and the lack of forward and backward linkages and declining industrial productivity across sectors.

This divide is evident in the import-export ratios of pharmaceutical products on the continent. Although the currency value of pharmaceutical production throughout Africa is difficult to accurately estimate, most countries in sub-Saharan Africa import 70%-90% of drugs consumed. Countries with a high degree of self-reliance in production are South Africa and Morocco, with respectively an estimated 65% and over 70% of national medicines demand being met by local production. Many other countries import 95% or more of the value of their national pharmaceutical markets[16]. An approximate estimate that African production accounts for 20%-25% of captive market demand is not out of order. The Tanzanian pharmaceutical market is representative of many markets, where an estimated 12% ($130M) of total sales are generated by domestic production firms[17]. These firms are what is left of several large local companies that eventually underwent foreclosures over time.[18]

The section discusses what it takes to establish pharmaceutical production, highlighting the role of finance in the process. Sub-section 2 elaborates on the role of finance in the pharma production process; accounting for the risks and uncertainties of pharmaceutical production in Africa, and how that contributes to the high costs of capital. The section then discusses ways in which governments can intervene to reduce the risks inherent to pharma production. The analysis in this section should be considered against the backdrop of a general economic principle that emerges from industrialization and technology studies: if you start from a backward point, you need much more support. The same is true of Africa today in the area of local production.

5.2 African Pharmaceutical Companies in the Global Context

Global originator pharmaceutical companies are huge corporations. The global pharmaceutical market totals approximately $1.3Tn in sales. Although the market is highly fragmented with no company holding a dominant position in any market, the top 10 global pharma companies have

products/#:~:text=GEXIM'S%20Support%20for%20the%20Pharmaceutical,pharmaceutical%20manufacturing%20sector%20since%202017

[16] Oomen C. Kurian, EXPANDING PHARMACEUTICAL LOCAL PRODUCTION IN AFRICA: AN IDEA WHOSE TIME HAS COME? (2019) Observer Research Foundation https://www.orfonline.org/expert-speak/expanding-pharmaceutical-local-production-in-africa-an-idea-whose-time-has-come-49805/

[17] Dickson Pius Wande et. al., PHARMACEUTICAL IMPORTS IN TANZANIA: OVERVIEW OF PRIVATE SECTOR MARKET SIZE, SHARE, GROWTH AND PROJECTED TRENDS TO 2021 (2019). PLOS One; https://doi.org/10.1371/journal.pone.0220701

[18] Padmashree Gehl Sampath, RECONFIGURING GLOBAL HEALTH INNOVATION (2009).

total sales of about $427Bn (Pharmaceutical Technology; 2020)[19]. Large pharmaceutical companies rank as the most profitable large sector of capitalized markets with average EBITDA of 29.4% in the 2008-2018 timeframe, versus 19% for other industries[20]. The US Government Accounting Office found that originator (patented drug) pharmaceutical companies averaged 15%-20% profits after taxes (2006-2015), with margins for other sectors averaging between 4% and 9%[21]. The latest market capitalization figures for Pfizer and Johnson & Johnson, respectively, are $199.7Bn and $429.4Bn (NYSE).

Globally, generic companies operate on a much smaller revenue scale than originator pharma's. Although over 90% of global medicines are generic drugs, the revenues for generics ($224Bn) amount to approximately 20% of total pharmaceutical sales[22]. The top 10 global generic pharma companies had global sales of about $48Bn in 2018, with two companies (Teva and Sandoz) accounting for more than 50% of this total[23]. The Indian pharmaceutical industry operates at an average pre-tax margin of 10%. The top 10 Indian pharmaceutical companies have annual revenues that range from about $2Bn - $4Bn[24].

Many of the largest African pharmaceutical companies are divisions of multi-nationals (Pfizer, GSK, Sanofi, Sandoz). Aspen Pharmacare, a multinational company headquartered in South Africa is the largest African pharmaceutical company. Aspen was founded and is headquartered in South Africa. Aspen's sales in 2019 amounted to $2.6Bn (ZAR38.9Bn) with a net profit of $316.5M and a current market cap on the NYSE of $4.3Bn. Thus, the very largest of African pharmaceutical companies has a scale of operations that would rank in the top 10 of Indian pharmaceutical companies, but are only a fraction of the sales and capitalization of large originator companies[25].

Indigenous African pharmaceutical companies, however, are normally far smaller than Aspen. Emzor Pharmaceuticals is a premier pharma producer in Nigeria, which formulates approximately 2,000 tons of paracetamol annually. Despite being one of the largest of over 200 pharma

[19] Pharmaceutical technology 2020: https://www.pharmaceutical-technology.com/features/top-ten-pharma-companies-in-2020/
[20] Fred D Ledley, Sarah Shonka McCoy, Gregory Vaughn, Ekatarina Galinka Cleary, PROFITABILITY OF LARGE PHARMACEUTICAL COMPANIES COMPARED WITH OTHER LARGE PUBLIC COMPANIES. JAMA. 2020;323(9):834-843. DOI: 10.1001/jama.2020.0442
[21] GAO-18-40 (2017): https://www.gao.gov/assets/690/688472.pdf
[22] Pharma Franchise, (2019). TOP GENERIC PHARMA COMPANIES IN INDIA https://www.pharmaadda.in/top-generic-pharma-companies-in-india
[23] Pharmashots.com 2019: https://pharmashots.com/20409/top-20-generic-pharma-companies-based-on-2018-revenue/
[24] Statista, 2019: https://www.statista.com/statistics/999327/indian-pharmaceutical-industry-net-profit-margin/
[25] Aspen Pharmacare: https://www.aspenpharma.com/

companies registered in Nigeria, Emzor's annual revenue was reported to be $17.5M in 2019[26]. Sam Pharmaceutical in Lagos has reported revenues of $31M[27]. May and Baker (NG) reported revenues in 2020 of $21.3M[28]

The pharmaceutical sector in Africa, on the whole, is also very fragmented, with a few large companies and a large number of small companies engaged in pharmaceutical production. Many of the companies registered do not really manufacture. A case in point, there are over 200 pharmaceutical companies registered in Ethiopia. As is the norm in Africa, most of these companies import FDFs and only distribute products or perform finished packaging operations before distribution. No more than 12 companies in Ethiopia formulate APIs into finished dose forms (tablets, capsules, sachets, suspensions/solutions).[29] The largest Ethiopian producers include Julphar Ethiopia, Ethiopian Pharmaceutical Manufacturing Company, Pharmacure, and Zydus Cadila, but none of these companies has revenues as high as $30M/year.

These figures begin to describe a likely scope for the potential of financial investment to increase African capacity to manufacture pharmaceuticals and other healthcare products. If $2Bn were available as a pool (e.g.), to invest in building manufacturing capacity, this would make a huge difference to the industry throughout all of sub-Saharan Africa. The capacity of any single company (except the very largest) to absorb $100M in investment is questionable. But the infusion of $10M in capital for expansion with many well-established firms in Africa at favorable interest rates could hugely increase capacity.

5.3 An Internal, Industry Perspective on Finance

In local production, firms experience a significant time lag from the time they make the decision to invest to the time they can produce to realize sales from investment. This time lag may be quite different in the respective case of drugs, vaccines, PPE, and diagnostics. The role of finance in pharmaceutical production can be depicted in the form of four stages shown in Figure 3. A number of capabilities become relevant in this process. First, technical knowledge is required to build pharmaceutical manufacturing, which might include training of existing staff but also extend to creating appropriate skills in universities, regulatory agencies, key opinion leaders in national medical practice, or pharmacy training institutes. Next, pharmaceutical production is

[26] https://www.dnb.com/business-directory/company-profiles.emzor_pharmaceutical_industries_limited.17d38b3b0028ccdaf1f17df906500f39.html#:~:text=EMZOR%20PHARMACEUTICAL%20INDUSTRIES%20LIMITED%20has,million%20in%20sales%20(USD)

[27] DNB Profiles: https://www.dnb.com/business-directory/company-profiles.sam_pharmaceutical_ltd.fd7ff2a007599da0882b83c0d42b28e7.html

[28] DNB Profiles: https://www.dnb.com/business-directory/company-profiles.may_and_baker_nigeria_plc.450c375cde564b5f81ad2450a2ace5cd.html

[29] The Africa Report (2016): https://www.theafricareport.com/1941/pharmaceuticals-pills-for-the-ethiopian-populace/#:~:text=Cadila%2C%20Julphar%20Ethiopia%2C%20the%20Ethiopian,and%20medical%20consumables%20in%20Ethiopia

capital intensive, requiring high standards of regulation and quality assurance. Finally, pharmaceutical production is finance intensive. There is a need for direct financing of activities right from the start, and such financing needs to be sustained until projects achieve scale.

5.3.1 Business plans, risks and uncertainties

Any normal business plan sets out the risks inherent to maturing through these stages, while increasing investments into production capacity. This would account for a number of supply and demand side factors that play a role in signaling the viability of the project in the pharmaceutical sector.

On the supply side, pharmaceutical production is similar to any manufacturing activity, relying on the ability of the firm to source infrastructure (uninterrupted electricity, clean water and transport) in an efficient manner. There are plant design costs, which typically amount to 15% of total facility construction costs. Equipment and utilities (HVAC) are especially important to pharmaceutical production. Equipment is expensive and must be imported for African production. HVAC for pharmaceutical production requires higher design standards and maintenance cost versus most other types of production, since end products are for medicinal use and might require sterile or aseptic conditions for manufacturing and packaging.

Next, pharmaceutical firms require cheap and reliable access to raw materials in order to achieve competitive costs of production. In the case of drugs, this implies sourcing active pharmaceutical ingredients (APIs), excipients and other packaging materials on reasonable, or preferential terms. Same is true in vaccines, where antigens, adjuvants and vials play a critical role.

The availability of capital and skilled labour, such as pharmacists, and chemistry graduates (for processes of drug production), marketing personnel, and managers, all of which are required to build production plants that can manufacture according to current good manufacturing practices is also important. A supportive business environment – in terms of ease of negotiating licenses, availability of special economic zones, R&D grants, export incentives –not only reduce risk, but also enhance the probability of reaching break-even sooner than anticipated.

In addition to these supply side variables, business decisions depend on access to markets. The size of the domestic market, the extent of competition, and distribution channels (public and private) that the firms can tap into all determine product selection and product baskets. Possibilities of technological upgrading, availability of skilled labour, forward and backward linkages (into supply chains) also play a key role in incentivizing firms to invest into production. On the one hand, it facilitates the production of quality products no doubt, but on the other, it also promotes technology upgrading critical to increase plant efficiency, and productivity. These factors also play a critical role in enabling firms to streamline production processes that are more cost-efficient, and to engage in incremental and follow-on innovations. Innovation studies note

critically how this kind of learning by doing, learning to compete has complementarities with how firms survive and thrive even in adverse conditions[30].

Finance thus, has a complex relationship with all of the demand and supply side parameters in local production. At a general level, business plans calculate risk and uncertainty by assessing these factors, but there are a number of unknowns that can arise and impose costs at each of these stages.

5.3.1.1 At Stages 1 and 2 of production

In the early stages, the risks faced by firms materialize in the following costs:
(a) Infrastructure costs: Both land and plant machinery are sensitive to their life cycles. It is not uncommon to incur losses in the early years, when processes are being adjusted and heavy investments are being made, particularly because facilities tend to not function at full capacity. Profitability only increases in later years when systems are up and running to full capacity efficiently.
(b) The costs of doing business: There are generally several additional costs of doing business in new environments, which may lead to delays in getting licenses, employing people, signing business contracts, establishing supply chains, etc. These can cause delays in the anticipated timeline to set up production capacity.
(c) Costs of accessing markets: this can involve search and reputation costs, costs imposed by penetrating markets with many competitors, and costs of getting local regulatory approvals.
Some of these early-stage risks are usually mitigated by regulation. For example, industrial regulations can make it easier for firms to access licenses, labour market rules help movement of labour, and generally, regulations seek to facilitate business growth and enterprise development.

5.3.1.2 At Stages 3 and 4 of production

By stage 3, the firms are expected to continue to invest into expanding production capacity, in the hope that the early-stage investments (the static costs) into setting up business can be recovered by expanding sales product lines and manufacturing at full capacity. In these stages, particularly deciding to invest in a developing country, there may be additional costs in terms of accessing technologies, market uncertainty, determining the fair value of some assets, depreciation and amortization rules, and currency fluctuation.

5.3.2 Risks and uncertainties of pharma production in practice

In low-income contexts, these stages do not unfold as they do in other countries that have well-developed industrial capacity, markets and infrastructure. Several additional risks abound. Some of these – such as currency fluctuation risks – can be factored into business plans upfront. But

[30] See for example, Alice Amsden, THE RISE OF THE REST (2001); Banji Oyeyinka and Padmashree Gehl Sampath, LATECOMER DEVELOMENT (2009).

many others materialize during the process to varying and unpredictable degrees, increasing the risk of investment.[31] These risks are explained here with specific reference to operating in Africa and are mapped in table 1.

5.3.2.1 System infrastructure risks

Firms operating in developing countries – especially those seeking to be first movers in production of any kind (APIs, vaccines, diagnostics, etc.) – experience various barriers. For example, routine architectural design costs of about 15% can become a much higher percentage of total construction financing because very few architectural design experts for pharmaceutical plants are based in Africa. External experts are several-fold more expensive than in-country expertise. Then there are other factors that impose specific production costs on a day-to-day basis. Delays caused by the absence of port and transport infrastructure, or unreliable access to power, or shortages or bottlenecks in supply of inputs, changing tax regimes, corruption, can all imply additional infrastructure costs at the plant level. To hedge some of these risks, plants invest additionally – like into backup power generators, or storage capacity to hold inventory. Similarly, the absence of specific kinds of skilled labour might imply additional costs to source it from abroad. These materialize as a result of low public investments, but risk reducing the efficiency at the plant level.

5.3.2.2 Industrial risks

These materialize from a weak regulatory regime that incentivizes industrial development in general, but creates additional costs in input sourcing and the setting up of supply chains and production. In the case of drugs, local firms end up competing with established international companies that have inexpensive internal source inputs in their home countries, captive API production capacity (which accounts for a large share of the costs) and operate with specific tax, business and export advantages. Weak industrial coordination or a lack of coherence in regulatory regimes also creates perverse incentives in several countries. For example, a large number of African countries that prioritize local production of pharmaceuticals, also until recently, had tariff regimes with lower tariffs for the imports of finished formulations but have high mark-ups for intermediate inputs.[32] Finally, while land is often cheap, there are relatively higher costs of industrial infrastructure in most African countries, with a lack of special economic zones or industrial parks that prioritise pharmaceutical production, or impose penalties when industrial electricity/ or other infrastructure quotas are not fully used in initial stages of production set up.[33]

[31] Interviews various [Details to insert].
[32] See for example, Kenya until 2016, and Tanzania until recently.
[33] Interviews La Gray [Details to insert].

5.3.2.3 Sector specific risks

There are a number of sector specific risks, that impact on whether firms move to stages 3 and 4 of production, to reach scale and achieve quality of production. These relate to the acceptance of newly produced products in local markets, and by extension, how they are received in national and international procurements.

To begin with, a range of industry specific infrastructure (for testing, quality assurance, and quality control) are missing in a large number of countries, and this adds specific costs to firms seeking to produce quality assured products. Firms also lack the know-how and support required to manage registration processes, including the preparation of dossiers, demonstration of bioequivalence, and pre-approval inspections. Long delays and high costs of product registration, difficulties in accessing neighboring markets, and setting up distribution channels, are all rendered harder by the fact that they compete with foreign firms that have cost advantages.

Finally, mark-ups along retail chains, procurement practices in government or public sector institutions, predatory pricing by foreign firms (and the lack of oversight thereof) –also their ability to access markets, causing temporary, or intermittent delays in product sales. There are high costs of building up reputation in these markets and interviews conducted with local producers in several African countries suggest that oftentimes, local producers are in an uphill battle, seeking to chart new ground in the presence of several established foreign suppliers.

Without additional incentives (economic and sector specific) that help them overcome these costs, local firms that are still struggling to compete, are usually unable to price competitively in tendering processes, and stand a high risk of being undercut by Indian/ other firms.[34] These setbacks and risks in reaching scale affect the ways in which firms can raise working capital during stages 2 and 3 of Figure 3.

5.3.2.4 Political risks

Additional political risks of regime change, regulatory upheavals, change in direction of industrial policy (from import substituting to export-led, or vice versa), can all impact on how the production processes unfold, as shown in Table 1.[35]

[34] See Section 7 by Walwyn.

[35] For example, a large number of African countries moved from import-substituting industrial policy regimes to export-led regimes in the 1980s as a result of donor interventions to achieve macroeconomic stability. This impacted the incentives that local firms could access in manufacturing in general, and the pharmaceutical sector in particular. See for example, UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT: FOSTERING INNOVATION POLICY FOR INDUSTRIAL DEVELOPMENT (2015).

Table 1. Risks inherent to pharma production in low-income contexts

Risk category	Description	Effects
System infrastructure risks	Materialize as a result of low public investments	No water No electricity No skilled personnel
Industrial risks	Materialize from weak industrial environments	Higher tariffs for intermediate goods. Difficulties in obtaining licenses Inability to find export venues Inability to source market data, patent information, etc.
Sector specific risks	Materialize from a lack of support through national institutions for pharmaceutical production	Costs imposed by delays in product registration Lack of quality assurance, quality control infrastructure/ skills Costs of missing sector specific expertise, especially for vaccines and diagnostics Higher costs of accessing fragmented African markets Discrimination by donors, and national procurement agencies
Political risks	Materialize form political instability	Change in policy direction Change in incentives

5.3.3 What materializes when: uncertainty and outcomes

Granted, these additional categories of risks arise form a range of shortcomings in the countries/ contexts that firms operate in, but assume importance given that they increase the uncertainty of breaking even, and eventually making profits. Interviews with local firms suggest that even when local firms have capital to make the initial investments, the absence of supply and demand side variables affect each stage of the production process.

The Ethiopian pharmaceutical industry is representative of widespread issues that affect routine operations. Manufacturing equipment is not produced on the Continent and must be imported from India, China, or Germany (e.g.). Raw materials for production (e.g., APIs, excipients, capsules, glass vials, syringes, even laboratory reagents for testing) must also be imported. Preventive maintenance and routine metrology of production lines is also one of the fundamental requirements of GMP operations. This requires holding a substantial inventory of critical spare parts that are routinely replaced before they fail. Equipment failures during production most often mean that the affected product cannot be sold. In China, India, and high-income countries these issues are only a problem for the cost of production. In Africa these are critical issues for foreign exchange. Variable exchange rates and access to hard currency to purchase these items are very often mentioned by African producers as critical bottlenecks for expanding production.

A high rate of occupancy is also important for pharmaceutical production to be profitable. Preventive maintenance requirements dictate that the most efficient pharma manufacturing plants can operate at perhaps 80% occupancy rates. African companies often report routine occupancy rates of 30%-50%. This is often reported to be due to large delays in ordering and receiving replacement parts needed when equipment failures occur. Lack of hard currency to purchase raw materials to fulfill orders is also often cited as a hindrance to local production.

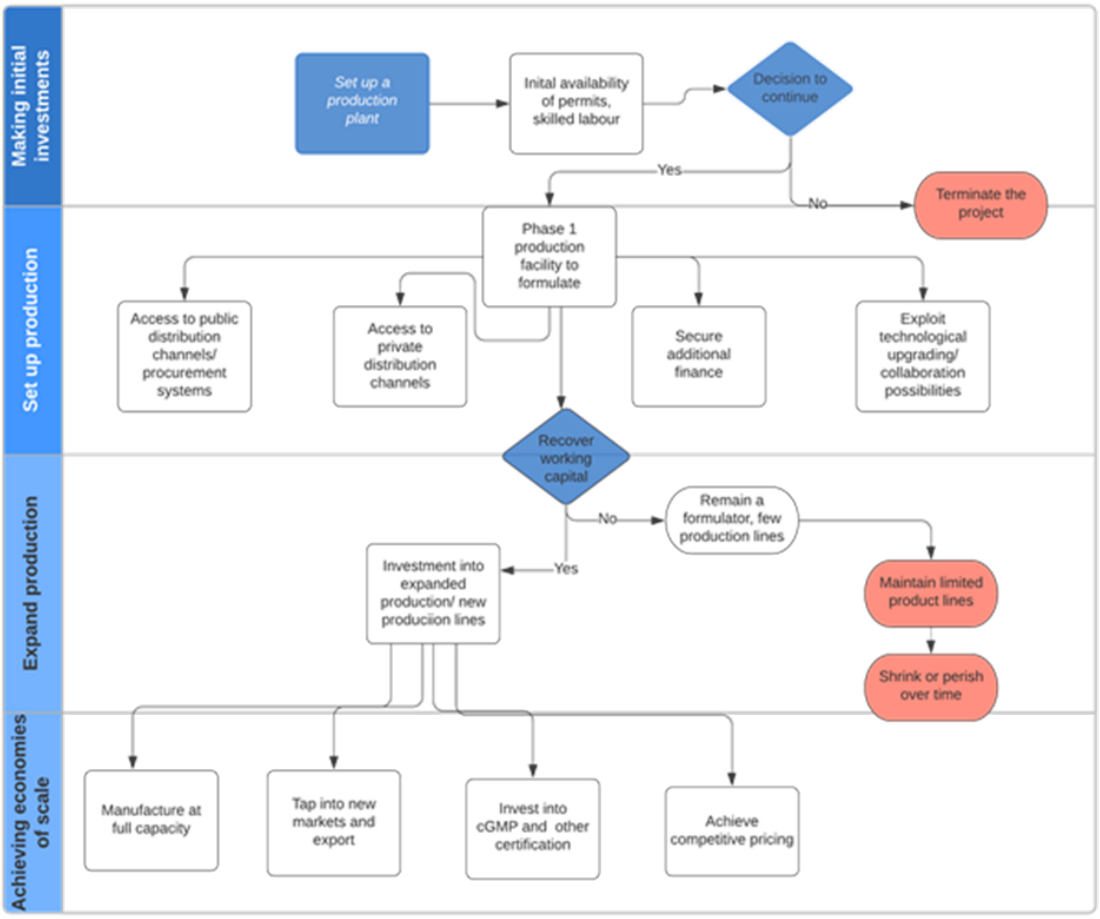

Figure 3. The role of finance at different stages of pharmaceutical production

In short, these kinds of institutional and market uncertainties make it harder for firms that mobilize initial set up costs (land, plants and machinery), to secure working capital, and eventually find additional investments to upgrade. Key decisions are impacted by such limitations in finance in terms of company operations, as shown in Figure 3 (in red). These relate to:

5.3.3.1 The selection of initial products, and the overall capacity of production

Many African pharma companies offer a very conservative line of products; e.g., analgesics, simple anti-infectives, malaria treatments, topicals, and metformin for diabetes. Widespread

local manufacturing of medicines for largely unmet medical needs – Hepatitis B and C, oncology, advanced diabetes, cardiovascular – the availability of these medicines throughout Africa would hugely affect mortality and morbidity.

5.3.3.2 Expansion to add new product lines or additional capacity

African companies are generally reluctant, however, to offer products new to the local market. Given the typical revenues of an African Pharma company this is not surprising. The cost of registering and launching a failed product can be dangerous to a company with less than $10M in sales. Public Sector or hospital pharmacy procurement is a substantial percentage of the market in most countries. Building markets in the anticipation of improved public health is rare except in the cases of HIV, TB, and Malaria. These areas where market entrance has been successful are largely supported by public sector procurement. As an example, even though there are high rates of infection for HCV in Nigeria and treatment could be affordable to most households, companies are not willing to register and sell treatments because there is no clear market demand. In higher income countries markets are built by physician and consumer education. In Africa, physicians largely do not test for many treatable diseases because the products are not available. Conversely, products do not become available because there is no market.

5.3.3.3 Expansion to upgrade quality

Expansion of production and acquisition of new equipment and technologies to upgrade quality – cGMP, WHO prequalification, USFDA and others – is equally affected. Eventually, unable to break even, local companies reach sustainability by finding niches where they operate as low cost, small margin manufacturers of a limited number of products. These failures are often cited as reasons why imports of cheaper alternatives may be better than supporting local production, given that local firms may simply end up being unable to break even, and eventually, transferring the costs of producing these drugs to the consumer.

5.3.4 High costs of capital and its impact on firms

From a finance perspective, weak infrastructure for industry and technology, shortage of skilled labour and the inability to tap into markets, all act as proxies signaling low expected returns in the sector, making it hard for local firms to access capital. In addition to these, the historical experience of firms that have struggled with recouping investments and breaking even on the continent, also tends to inform new financing initiatives. As a result, while there is a large amount of private capital available on the continent (see section 1), it tends to flow into other sectors and businesses, where the rates of return are more secure.[36] The pharmaceutical sector, in

[36] See Section 3 on financial mapping.

general, is considered to be highly risky to invest in, unless other factors that impede investments (as captured in table 1) are accounted for.[37]

Any small, medium or large local pharmaceutical firm seeking debt or equity financing, encounters rates that tend to be extremely high (if at all available). This is why, despite a plethora of financial options available in the market, most local firms in Africa finance their activities primarily using some combination of private equity and bank loans.[38] This in particular, imposes hardships even when firms had raised personal equity to move from stages 1 to 3, they firms faced difficulties to mobilize working capital to move from stage 3 to stage 4, in Figure 3.

The advantages possessed by external producers is also a really important contributor to building successful production capacity. Cipla's partnership with Quality Chemicals in Uganda is noteworthy as one example. Despite many hurdles in initial stages, this partnership is providing fixed-dose combinations (FDCs) for treatment of HIV and malaria treatments to Uganda and is exporting to twelve other African countries as of 2020. The company has a valuation of approximately $240M as of 2018.[39]

Beyond the case study of CiplaQuality chemicals, collaborations of African companies with producers in India (Zydus-Cadila in Ethiopia) and China (Shansheng and Humanwell; Burkina S.A., Ethiopia, Mali) illustrate the value of partnerships in short-cutting the long timelines and investment required to achieve excellence in pharmaceutical production. This reinforces the need for external collaborations in building African industrial capacity, simply because it helps local firms overcome some of these risks more easily.

But for each of these firms that have managed to build collaborations, there are so many initiatives that have not succeeded. In these instances, firms are not able to afford the high cost of financing capital especially in light of recurrent challenges they face to in day-to-day operations listed in this section. In the case of at least one firm, La Gray Chemicals, interviews show that finding business partners to invest equity, led to a complete change in direction of production itself, from the initial objectives of setting up a production plant for API production to simply recovering investments through sales and distribution activities. In many other instances, the difficulties in mobilizing capital affects access to markets because of questionable quality, as well as executing and fulfilling purchase orders due to lack of raw materials, spare parts, and APIs. Tangibly, these kinds of experiences translate into a distrust between firms and private lenders; a reliance on internal financing, despite its adverse impacts on the production ambition; and delays and interruptions in building capacity and introducing new products in markets.

[37] Interviews []
[38] Interviews [], Questionnaire results.
[39] Warren Kaplan and Richard Laing, Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues and Opportunities for Further Research, (World Bank, 2005).

6. Promoting African Pharmaceutical Production: Investment Opportunities and Best Practices for Consideration

6.1 Introduction

The previous section has highlighted the numerous risks, and capabilities divides that hinder the expansion of local production in Africa. These challenges notwithstanding, the time is ripe to address this capability divide from several perspectives. To begin with, there is a high degree of optimism about the size of the pharmaceutical market in Africa. Pharmaceutical sales in African countries were estimated at $28.5Bn in 2017, with projected growth to $56-$70Bn by 2030[40]. McKinsey has often referred to the African continent as the only pharmaceutical market where genuinely high growth is still achievable). Although figures are not totally comparable because of the differences in distribution to patented, generic, OTC, and herbal medicines this can compared with the market size of the US ($490Bn), China ($138Bn of which approximately 20% is exported), and India ($40Bn of which approximately 50% is exported). Second, this rising pharmaceutical demand in Africa - a result of expanding urbanization, increased income, growing public sector procurement and growing population, and converging epidemiological profiles[41] - is now placing an increasing burden on public health budgets to source cheaper drugs.[42] Since the start of the COVID 19 crisis, the difficulties in ensuring supplies – first for PPEs, then drugs and now vaccines - on the continent have re-focused attention on how such a growing market, and local needs, can be leveraged to promote local production. Last but not least, investing in business to resuscitate economies in a post-COVID world may serve two inter-related goals if countries were able to use the finances to build local production.

But as policy makers turn their attention to financing new fostering local production of pharmaceuticals, there is a need to understand what opportunities potentially exist for

[40] Goldstein Market Intelligence: African Pharmaceutical Market Analysis by Therapeutic Class by Drug Categories, by Inhalants, by Anabolic Steroids & by Region with COVID-19 Impact. Forecast Period 2017-2030. (January 7, 2021) https://www.goldsteinresearch.com/report/africa-pharmaceutical-industry-market-size-forecast#:~:text=African%20Pharmaceutical%20Market%20Outlook,5.5%20billion%20a%20decade%20earlier.

[41] A comparison of top ten estimated causes of death from 2000 to 2016 by income level shows that as opposed to 2000, where the leading causes of mortality in LMICs were a mix of non-communicable and communicable diseases, and in LICs were primarily communicable, maternal/perinatal and nutritional conditions, by 2016, tuberculosis does no longer appear in the top ten causes of mortality for both LMIC and LIC categories, alongside lower respiratory infections and HIV/AIDS, which have also fallen in the ranking. See Global Health Estimates 2016: Disease Burden by Cause, Age, Sex, By Country and by Region, 2000-2016 Dataset, Available from the WHO at: https://www.who.int/healthinfor/global_burden_disease/estimates/en/index1.html

[42] https://www.mckinsey.com/~/media/mckinsey/industries/pharmaceuticals%20and%20medical%20products/our%20insights/africa%20a%20continent%20of%20opportunity%20for%20pharma%20and%20patients/pmp%20africa%20a%20continent%20of%20opportunity%20for%20pharma.ashx

pharmaceutical investments on the continent, and whether one can extract lessons from past and current experiences of firms on the continent (discussed in the previous section) and ongoing policy efforts in Africa and elsewhere. This section tackles these questions. It begins with juxtaposing the risks identified in the previous section with what kinds of production are ongoing and feasible. It then moves on to extracting lessons from current examples, and then finally suggests some of the best practices from current experiences.

6.2 Overview of Pharmaceutical Manufacturing Opportunities in Africa

6.2.1 Why Local Pharmaceutical Manufacturing is Desirable

The inherent desirability of promoting local pharmaceutical production has been debated by many scholars, practitioners and policy experts. The potential benefits of local pharmaceutical manufacturing, however, are numerous:

- Increased supply of critical treatments
- Enhanced national security/ decreased risk of supply interruption
- Rapid response to local epidemics and decreased likelihood of supply interruptions
- Earlier introduction of medicines that would not otherwise be available
- Convenience of regulatory oversight
- Improved quality and reduced instances of fake, counterfeit, and substandard medicines
- Competition on pricing from the presence of multiple suppliers
- Retention of highly skilled/trained workforce and creation of well-paid jobs (Human Capital Development)
- Economic development
- Reduction in outflow and potential increase in availability of hard currency through exportation

These benefits are all the more appealing against the sobering reality of supply outages for various healthcare products that have occurred in essentially every country in the world resulting from the SARS CoV-2 pandemic. In the least, this helps to reposition the debate, moving it from simply the desirability of local pharmaceutical manufacturing in Africa, to the necessity to consider local pharmaceutical manufacturing in Africa. The authors of this report are supportive of efforts to increase African production of pharmaceuticals.

6.2.2 Scope of Pharmaceutical Manufacturing

The health needs of the SARS CoV-2 pandemic include vaccines, diagnostics, PPE, and antiviral treatments (Diagnostics, Vaccines, Treatments; DVT). Each of these requires different technology platforms for production. The investment capital, timeline, market building activities, supply chain, and requirements for regulatory approval also differ for each. These are briefly outlined as

a background for understanding the differences in financial support structures and amount/timeframe of capital support required.

African countries are not all capable of manufacturing a comprehensive range of pharmaceutical products. South Africa and Morocco are already relative success stories in this regard. Botswana, Egypt, Ethiopia, Kenya, Nigeria, Tunisia, and Uganda are also countries that have various programs to promote pharma manufacturing. An important factor for success of national pharmaceutical production in Africa is the ability to export, growing revenues by achieving a regional or pan-African presence.

The Plan of Action for pharmaceutical manufacturing development in Ethiopia (2015-2015) is noteworthy for clearly illustrating the "Pharmaceutical Value Chain"[43]. Most African pharmaceutical companies operate in Level 1 or 2 of the value chain, importing medicines and possibly performing packaging and labeling before distribution. These functions contribute relatively little value to the product, though they are necessary elements of the Supply Chain. Finished product manufacturing (Level 3) is practiced by a relatively small but very important number of African companies. When African countries announce targets for increasing the percentage of local pharmaceutical manufacturing, they generally refer to operations at Level 3 in the Value Chain.

API manufacturing (Level 4) is predominately carried out globally in India and China. This involves chemical bond breaking and forming to create more complex molecules from readily available fine chemical starting materials (chemical synthesis) or fermentation. API production also includes cultivation/extraction of natural products. This is a very high value-added component of the chain. Aside from two companies in South Africa, Pharco Pharmaceuticals (Egypt) is the only company that is practicing routine commercial production of APIs in Africa[44], and this is for the API sofosbuvir only.

Research and development (Level 5) is where originator pharmaceutical companies generate huge value by patenting novel therapeutic treatments. Only a very few examples of new drugs coming to the market from Africa are known. One of these (NIPRISAN) at NIPRD and XeChem in Nigeria is based in "reverse pharmacology".[45] Pharco (Egypt) has been intimately involved in the development of the direct-acting antiviral drug ravidasvir for Hepatitis C treatment.

[43] NATIONAL STRATEGY AND PLAN OF ACTION FOR PHARMACEUTICAL MANUFACTURING DEVELOPMENT IN ETHIOPIA (2015-2015). https://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf?ua=1
[44] Pharco Pharmaceutical at: https://www.pharco.org/
[45] Charles O Wambebe et. al., EFFICACY OF NIPRISAN IN THE PROPHYLACTIC MANAGEMENT OF PATIENTS WITH SICKLE CELL DISEASE (2001). Current Therapeutic Research, 62(1), 26-34.

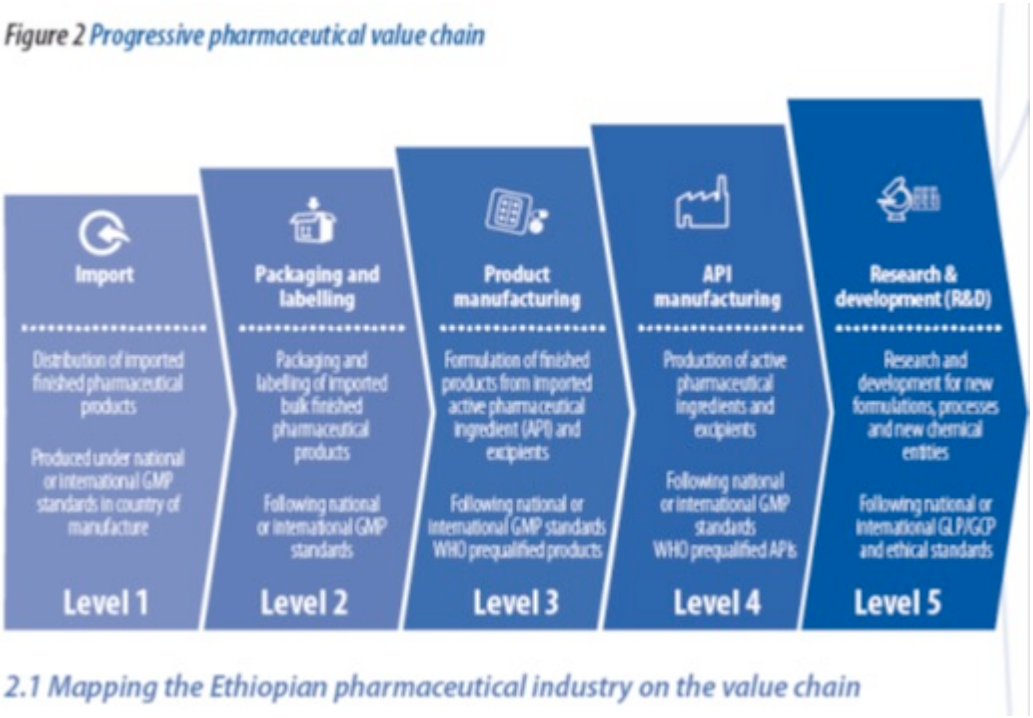

Figure 4. The pharmaceutical manufacturing value chain

6.3 Manufacturing of SARS CoV-2 Related Healthcare Products

Vaccines will be an important tool in ending the Covid-19 pandemic. Several vaccines have been approved by various countries for preventing infection, including two revolutionary new mRNA vaccines (developed by Pfizer and Moderna), two vaccines produced in China (developed by Sinovac and Sinopharm), and another in Russia. A vaccine from Oxford/AstraZeneca that will be manufactured by the Serum Institute of India is nearing approval.

Personal Protective Equipment (PPE) is needed for all routine hospital and clinical operations, but Covid-19 prevention efforts drastically increase the need for use of PPE, even in routine daily use. PPE includes masks, shields, hair covering, gowns, gloves, overalls, shoe covering, sanitizers, deep cleaning solutions, and even air purifiers.

Diagnostics for the SARS CoV-2 virus are incredibly important in detecting and limiting the spread of infections. Diagnostics may be divided into two major types. Point-of-care test kits contain both sampling and diagnostic test materials that allow for the rapid determination of infection. Laboratory tests are more precise, allow the determination of various types of antigens, and can provide measurement of viral load. But these tests are more expensive and take much longer time to return results.

Therapeutics for Covid-19 include the use of steroidal anti-inflammatory agents such as dexamethasone, as well as antivirals (remdesivir), and biologics (baricitinib). No therapeutics other than vaccines are presently approved for prevention of infection either as purely precautionary for those at risk or for those who are known to have been recently exposed to the virus.

The pandemic has created shortages and supply interruptions, moreover, for many other medicines in nearly every country in the world. Lockdowns and restrictions in supply chains have caused at least 200 drugs to be in short supply, particularly those for acute (hospital or surgical) use. These include short-acting anesthetics, analgesics, neuromuscular blockers, and anti-inflammatory drugs. Thus, the Covid-19 pandemic has highlighted a need for nearly every country in the world to seek ways to enhance national security and access to essential medicines.

6.3.1 Vaccines Manufacturing

Vaccines are especially important to public health programs. Governments and donors have historically invested in vaccines production in low-resource settings[46]. Implementing production of vaccines requires addressing several challenges. The strategies for vaccines production in an African setting and business planning for implementation have been discussed[47].

A representative manufacturing process for vaccines is shown in Figure 5[48]. To emphasize, these steps are solely associated with establishing a reliable manufacturing process for vaccines. Thus, the process outlined maps directly against the activities required for local production – no investment or effort is required in discovery, development, or clinical trials. Biological processes require assurance of sterility at each phase of operations. This is more complex than producing small-molecule therapeutics for oral or even injectable use. Thus, the cost of quality control operations in vaccines production is quite high[49].

Africa has limited capacity for vaccines production. Tunisia, Senegal, Egypt, Ethiopia, and South Africa have varying capabilities to produce and fill/finish vaccines. The African Vaccine Manufacturers Initiative (AVMI) is promoting technology transfer and expansion of capacity for

[46] PM Danzon, S Nicholson, THE OXFORD HANDBOOK OF THE ECONOMICS OF THE PHARMACEUTICAL INDUSTRY. Oxford University Press (2012); p. 537.
[47] Geoffrey Makenga et. al., (2019), VACCINE PRODUCTION IN AFRICA: A FEASIBLE BUSINESS MODEL FOR CAPACITY BUILDING AND SUSTAINABLE NEW VACCINE INTRODUCTION. Frontiers in Public Health, 7(56), doi: 10.3389/fpubh.2019.00056.
[48] Sanofi "Understanding the complexity of vaccine manufacturing"
[49] Stanley Plotkin, et. al., (2017). THE COMPLEXITY AND COST OF VACCINE MANUFACTURING – AN OVERVIEW. Vaccine, Jul 24;35(33):4064-4071. doi: 10.1016/j.vaccine.2017.06.003. Epub 2017 Jun 21.

vaccines production in Africa. The lead times for building and startup of vaccine manufacturing, however, are usually projected as 7-10 years [50].

The mRNA vaccines approved for Covid-19 (Pfizer and Moderna) are beyond the capability of African companies at this time. It must be mentioned in the context however that no one in the world was manufacturing an mRNA in March of 2019! As a practical observation, the vaccines being developed by Oxford/AstraZeneca, and Chinese and Indian companies originate from more traditional production platforms. These are much more likely to be amenable to manufacturing in Africa. The Indonesian Government has already announced a partnership with Sinovac to perform end-stage manufacturing of a Covid-19 vaccine for distribution within Indonesia and to other countries[51].

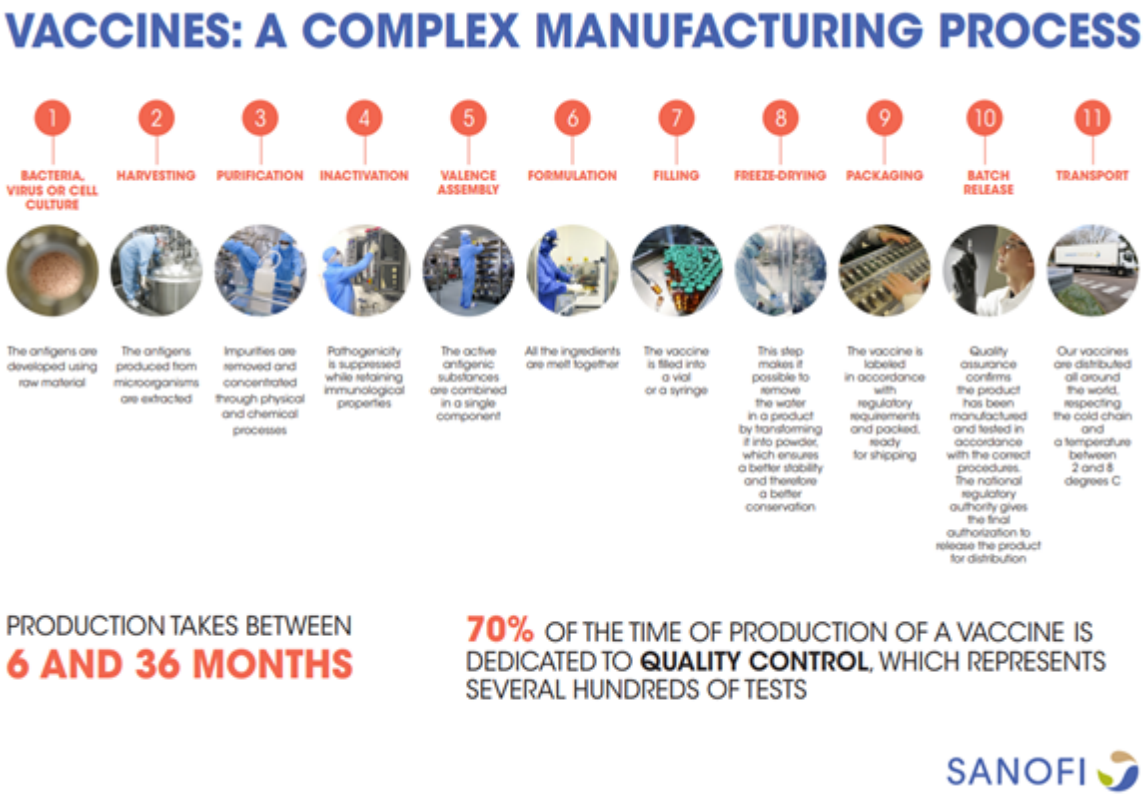

Figure 5. Process flow diagram for vaccines production (Sanofi).

[50] William Ampofo, (2016). VACCINE MANUFACTURING IN AFRICA: https://www.who.int/immunization/research/forums_and_initiatives/1_Wlliam_Ampofo_Vaccine_Manufacturing_Africa.pdf?ua=1

[51] SCMP News China (2020): https://www.scmp.com/news/china/science/article/3116707/mass-sinovac-vaccination-programme-set-begin-indonesia-followed

The Biovac case study (see Section 7.2) elucidates the investment and lead times required to develop vaccines production in a South African experience. The reason this venture has so far been sustainable is that a Public-Private Partnership with sustained Government support has allowed the company to operate with the required investment and pricing with guaranteed public sector procurement. This has allowed BioVac over 18 years to reach the cusp of becoming a fully sustainable enterprise.

6.3.2 Personal Protective Equipment

Manufacturing Personal Protective Equipment – including hand sanitizers, gloves, masks, gowns, and other protective medical clothing – is the least technologically demanding area for SARS CoV-2 healthcare needs. This is also an area where local manufacturing is currently or potentially capable of supplying national needs for some countries. Multiple other factors including comparatively low capital investment required to operate in this space are also promising for local production to meet African needs.

Demonstrably, some capacity exists, and firms are interested in entering the PPE space as judged by the numbers of registered producers vs. the same period of 2019.[52] As an indication of the number of suppliers for COVID-19 related PPE, Reuters reported in July 2020 that 102 producers of PPE in Gauteng Province (RSA) alone were being audited for performance against Government contracts issued to provide pandemic-related PPE[53].

The picture for production of PPE in other African countries, however, indicates that existing capacity is inadequate. Dr. John Nkenasong, Director of the African CDC estimated that Africa overall imports 95% of its PPE requirements[54]. The challenges to local PPE production include establishing/adopting uniform international standards and testing capacity, quality assurance, and regulatory capacity for product approvals.

Countries with an existing textiles industry are potentially capable of establishing significant local PPE production by increasing the capabilities of existing companies. Hawassa Industrial Park in Ethiopia has 12 companies in various stages of regulatory approval to supply PPE for both national needs and export.[55] The Industrial Park has been a center of textiles production for some

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[52] https://www.tralac.org/blog/article/14956-south-africa-s-ppe-shortage-what-can-we-learn.html

[53] https://www.reuters.com/article/us-health-coronavirus-safrica-corruption/south-africa-probes-medical-suppliers -over-covid-19-tender-allegations-idUKKCN24V2VX?edition-redirect=u

[54] Africa task force for Coronavirus Response (AFTCOR) virtual workshop to publicize and promote manufacturing of PPE in Africa (2019): https://africacdc.org/news-item/workshop-on-promoting-manufacturing-of-personal-protective-equipment-in-africa/

[55] Hawassa Industrial Park Gears Up to Export Masks, Bio Suits: https://addisfortune.news/hawassa-industrial-park-gears-up-to-export-masks-bio-suits/

time, with 22 companies primarily in textiles production at the site. The Government of Ethiopia has established a national commission to assist companies in transitioning from traditional textiles manufacturing to additional production of PPE suitable for healthcare use.[56] Transgreen Nigeria, Ltd., is the country's first certified producer of medical face masks. Transgreen reports it has received orders for its masks from the USA and countries in West Africa including Ghana, Sierra Leone, and Côte d'Ivoire.[57]

PPE is likely the most promising sub-market of Covid-19 related healthcare products for rapid local production meeting international standards of quality. The WHO has published a report on supply chains, bottlenecks, and policy implications for addressing the global shortage of PPE resulting from the pandemic.[58] UNIDO has published a Roadmap for developing/improving PPE production in Egypt.[59] That report identifies six pillars for developing PPE production in-country:

- Raising public awareness of the importance of PPE;
- Investing in spun-melt technology (for fibers production);
- Strengthening audit and regulatory bodies;
- Providing business development services to the PPE sector;
- Increasing PPE supply by building Public-Private partnerships;
- Repurposing manufacturing facilities as a temporary measure to produce PPE.

These points are informative to consideration of the role of finance in supporting the expansion of PPE manufacturing internally for African countries. Several factors appear to be favorable for the local production of PPE:

- Low capital investment for manufacturing;
- Widespread availability and relatively low complexity of technology;
- Local availability of raw materials in many countries;
- Modest timeframes for production startup;
- Relatively moderate regulatory requirements for registration/approval.

On balance, PPE appears to be an attractive area for local manufacturing to enter the markets in Africa. The amounts of capital required for market entry are such that government investment and conventional sources of capital for business startups in specific countries can be leveraged

[56] https://www.investethiopia.gov.et/index.php/covid-19/support-for-ppe-manufacturing.htm
[57] https://nipc.gov.ng/2020/09/02/medical-facemask-maker-transgreen-to-expand-operations/
[58] Global shortage of personal protective equipment amid COVID-19: Supply chains, bottlenecks, and policy implications. https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf.8
[59] https;//www.unido.org/news/unido-launching-roadmap-developing-ppe-production-egypt

to provide a significant fraction of the capital required for converting more traditional clothing industries to the production of PPE.

6.3.3 Diagnostics

Diagnostic tests for SARS CoV-2 are of two different types. Viral tests will detect whether a person is infected with the virus. A sample of nasal or oral swab, or saliva is tested for the presence of SARS CoV-2 or nucleic acid or antigen. Viral tests are used to detect acute infection (symptomatic or asymptomatic). Test results are also used to guide contact tracing, isolation requirements, and treatment options. Some samples must be analyzed in a laboratory setting and require 1-3 days to obtain results. Other tests are point-of-care (POC) with results available within as little as an hour or less. POC tests generally are lateral-flow tests that detect antibodies. Laboratory tests are generally ELISA assays or chemiluminescent immunoassays.

Antibody tests will show the presence of serological antibodies against the virus, thus indicating whether a person has been infected in the past (or indeed the present). Antibody tests do not however provide a clear-cut indication of active infection. A positive antibody test merely indicates that an individual has been exposed to the virus and has generated antibodies against it. Antibodies will also be generated against the virus after vaccination. Thus, as more people receive Covid-19 vaccines, the results from such testing will be more of an indicator of widespread immunity in the population than indicators of exposure to the virus as at present. Several other types of tests including surrogate virus neutralization testing (sVNT) and neutralizing antibody detection techniques are in development for SARS CoV-2 testing.

The exposure of an individual to the SARS-CoV-2 virus causes the production of both IgG and IgM antibodies within 2-3 weeks of the appearance of significant viral load. Several serological assays for SARS CoV-2 have been approved for use – often on an emergency basis only - by NDRAs. Antibody tests for the virus variously measure IgG, IgM and IgG, or total antibody counts. The required antibody levels to confer immunity and the duration of an effective antibody response are presently unknown, as insufficient data is available to answer these questions.

The WHO has issued interim testing guidance for laboratory testing, molecular assays, and reference laboratories for confirmatory testing for COVID-19.[60] WHO has also issued advice on the use of POC immunodiagnostic tests for COVID-19.[61]

The necessary guidance is in place for African countries to follow WHO advice in establishing procedures and administering large-scale testing for the SARS-CoV-2 virus. One of the bigger

[60] https://www.who.int/publications/i/item/10665-331501

[61] https://www.who.int/news-room/commentaries

problems in this crowded field, however, is the huge number of tests available for various, slightly different types of testing. As of February 2021, over 70 testing procedures and kits are approved by various National Drug Regulatory Agencies throughout the world. The tests used to detect the virus have some incidence of both false positive and false negative results. Each assay also requires both a means of sampling as well as some form of platform to assay the sample. Each of these tests is also protected by Intellectual Property. Although many African countries are not obliged to observe TRIPS regulations regarding pharmaceutical patents, the ability of most countries to manufacture diagnostics is critically dependent upon the availability of technology transfer. The standardization of testing and arriving at one or a limited number of test providers is further needed to arrive at a common basis for effective, efficient testing.

When technology is available, the production of diagnostic kits for testing is often a relatively uncomplicated matter. GMP is required for production as well as process validation and NDRA registration and approvals. But the capital investment required for diagnostic production is most often much less than for producing medicinal FDFs and certainly vaccines. The availability of reagents to manufacture testing kits can be limiting to production. International efforts to promote diagnostics production in Africa are in progress.[62] (African countries are familiar with testing for HIV, TB, and malaria and WHO Prequalified testing labs are a priority in many countries. Planning is underway to produce diagnostic kits in Kenya, Morocco, Senegal, and South Africa. The Africa CDC has a Partnership to Accelerate Covid-19 Testing (PACT) consortium. The lack of reagents and standardization of test kits, however, remain as serious bottlenecks to success.

Diagnostics and widespread testing are an Achilles Heel without which any African efforts to contain COVID-19 cannot succeed. Technology acquisition and transfer are essential to produce test reagents and kits locally. The investment required to implement diagnostic production for such kits is in the single-digit millions of USD. The margin on these tests cannot be large, but the volume of testing performed will be very high. Laboratories that are fundamentally capable of analyzing the results of testing are dotted across the continent. Investment is needed to implement local capabilities for the manufacture of diagnostics for COVID-19 in Africa. And meeting this need is critical to controlling the pandemic.

6.3.4 Therapeutics

Multiple biologic treatments have been granted Emergency Use Authorization for Covid-19 (tocilizumab; bamlanivimab; casirivimab + imdevimab) for the treatment of Covid-19. These biologics are all patented treatments. Even with licenses and technology transfer, it would be several years and likely hundreds of millions USD of investment before African manufacturing of these agents could effectively meet a significant market demand. These treatments also tend to

[62] John Nkengasong, (2020). LET AFRICA INTO THE MARKET FOR COVID-19 DIAGNOSTICS. https://www.nature.com/articles/d41586-020-01265-0.

be much more expensive than small-molecule therapeutics. Although there is a great reduction in manufacturing cost between originator and biosimilar drugs, these treatments are still not going to be affordable for most patients without mass treatment programs with public funding.

Small molecule treatments for Covid-19 include the anti-inflammatory drugs dexamethasone and methylprednisolone, and the antiviral remdesivir. These drugs could reasonably be formulated (Level 3 of the Value Chain; Figure 3) in Africa. The steroid APIs dexamethasone and methylprednisolone are available in the international market. Production of Key Starting Materials for these APIs is carried out only in China. Several countries purchase these KSMs and manufacture the corresponding APIs. The funding of fermentation process development to turn lanosterol and sitosterol (from soybeans) into oxymesterone (and then to fluoxymesterone) for steroid APIs (Level 4) production is potentially attainable and would offer the global pharma markets an alternative to sourcing these KSMs from China. The Chinese fine chemicals industry might plausibly be willing to transfer this technology to African companies as a collaborative venture.

Remdesivir is licensed by Gilead Sciences to several companies in India and Pakistan for production and sales to low- and middle-income countries[63]. Remdesivir is a moderately complex API to synthesize, it is unlikely that any African company would readily take on the synthesis of several steps in the API production process. Remdesivir is also a complicated formulation (citation needed)[64]. The API is formulated with an equivalent weight of beta-cyclodextrin in a sterile, lyophilized vial. The capabilities for producing these types of FDFs in Africa (Level 3 production) is limited, but countries in North Africa, as well as Botswana, Uganda, and Nigeria in addition to South Africa possess the technologies for this.

The Covid-19 pandemic has revealed a substantial gap in nearly all countries of the world. Generic medicines are almost entirely formulated (Level 3 production) with APIs (Level 4 production) manufactured in India and China. India moreover relies upon KSMs or APIs from China for nearly 70% of its own Level 4 production. For instance, China produces nearly 100% of the world's supply of 6-aminopenicillinic acid. This is the KSM for all beta-lactam antibiotics (penicillin and cephalosporin drugs). China produces all of the world's supply of erythromycin by fermentation. This is both an API and a KSM for production of azithromycin and telithromycin. China produces 100% of the world's supply of paracetamol/acetaminophen API (over 120,000MT/A). China similarly produces over 95% of the world's Vitamin C and many other APIs for drug, veterinary, and vitamin use.

[63] Voluntary Licensing Agreements for Remdesivir: https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir

[64] https://www.uptodate.com/contents/remdesivir-drug-information#:~:text=Note%3A%20The%20remdesivir%20formulations%20contain,g%20per%20100%20mg%20remdesivir.

Many FDFs were in short supply or out-of-stock throughout the world when the supply chains for pharmaceutical production were interrupted in March-May 2020 by the pandemic. Over 200 drugs had supply interrupted in the US alone. Acute care drugs such as midazolam, cis-atracurium, rocuronium, and dexamethasone(!) went out of stock in many places. An opportunity thus exists for African producers – if they are capable – of positioning themselves as a collaborative alternative to China to supply the rest of the world as well as Africa.

6.4 Formulating Policy and Supporting African Pharmaceutical Production

To begin capitalizing on these issues, at least in parts, it is necessary to recall that Africa is a continent, not a country. The African Union comprises 54 Sovereign States and eight Regional Economic Communities. Product registration/approvals, distribution, and marketing to different segments of the African market is complex and expensive. Considering just the differences in packaging and labeling required for distribution of a single medicine across the broad range of African countries is daunting from the perspective of a producer.

The African Union has been a consistent promoter of local production of medicines. The Pharmaceutical Manufacturing Plan for Africa (PMPA) was published by the African Union Commission in 2006, with a series of recommendations to promote local pharmaceutical manufacturing in the subsequent Business Plan for the PMPA in in 2007. The regional harmonization of medicines regulation and other wide-ranging efforts through the African Union Development Agency - New Partnership for African Development (AUDA NEPAD) have more recently realized startling successes in building a framework for free trade and cross-border markets. As of today, these successes hold great promise for promoting success in building pan-African pharmaceutical markets. At present this is however only an emerging reality.

Individual country governments in Africa also provide incentives for national pharmaceutical production. Notable efforts include initiation of a Pharmaceutical City within the Suez Canal Economic Zone in Egypt. The Government of Egypt has offered substantial non-cash incentives to Indian producers of Active Pharmaceutical Ingredients to start up API manufacturing in Egypt. With an emerging capability in Finished Dose Forms (FDFs), Egypt has prioritized APIs as critical to boosting local production[65]. Ethiopia is completing the Kilinto Industrial Park near Addis Ababa in partnership with the Chinese firm Tiesiju Civil Engineering Group with an investment of $204M financed by the World Bank[66]. Morocco has a continuing history of local production that predates the introduction of Good Manufacturing Practice regulations in the 1990s that caused most African Pharma companies to cease production. With healthcare expenditures of $6.15Bn in 2017 and a national health insurance program that seeks to cover over over 80% of the population in

[65] https://www.thehindubusinessline.com/news/science/suez-canal-economic-zone-woos-indian-drug-makers-with-incentives/article33348356.ece#

[66] Xinhuanet 2020: http://www.xinhuanet.com/english/2019-05/27/c_138094691.htm

2021, Morocco forecasts a pharmaceutical market of $1.9Bn in 2021 [67]. Morocco also has the advantage of longstanding local production in partnerships with international pharmaceutical companies including Maphar, Cooper Maroc, and Sanofi Maroc.

But there is a need for much more support and coordination to promote technical knowledge of the kind needed for manufacturing. Non-Governmental Organizations (NGOs) have been significant promoters of technology and workforce development in Africa. The United Nations Industrial Development Organization (UNIDO) has been a staunch supporter of promoting local production for many years. One of us (JF) has benefited from the UNIDO-GiZ support for building a pilot plant for pharmaceutical production and training at the Kilimanjaro School of Pharmacy (TZ)[68]. UNIDO has joined together with UNAIDS and the WHO to promote South-South and BRICS collaborations to help build local pharmaceutical production[69]. The WHO Local Production Program has been particularly noteworthy in assisting countries with establishing normative standards, roadmaps, strategies, and partners for development. The US Pharmacopeia (USP) has focused on assisting partner countries in Africa to build regulatory frameworks and assure the quality of medicines in the PQM/PQM+ (Promoting the Quality of Medicines) programs. The PQM+ program is funded at $169M over 5 years[70].

These efforts, however, do not significantly address the need for direct financing for pharmaceutical production – i.e., the subject matter of this report. The African Union does not provide financial assistance to individual companies for capital or operating expenses. NGOs (notably including the Bill and Melinda Gates Foundation) and external government agencies (USAID, USP) most often have strict rules against providing financial support for "bricks-and-mortar" construction. Exceptions to this generalization include Public Private Partnerships. The Biovac PPP with the Government of South Africa for vaccines production is discussed in detail as a case study in this report (see Section 7.2). Another exception is the European Union award of approximately €40M to Tanzania Pharmaceuticals Industry (TPI) Ltd[71]. As evidenced by the TPI story (not discussed further in this study), not all PPPs are successful.

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[67] Pharmaworld Magazine (2018): https://www.pharmaworldmagazine.com/from-morocco-the-opportunities-for-the-pharmaceutical-industry/

[68] http://www.tzdpg.or.tz/fileadmin/documents/dpg_internal/dpg_working_groups_clusters/cluster_2/health/JAHSR_2019/MTR_HSSP_IV_Health_Commodities_Thematic_Report_.pdf

[69] Michel Sidibe, Li Yong, Margaret Chan,(2014). COMMODITIES FOR BETTER HEALTH IN AFRICA – TIME TO INVEST LOCALLY. Bulletin World Health Organization, 92:387-387a; doi: http://dx.doi.org/10.2471/BLT.14.140566

[70] https://www.usp.org/our-impact/promoting-quality-of-medicines

[71] Robert Mhamba, Shukrani Mbirigenda (2010). THE PHARMACEUTICAL INDUSTRY AND ACCESS TO ESSENTIAL MEDICINES IN TANZANIA. https://www.semanticscholar.org/paper/The-Pharmaceutical-Industry-and-Access-to-Essential-Mhamba-Mbirigenda/bd3e458f5892473ae9e5cfa21c2bc8233b3adb35

This brings us to a key lesson from local production on the continent, especially if firms are to diversify into new kinds of activities: Cost of capital is too high, as discussed in Section 4. But, financial lenders in Africa have also been slow to develop a common understanding with producers of the details of the business of pharmaceutical production and marketing. The case of LaGray chemicals illustrates ways in which the processes for financing need to be strictly monitored to assure that capital is made available in ways that encourage success.

6.5 Evidence Based Policy Recommendations

Making policy alone, therefore, will not be sufficient. In this section, we build on the information gathered in the questionnaires, and ongoing efforts in Africa and elsewhere, to pinpoint a number of best practices that should be applied to the African context. Our recommendations for consideration of financing and mechanisms are formulated to promote generic drug production, not R&D for drug discovery. Many countries have built strong generic industries at a range of scales (China, India, Bangladesh, Thailand, Morocco, Brazil...). But, forty years and more of sustainable production in China and India have not yet resulted in these countries bringing significant numbers of new drugs (Level 5 production) to the market.

We find that the public sector, financial institutions, and producers strongly benefit from a process of (non-medical) triage in which producers have inputs to defining and prioritizing how to address critical limitations. Several companies interviewed note that it is easy to secure a government promise for land and preferential tax rates. But ready access to foreign exchange is limiting for access to equipment, spare parts, APIs and other raw materials (e.g., glass vials, capsules, even finished packaging). Other notable limitations include improvement of land for access to transport, basic services (fire, security and sewage). Creating pools of finance that are readily accessible for producers to address the bottlenecks identified in **Section 5** is important to promote success.

6.5.1 Coordinate industrial development and infrastructure for the pharma sector

6.5.1.1 - Set targets for production and enact policy incentives that aim to promote the capacity of local firms

Setting and incentivizing national targets for production can help monitor outcomes. In India, for example, the Drug Policy of 1978 set out to increase the capacity of local firms to produce. The government offered Indian enterprises incentives to produce formulations up to 10 times the value of bulk drugs (thereby allowing them to produce a high proportion of non-basic drugs, although the emphasis in the national drug policy was on the production of APIs). Foreign firms were faced with tighter restrictions in formulations to create space for Indian companies, and also were made subject to the Foreign Exchange Regulation Act of 1973 which limited their control to 40% in Indian companies.

6.5.1.2 Provide a range of schemes that target industry infrastructure and promote investments

A number of policy initiatives – related to tax, subsidies, grants, industry facilities, export support - can all reduce the industrial and sector specific risks, thereby enabling local firms to function better. Table 2 below contains a list of policy initiatives by the Indian government that have been active since 1991, if not before, to highlight how such incentives can signal a continuous commitment to the growth of the sector.

Table 2. Schemes for pharma sector development: India[72]

Name of the Scheme	Year of Commencement	End Period of Scheme
Tax rebates: Development rebate under Section 33 for acquisition of new machinery/plant. Deduction for expenditure on scientific research under Section 35 of Income Tax Act, 1961.	1961	Still in force
Drugs and Pharmaceutical Research Programme:	1994	Still in force
Schemes by the Technology Development Board	1995	Still in force
Market Development Assistance Scheme: Assistance is provided to exporters for export promotion activities abroad by participation in EPC etc. led Trade Delegations/BSMs/Trade Fairs/ Exhibition by way of travel expenses by air and expenses on stall.[73]	2001	Still in force
Market Access Initiatives (MAI) Scheme: Under this scheme financial assistance is provided for Marketing Projects Abroad, capacity building, support for statutory compliances, conducting studies and project development. Individual exporters are eligible for support on several fronts.	2003	Still in force
Schemes by the National Biotechnology Department: The Department of Biotechnology has set up Biotechnology Industry Research Assistance Council ('BIRAC') to empower the emerging Biotech enterprises to undertake strategic research and innovation, addressing nationally relevant product development needs.[74] It provides assistance at various stages of product development including from the incubation to commercial launch of product[75].	2008	Still in force
Assistance to Pharmaceutical Industry for Common Facilities: To improve the infrastructural facilities, environmental compliance and improve waste management within a pharma manufacturing cluster, the scheme proposes to set up common facilities centre which will include Common Testing Centres, Training Centres, R&D Centres, Effluent Treatment Plants, Common Logistics Centres. Maximum limit for the grant	2014	Still in force

[72] See Report by Batra for this Study, Addenda.
[73] https://pharmexcil.com/v1/docs/MDA/MDA_April2006.pdf.
[74] https://www.birac.nic.in/desc_new.php?id=89.
[75] For a breakdown of the BIRAC schemes, see Batra, Report for this Study, Addenda.

Name of the Scheme	Year of Commencement	End Period of Scheme
in aid under this category would be Rs 20.00 crore per cluster or 70% of the cost of project whichever is less.		
Production Linked Incentive (PLI) Scheme: For the promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India	2020	2029-30
Scheme for Promotion of Bulk Drug Parks: The financial assistance under the Scheme will be provided for creation of common infrastructure facilities in three Bulk Drug Parks proposed by State Governments and selected under the scheme.	2020	2024-25
Remission of Duties and Taxes on Exported Products (RoDTEP): introduced as a replacement to the Merchandise Exports from India Scheme [Under the Foreign Trade Policy 2015-2020], to refund the embedded duties suffered in export goods. [76] The Merchandise Exports from India Scheme which had a 3% reward to pharmaceutical products exported to both category A and B countries.[77]	2021	Not mentioned

6.5.2 Use as many ways to 'create' markets as possible

In cases where domestic markets are small, there are many ways to create markets. A prominent mechanism is setting quotas for local producers in procurement processes, whereby governments can assure firms of the market demand for specific products. Another way to create markets is to close them partially or completely on select counts.

6.5.2.1 Quotas, or other requirements for procurement[78]

In many countries, enhanced use of quotas for local producers are being used, or requirements are being set out to guide procurement in favour of local firms. In Russia, as of 1 January 2017, local production of the finished dosage form made a prerequisite in order to qualify as a Russian manufacturer,[79] and several kinds of medical products/devices not originating from the Eurasian Economic Union were entirely banned from both state and municipal level procurements in Russia to promote local production.[80] The government has been, in parallel, encouraging foreign manufacturers to switch to full cycle production in country by providing a number of financial and other incentives to foreign producers.[81]

[76] https://fieo.org/uploads/files/file/Final%20Press%20Release%20RoDTEP_V1_4(1).pdf.
[77] See Appendix 3B, MEIS Schedule Table 2,ITC (HS) code wise list of products with reward rates under Merchandise Exports from India Scheme (MEIS) available at http://dgftcom.nic.in/Exim/2000/PN/PN15/pn0215.pdf, P 78-85.
[78] Padmashree Gehl Sampath, Trade and Non-Trade Barriers and Their Impact on Access to Medicines, National Law School of India Review, June 2021 (forthcoming).
[79] Regulation of the Russian Government No.719 dated 17 July 2015.
[80] Resolution of the Russian Government No.102 dated 5 February 2015.
[81] Federal program for development of pharmaceutical and medical industry for the period until 2020 and subsequently - approved by Regulation of the Russian Government No.91 dated 17 February 2011.

6.5.2.2 Restrict certain categories of drug production to local producers

In the Bangladesh pharmaceutical sector, for example, the national policy explicitly reserves the national market for local firms in product categories where they have the competencies. Imports are allowed only in those categories where local products are unavailable (Gehl Sampath, 2019; Azim, 2018). Countries that have mandated the discontinuation of importation of critical medicines, when proof is evidenced that national suppliers are able to fulfil country demand include Morocco.

6.5.3 Target the promotion of pharmaceutical financing

There are a number of ways in which the government can directly and indirectly offer financing. In indirect schemes, the government can act as an intermediary, facilitating loans from private banks under specific conditions. Examples of policy initiatives are discussed below.

6.5.3.1 Offer direct governmental financing

Some African countries are now beginning to offer such programs. In Nigeria, on March 25, 2020, the Central Bank of Nigeria (the "CBN") issued a circular to Deposit Money Banks ("DMBs"), and the public, announcing a 10-year scheme for credit support for "indigenous" pharmaceutical companies, and health care value chain players for the purpose of strengthening the sector's capacity to meet potential increase in demand for healthcare products and services. Although the word "indigenous" is not defined in the Guidelines, the introduction notes that *the scheme is to provide credit to indigenous pharmaceutical companies and other healthcare value chain players intending to build or expand capacity*; and Section 2.3 notes the objective of the Scheme to *to improve access to affordable credit by indigenous pharmaceutical companies to expand their operations and comply with the WHO GMP* (emphasis added).

6.5.3.2 Focus financing specifically on small and medium sized firms

All kinds of firms matter, and the Indian policy framework offers interesting insights on schemes particularly offered to small scale firms in India, given that they face additional hurdles in accessing finances from banks and other agencies. Two important ones, which could be replicated in African countries include:

(a) The Pharmaceutical Technology Upgradation Assistance Scheme[82] is intended for Small and Medium Pharma Enterprises (SMEs) so that they may be able to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards. The government offers assistance is in the form of interest subvention against sanctioned loans

[82] https://pharmaceuticals.gov.in/sites/default/files/Pharmaceutical%20Technology%20Upgradation%20Assistance%20Scheme%20%28PTUAS%29.pdf.

by any scheduled commercial bank/financial institution both in Public and Private sector will be provided to 250 pharma SMEs of proven track records. [83]

b) The Small Business Innovation Research Initiative (SBIRI): SBIRI provides early-stage funding for high-risk innovative research in small and medium companies led by innovators with science backgrounds to get them involved in development of products and processes which have high societal relevance.[84] The assistance to a start-up will be up to INR 7 crores (approximately US$100,000) against equity.[85]

6.6 Enact Multiple Policy Incentives Offering More Detailed Support

Offering more detailed policies to interpret and implement certain policy mandates really help the pharmaceutical production process to become competitive. Such policy layering can comprise of policies that target related upstream or downstream sectors, or specific kinds of firms.

6.6.1 Focus on related industries

Many sectors link directly and indirectly to the pharmaceutical sector. These help structure supply chains and promote innovation. Biotechnology is one such upstream sector, but a number of downstream sectors – such as for packaging, capsule creation, exist. Ethiopia, for instance, has successfully created backward linkages to hard shell capsule manufacturing in-country. Fostering these creates a better business environment for the pharmaceutical sector.

In Nigeria, the Central Bank of Nigeria Healthcare Research and Development Grant Guidelines[86] (as amended, September 2020)[87] (the "**HSRDIS Guidelines**") are, on similar lines, intended to "help strengthen the public healthcare system with financing of research and development in new and improved drugs, vaccines and diagnostics of infectious diseases in Nigeria". The focus of the HSRDIS is to develop a Nigerian vaccine, drugs, and herbal medicines/medical devices against the spread of COVID-19 and any other communicable or non-communicable diseases. To facilitate this objective, the HSRDIS is expected to make grants available to biotechnological and pharmaceutical companies, institutions, researchers, and research institutes, for the promotion of R&D with regards to drugs, herbal medicines/medical devices, and vaccines for the control, prevention, and treatment of infectious diseases.

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[83] *Also see* Annual Report, 2019-2020, Department of Pharmaceuticals available at https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf.
[84] https://www.birac.nic.in/desc_new.php?id=217
[85] *Id.*
[86] Available at https://www.cbn.gov.ng/Out/2020/CCD/Healthcare%20RnD%20intervention%20guidelines.pdf
[87] Amendments reflected here https://www.cbn.gov.ng/Out/2020/DFD/AMENDED%20HSRDIS%20GUIDELINE%20SEPTEMBER%202020.pdf

6.6.2 Focus on assuring markets

We have mentioned the need to assure a market for local producers. The smaller scale of revenues for African pharma makes producers risk averse. Most companies also cannot be successful without reliable sales into public procurement programs. Even the USA promotes generic production by granting limited monopoly (6-months) for first generic approvals, and supports US production by mandating that government agencies purchase medicines from US suppliers. Tariffs, preferential pricing, and limitations on imports are important public policy determinants of success. But finance to assure local demand requires less direct approaches.

7. Case Studies of Pharmaceutical Localization

7.1 Scope

Two case studies have been undertaken in this phase of the OSF project. Both studies are based on detailed research already published, and then updated using interviews and more recent secondary data (such as company reports and public documents).

In the first study, the development and implementation of the Biovac has been covered. Biovac is the only successful human vaccine manufacturer currently operating in Africa. Established in 2002 as a public-private partnership covering vaccine research and development, manufacturing and supply, the Biovac Institute has grown from an initial base of 24 staff and a revenue of R188 million to an organization of 314 people and an annual revenue of R2.4 billion (2019) (Makhoana, 2020; Walwyn and Nkolele, 2018b). The case study has investigated how funding has been raised for the entity and to what extent the PPP has hindered or assisted access to finance.

In the second study, the project initiative known as Ketlaphela has been covered. Ketlaphela was developed to manufacture antiretroviral (ARV) active pharmaceutical ingredients (APIs) in South Africa, but failed to raise finance or secure government support. As a result, the initiative has never materialized into a manufacturing facility (Tomlinson, 2020). Although the company is still operating as a 100% subsidiary of Pelchem, it has an insignificant revenue (< $10,000) and has never traded as a pharmaceutical company.

The main research question in both case studies is how finance was (or was not accessed) and the factors that determined what type of finance was used. A number of sub-questions were also explored, including the theory of change in terms of access to medicines and local DVT production, the overall structure of the financial sector, the perception of financial risk, and how this risk could be changed with advocacy and policy intervention.

7.2 Biovac

7.2.1 Introduction

Biovac is a vaccines company based in Cape Town, which was established in 2003 as a public-private partnership (PPP) between the Government of South Africa and the Biovac Consortium (Walwyn and Nkolele, 2018b). The latter is a 100% private local entity which holds a controlling share in Biovac (52.5%), with the remainder allocated to the Department of Science and Innovation (35%) and the Technology Innovation Agency (12.5%). The agency is 100% owned by the department and is a Schumpeterian development agency (see Figure 6).

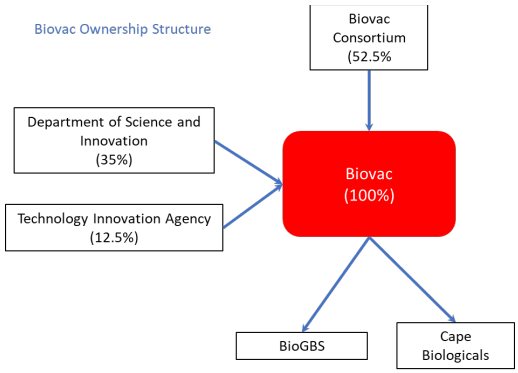


Figure 6. Ownership structure for Biovac

Although the ownership structure contributed to Biovac's survival within South Africa's public health system, it was the long-term arrangement under the PPP's Supply Agreement which led to the entity's sustainability. The agreement appointed Biovac as the sole supplier of all public sector vaccines, and, in exchange for the procurement and distribution services, permitted it to charge the various provincial health departments a price premium of 10% to 20% in addition to the purchase cost of the vaccines (Walwyn and Nkolele, 2018a; Frost & Sullivan, 2016).

The premium was used to raise the required capital for the construction of the vaccine manufacturing and distribution infrastructure and the partial realisation of a world class local vaccine manufacturer. Such an arrangement is best described, within the World Bank typology of PPPs, as a private ownership/public finance initiative in which the private partner owned a controlling share of the assets but secured investment funding from public entities.

The Supply Agreement was one of four contracts which formed the basis of the PPP, with the others being the Shareholders Agreement, the Subscription Agreement and the Strategic Equity Partner Undertakings. The agreements initially covered the period 2004 to 2010 but were subsequently renewed to June 2020. The obligations of the PPP in terms of developing local vaccine manufacturing and distribution, and the participation of other partners, were clearly specified in the agreement on the Strategic Equity Partner Undertakings, which included, among other aspects, the requirement to "establish a strong research and development (R&D) capability focused on the development of locally relevant vaccines" and the "ensuring a domestic capacity in vaccine production which will enable the South African health authorities to respond to disease outbreak emergencies" (Walwyn and Nkolele, 2018a).

7.2.2 Expansion of Biovac under the Public-Private Partnership

Since the formation of the PPP, Biovac has grown substantially in terms of revenue, number of employees and capital assets, as shown in Figure 7 and Figure 8. Originally a sub-department of

the National Department of Health with 30 employees, a revenue of less than R50 million and an antiquated infrastructure, it is now an independent entity with over 300 employees, a revenue of R2.4 billion and a comprehensive array of new facilities including aseptic facilities for the formulation and filling of vaccine doses into vials and syringes.

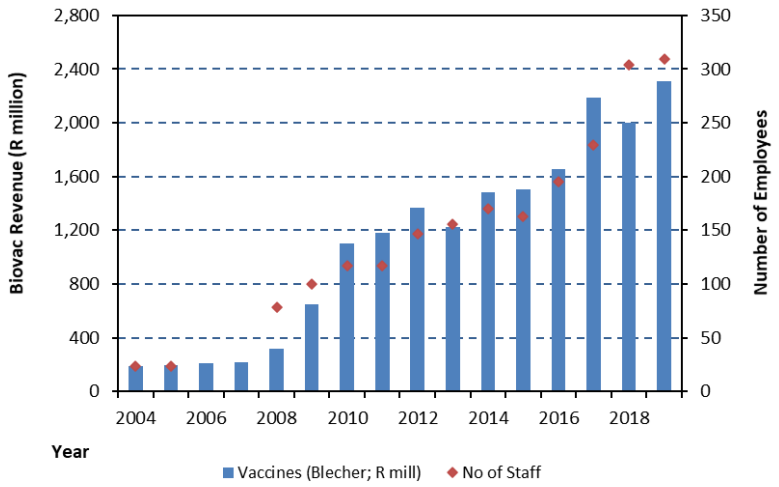


Figure 7. Growth in Biovac's revenue and number of employees

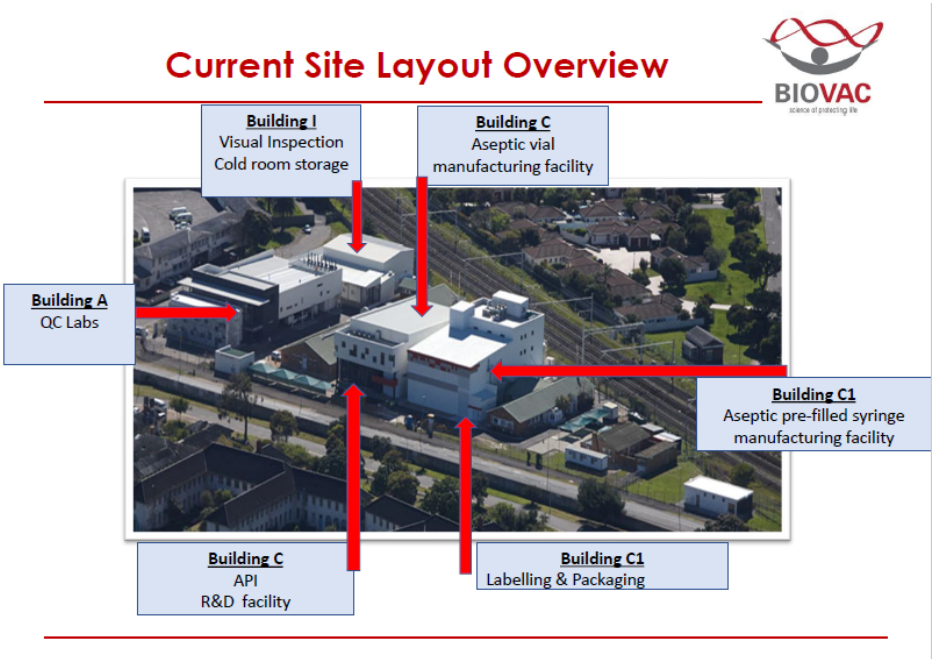


Figure 8. New facilities on the Biovac site since 2003

One of the core requirements within the Shareholders Agreement was the establishment of local manufacturing capability. Despite the commissioning of the necessary plant and equipment for this task and the existence of a number of technology transfer agreements with international companies, Biovac has not yet produced commercial quantities of filled vaccine for the local or international market (Makhoana, 2020). Its strategy has been to follow a reverse integration path, with the initial stages of the PPP being used to build the infrastructure and the team, focus on packaging and labelling, pursue technology transfer arrangements with Sanofi (for dose formulation and filling of vials from bulk antigen) and Pfizer (for dose formulation and filling of syringes from bulk antigen), and finally undertake the manufacture of bacterial vaccines based on in-house technology (Tomlinson, 2021).

7.2.3 Present Status

As of December 2020, the technology transfers with Sanofi (for Hexaxim[88]) and Pfizer (for Prevnar 13[89]) have been completed and large-scale (700,000 doses) process-validation batches have been prepared. These batches are required in order to meet the requirements for final registration as a manufacturer with the South African Health Products Regulatory Authority (SAHPRA). SAHPRA approval for Hexaxim was granted in November 2020 and the product is now in full production at Biovac (further references are included in Appendix A.2).

The initial inspection by SAHPRA for Prevnar 13 has also been completed and approval is expected in October 2021 (there is typically a nine-month period between the inspection and final approval).

Technically, Biovac is already a supplier in the market for Hexaxim and the initial validation batches have been released to the National Department of Health. Six batches of vaccine have now been manufactured but bulk supply will only commence in March 2021 since there is a three-month delay between filling and distribution due to the quality control and testing requirements.

Biovac's total capacity on the vial filling line is about 10 million vials per annum, depending on the volume of the fill and the complexity of the process. The capacity of the line is 15 million vials on water, but this is rarely achieved with antigen. The number of doses depends on the number of doses per vial. South Africa's offtake for Hexaxim is 4 million doses per annum, all of which will be supplied by Biovac. This is the largest single market for the Sanofi product; in total, the licensor sells about 20 to 25 million doses per year globally. It is noted that Biovac is the only licensor for this product and that Sanofi has not previously undertaken any technology transfer projects.

[88]Hexaxim is a hexavalent vaccine consisting of diphtheria and tetanus toxoids, acellular pertussis (2-component), recombinant hepatitis B surface antigen, inactivated poliomyelitis virus and Haemophilus influenzae type b polysaccharide conjugated to tetanus protein.
[89] Prevnar 13 is a pneumococcal conjugate vaccine.

The Sanofi hexavalent vaccine uses acellular pertussis, which is an advance on the whole cell pertussis product. The latter is still the basis of the GAVI product, which means that at this stage there is no international market, but it is anticipated that the market will emerge as countries opt for the acellular version (the latter does not induce the same allergic reaction in the vaccinee).

On the syringe filling line, Biovac has a total capacity of 10 million syringes (doses) per year. The Pfizer product, which will commence in November 2021, involves the manufacture of 3 million doses per year, all for the local market. There will be some spare capacity on this line for additional products.

Biovac still intends to be a "world class manufacturer of at least 100m doses per annum for local/international markets by 2030". It has built supplier relations with many global companies including Sanofi, Pfizer, Heber, Biofarma, Bharat Biotech, Biofarma, Serum Institute of India and Incepta. It exports into the region (Swaziland, Namibia, Mozambique and Botswana) and has an effective cold chain handling and distribution system.

Larger product volumes will only be possible if the company grows its export market, particularly through GAVI, but this will not be achievable with licensed product since GAVI markets are mostly supplied by the originator (licensor). Biovac is working on the development of its own products and intends at some stage in the future to start the manufacture of bulk antigen (through fermentation) based on in-house intellectual property.

7.2.4 Financing Biovac's Growth and Development

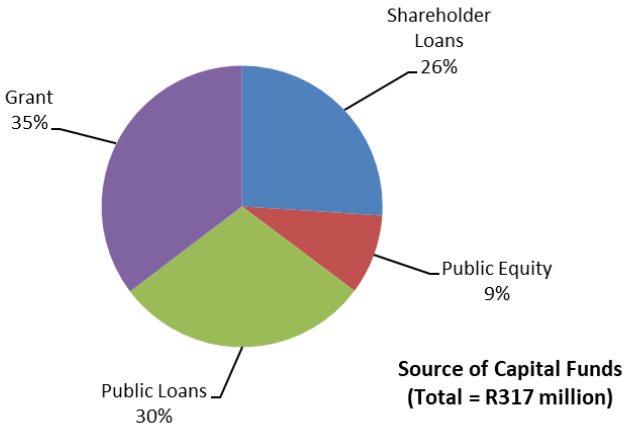
Although the PPP is now terminated, much of the funding for the expansion of the company's operating base has been obtained through the PPP price premium. Since 2003, the cumulative value of this premium has amounted to R1.8 billion, which has been used to fund the increasing working capital requirements including additional operating expenses for purchase of bulk product, implementation of the technology transfer deals, staff remuneration, training and recruitment.

The capital funds (CAPEX) for the major additions to the site's infrastructure, on the other hand, have been sourced from a variety of sources, including grants from donors, shareholder loans, public equity and low-interest public loans (see Figure 9). It is notable that over this period no private loans have been received. With the exception of the initial shareholder loans, all of the CAPEX has been funded by either public grants or loans/equity funding via public development banks (such as the Industrial Development Corporation) or agencies of the government.

The following important observations can be extracted from this analysis of the funding needs and markets for Biovac:

- Securing debt financing from private sources was too expensive or unavailable as a means of raising funds to support the growing company; the main constraint was the structure of the PPP with most private investors being unwilling to fund an entity with a large government shareholding due to the governance complications.
- On the other hand, the existence of the Supply Agreement over a 15 year period provided the necessary security for the company to raise funding from the Industrial Development Corporation. This is a textbook example of how public procurement and demand side policies can be used to leverage other sources of (public) funding. De-risking of pharmaceutical manufacture in Africa could be approached by enacting longer term supply agreements between potential manufacturers and the public health sector.
- Vaccine supply and delivery have long lead times, with bulk supply being required at least 6 months ahead of delivery and the need to maintain substantial stock of key vaccines. As a result, the working capital needs are considerable. Long lead times are a function of the quality control considerations and the unpredictable offtake by public health programmes.
- International donors could play a critical role in financing vaccine manufacturing facilities. Vaccines, such as the components of the Expanded Programme of Immunisation, are typically high volume/low margin public sector products which do not offer a private sector return on investment and require some proportion of public funding as a means of de-risking private investment and raising returns for private investors.

Figure 9. Source of funding for capital expenditure



7.2.5 Developing New Markets and Responses to SARS-CoV-2

Biovac has played a key role in the response of African countries to SARS-CoV-2 though the offices of the African Vaccine Manufacturing Initiative (AVMI). The AVMI was formed in 2010 with the

objective of “coordinating efforts of African vaccine manufacturers and other interested parties, who have a vision to see Africa produce its own vaccines and biologicals for both routine and emergency situations” (African Vaccine Manufacturers Initiative, 2020).

Working with governments, regional bodies, non-governmental organisations, the private sector, academic institutions, and relevant key opinion leaders, AVMI aims to create, through partnerships, an environment on the African continent, which is conducive to the emergence, development and sustainability of vaccine and biological manufacturers that meet global quality standards.

AVMI is hoping to be a key partner in the rollout of the COVID-19 vaccine in Africa, although how this partnership will be achieved is still unclear. In November 2020, President Ramaphosa established the African Vaccine Acquisition Task Team (AVATT), which will be responsible for the overall (pooled) procurement of vaccine for Africa. The total African requirement is estimated at 1,560 million doses, sufficient for 780 million persons, and the treatment programme cost will be $9.1 billion, consisting of $5.8 billion for vaccine purchase and $3.3 billion for vaccine delivery cost (based on the present estimate of $3.50 per dose, a two-dose regimen and a delivery cost of $4 per person). It is broadly proposed that the African COVID-19 Vaccine Financing Initiative (ACOVFINI) be used as the source of these resources.

The emergence of the market for a COVID-19 vaccine illustrates an important consideration for Biovac in its further development (Dorfman and Kirstein, 2021). Domestic markets in South Africa are generally too small to support feasible local manufacture, making access to international markets essential for manufacturers. In developing countries, these markets are supplied through GAVI which has detailed supply specifications with which a supplier needs to comply. Although GAVI did initially supply resources necessary to build the capacity of suppliers to meet the product specifications, it is now very challenging for new manufacturers to enter the GAVI markets. The suggestion from Biovac is for GAVI to use regional allocation mechanisms which split the total procurement between a range of suppliers according to their specific locations. This strategy is different from that adopted by Brazil/China/Russia, which are countries with large internal markets sufficient to support manufacturers focused on internal markets only.

7.2.6 Key Lessons from the Biovac PPP

Vaccines are a unique product within the health sector; the public health benefit of an effective vaccine far outweighs its cost of procurement and administration, with the result that vaccines in general are made for, paid for, and distributed by the public health sector. However, the manufacture of vaccines is mostly undertaken by the private sector. In this sense, the vaccine market is an alliance between the public and the private sector, in which the skills of the private sector are used to manufacture products that are distributed to a large extent by the public health system.

In most cases, the relationship between the two sectors is of a contractual nature. The private sector undertakes the development and manufacture of the vaccines, which it then sells under a procurement contract to the public sector. In some cases, however, the relationship is more closely established, with the formation of a PPP or a state-owned entity manufacturing vaccine directly for the public market. Biovac is an example of a vaccine PPP.

The PPP has a useful structure for the initial stages of the company, since it provided the security of the supply contract and hence enabled additional capital to be raised. More importantly, the price premium funded the working capital requirements and additional operational expenses. This structure seems to be a useful approach to building pharmaceutical manufacturing capacity within countries but it has major limitations in being able to attract private capital in the form of either equity or loan finance. The challenges of working with government departments and agencies as shareholders should not be under-estimated.

The longer-term sustainability of local vaccine manufacture requires access to international markets though GAVI. The Biovac management team recommended that this access be facilitated through a regional procurement strategy accompanied by training and capacity development which will ensure that the selected manufacturers are able to meet the volumes and product specifications as stipulated by GAVI.

The team also suggested the re-establishment of a body similar to the Developing Countries Vaccine Manufacturing Network, which in the period 1990s to 2000s had acted as a 'counterweight' to the multinationals. It is possible that COVAX could fulfil the role of public procurement in support of local manufacture, given that the cost of the vaccine for Africa will be at least $9 billion.

7.2.7 Summary of Normative Principles in Vaccine Manufacture

A. Vaccines are public health products characterised by high volumes and low margins.
B. Vaccine development and manufacture is heavily subsidized in developed countries.
C. In developing countries, GAVI plays a major role in terms of who succeeds and who fails in the vaccine markets.
D. Financial markets are institutions, governed by a set of rules which are only in some respects rational; mostly financial actors are governed by a set of implicit rules and norms which reproduce perceptions of risk in certain markets. As a result, de-risking of pharmaceutical investment through reframing the markets for public health products by advocacy and evidence-based information will be critical to providing adequate finance for the sector.

7.3 Ketlaphela

7.3.1 Introduction

Ketlaphela, as mentioned in Section 3, is a company established by Pelchem in 2011 in order to develop ARV API manufacturing in South Africa. There is a complicated history to Pelchem and the site on which it operates, beginning with an initiative by the apartheid regime in 1974 to develop nuclear weapons in the South Africa. The weapons programme required the local beneficiation of uranium oxide, which is found in abundance in the country, but had not previously been beneficiated. The purification process requires the formation of uranium hexafluoride, and the role of Pelchem was to manufacture hydrogen fluoride and generally manage the fluorine value chain. It was established alongside the enrichment facility at Pelindaba, just outside Johannesburg.

Both weapons programme and the local manufacture of nuclear reactor fuel were terminated in 1990, with the result that the strategic rationale for the ongoing operations at Pelchem were obviated. Although initially the company managed to diversify into other fluorine chemicals, such as xenon difluoride, these were insufficient to support a viable operation and it continued to seek additional diversification opportunities.

Ketlaphela was one such project (it is ironically illustrative that the name aptly translates as "I will survive no matter what"). The intention was to produce efavirenz (EFV), which contains three fluorine atoms in the molecule, as well as other ARV APIs for supply to the ART programme in South Africa. It is not clear as to who approached whom, but at some point during the period 2009 to 2010, Lonza and Pelchem entered into formal discussions on the establishment of a fully integrated pharmaceutical manufacturing company at the Pelindaba site. The core of the Lonza proposal was the local manufacture of the two ARV APIs, tenofovir disoproxil fumarate (TDF) and EFV.

Lonza had already been making EFV under contract for Merck, but had also developed an improved process which it was now offering to Pelchem. It was not clear whether Lonza had proprietary TDF technology but the chemistry was already widely published and readily available (Walwyn, 2013). It is interesting to speculate as to why Lonza chose to engage with Pelchem on a technology transfer project, given that the company had traditionally avoided such partnerships and itself acted as a contract manufacture. One of the contributing factors was that EFV had become a low margin product and could not be profitably manufactured on the site at Visp. The Pelchem option allowed Lonza to stay in the ARV market and boost its flagging profits at a time when the company was in some financial distress.

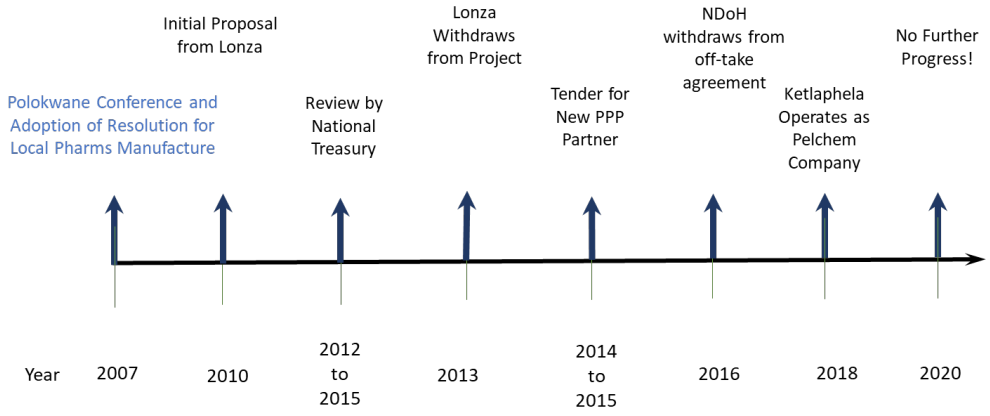
Local manufacture of pharmaceuticals, and particularly components on the Essential Drugs List, had been prominent on the agenda of the South African Government since the early 2000s. For

instance, Resolution 64 of the 2007 Polokwane Conference of the African National Congress (ANC) stated that:

> *"The ANC should explore the possibility of a state-owned pharmaceutical company that will respond to and intervene in the curbing of medicine prices."*
> (African National Congress, 2007)

Ketlaphela seemed an ideal solution to four crucial issues of the time, namely the predicament of Pelchem and its need to diversify; the industrial policy objective of building local pharmaceutical manufacturing capability; Lonza's own economic woes; and finally, access to essential medicines. Notwithstanding these powerful drivers to its possible success, the initiative failed, the reasons for which are now discussed. The timeline of the events relating to the company as shown in Figure 10.

Figure 10. Timeline for the rise and fall of Ketlaphela



7.3.2 Proposed Structure

Ketlaphela's proposed ownership structure and the responsibilities for each partner in the PPP are shown in Figure 11 and Table 3 respectively. The total private equity (a controlling share) was set at 51% with the remaining 49% being held by the Government through its state-owned entity Pelchem.

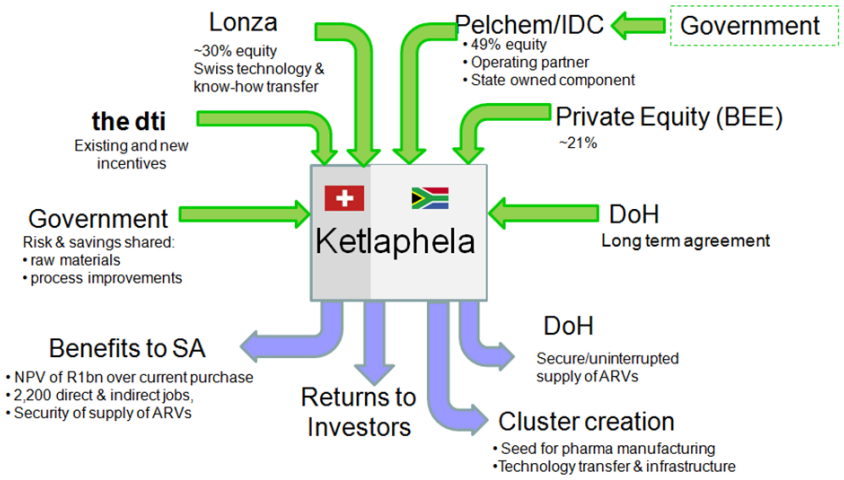


Figure 11. Proposed structure for Ketlaphela

Table 3. Partners and proposed contribution

Partner	Capital	Technology	Know-how
Lonza	R533m (~30%)	Process development valued at R150-300m	Pharmaceutical plant operations, training and quality systems (GMP)
Pelchem/ Necsa	R100m land & infrastructure value plus building location for the pilot plant.	Fluorochemical technology	The operations and management of specialty and hazardous chemical plants including SHEQ.
Industrial Development Corporation (IDC)	R870m (49%) (plus additional mezzanine funding of up to 20%)	None	Development finance
Private Equity (BEE)	R373m (~21%)	None	Local procurement preference

A summary of the relationship between the PPP and its important stakeholders is also shown in Figure 12.

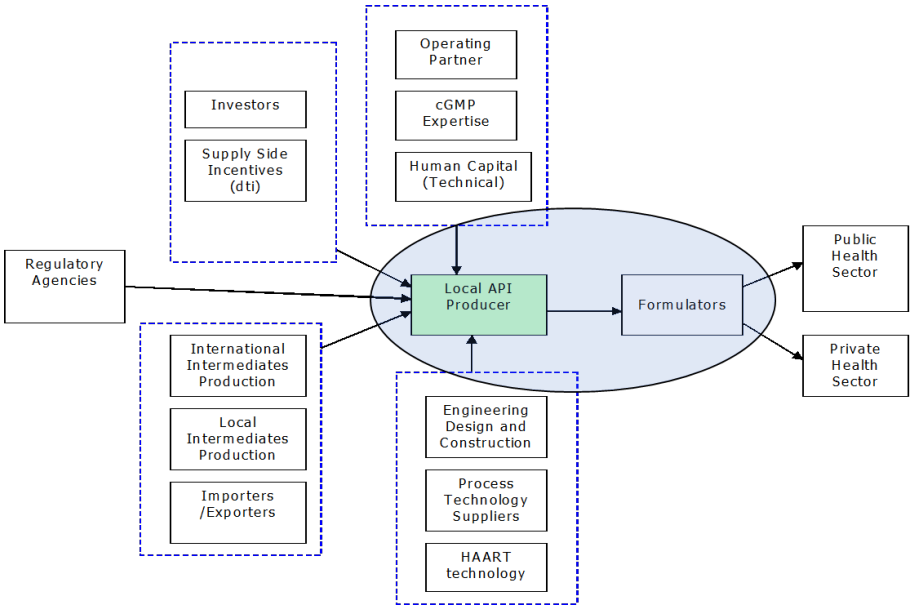


Figure 12. Relationship between Ketlaphela and its stakeholders

The capital cost of the facility was estimated at R1,475 million, of which Government was being asked to contribute R568 million, including R105 million for a fine chemicals pilot plant, in the form of a cash grant (see Table 4). In the first five years of operation, Government was also asked to contribute R1,474 million in the form of grants, bringing the total operational subsidy to R2,042 million or about R4,295 per kg of API (the weighted average selling price of API is R3,240 per kg).

Table 4. Details of capital expenditure

Capital Expenditure	**Investment (R millions)**
API Chemical Plant	860
Small Scale (Pilot) Plant	80
Waste Water Treatment	50
Energy Recovery / waste management	435
Land	50
Total Investment Costs	**1,475**

7.3.3 Unravelling of the Project

Although there seemed to be many reasons to conclude the investment, the project began to unravel in 2013/14, beginning with Lonza's withdrawal. The company was unhappy on several counts, including the slow decision-making process by the South African Government, but the main stumbling block was the reluctance of the South Africans to grant a controlling stake in Ketlaphela to their Swiss counterparts. In the view of the South Africans, Ketlaphela was established as a state-owned entity and access to the ARV tender in the proportion that was being demanded (40% of the tender to be set aside to the venture) could not be granted to a company which was not controlled by the state.

In response to Lonza's withdrawal, National Treasury instructed Pelchem to issue a public tender for a new partner, which was closed in 2015. Only one company submitted a bid, and this submission did not meet the tender's minimum criteria, with the result that the initiative was left without a technology partner and private sector investor. The scope was then adjusted to a smaller API facility, manufacturing not EFV and TDF, but a proposed new triple therapy of dolutegravir (DTG), emtricitabine (FTC) and tenofovir alafenamide (TAF). The total API manufacturing capacity was estimated at 250 Tpa, the technology for which would be sourced from the Medicines Patent Pool.

The new business plan also outlined a stage-wise entrance to ARV APIs, with the initial step being the establishment of a pilot plant for API manufacture, and the importing of finished product from an international supplier in order to gain initial market share in the ARV tender. Over time, the company would extend its footprint though backwards or upstream integration by undertaking local formulation using a contract facility and based on imported APIs, and then establishing larger scale API manufacturing for the key products.

Interestingly, the treatment regimen has since been changed from EFV/TDF/FTC to DTG/lamivudine (3TC)/TDF, with the latter known as the DLT regimen. However, Pelchem was unsuccessful in being able to raise funding for its new business plan from National Treasury and the project came to an almost complete standstill, although there are still the occasional resurrections in the media (Tomlinson, 2020). Several reasons have been cited for the National Treasury decision, including:

- the general failure of state-owned entities such as Eskom and South African Airways, placing large risk on the fiscus and leading to a general reluctance by National Treasury to countenance new entities
- the erosion of political support for PPPs, which were supported under Minister Manuel but not by his successors
- the absence of a black empowerment partner acceptable to the ANC (2016 was at the height of the state capture period!)

- reluctance by the National Department of Health to grant set aside 40% of the ARV tender to a single supplier
- strong opposition from the existing formulators (Aspen and others) to the entrance of a new pharmaceutical company
- weak support at Cabinet level for the industrial policy of the Department of Trade and Industry (dti).

As of end-2020, Ketlaphela is reported to be marketing hand sanitizer only, and there is no evidence that it has gained any traction in the ARV market.

7.3.4 De-Risking Local Manufacture

The Ketlaphela initiative permits a detailed calculation of the perceived level of risk for an international API manufacturer in entering African markets. Lonza was insistent on the following terms for its technology transfer and participation (see also Table 5):

- grant for the Energy Recovery Plant (R435m) (from the dti)
- grant for Land and infrastructure upgrade (R100m) (from the dti)
- grant for the Pilot Plant (R80m) (from the Department of Science and Technology)
- qualifying tax incentives (from National Treasury)
- working capital incentives/support (from the dti and IDC)
- designation of pharmaceutical products for preferential procurement to allow for price premiums to ensure reasonable returns (from the dti)
- long-term supply agreement @ 40% of the ARV tender (National Department of Health).

It is noted that although private financial intermediaries were approached for funding, there was no interest at all by such institutions. In their terms, “there was no business case in the absence of the 40% offtake agreement and the project simply does not bank”.

A separate feasibility study, undertaken for National Treasury in 2013, calculated that the return on shareholder funds for Lonza, if all the funding streams as indicated in Table 5 were to be granted, would be at least 45%, as compared to the 20% as stated in the proposal. Both returns indicate that the Swiss company was insistent on an extremely high rate of return, certainly out of all proportion relative to returns in other sectors or even areas of its domestic business. This single point brings into stark reality the perceived level of risk for such an investment by an international chemical company, and emphasizes the initial argument of this study, namely that de-risking of the sector in Africa is essential as a means to unlocking financial support.

Table 5. Summary of requested financial support from Government

Year	Government Support (R million)				
	Section 12 Tax Incentive	**Capital Items (Grant)**	**Operational Subsidy**	**Production Cost Rebate**	**Total**
2016	98	105[90]		7	210
2017		463[91]		91	554
2018			173[92]	286	459
2019				286	286
2020				286	286
2021				248	248
Total	**98**	**568**	**173**	**1,203**	**2,042**

7.3.5 Key Lessons from Ketlaphela

- Serving markets for public health products other than through direct purchase/public procurement is complicated and problematic.
- Expectations of a very high RoI by the private sector to mitigate the risk of Africa pharma!
- Governments cannot expect to retain a controlling share, even of companies serving public sector markets
- ARV API manufacture is highly competitive; despite the large market, RSA cannot compete without public finding
- Large donor organisations are part of the problem, as confirmed by the Biovac input. The procurement policies of GAVI, CHAI and others restricts the market to the WHO prequalified companies, which are mainly originators/multinationals. In essence, the multinationals have captured the global market through the procurement practices of the donor agencies. This arrangement needs to be changed with the introduction of local manufacturing provisions within such large supply contracts.

[90] Pilot plant
[91] Energy recovery unit (waste incineration)
[92] Grant to cover operational costs while awaiting regulatory approval

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Appendices

Appendix A. Synthesis of the Learning Event

Framing

There was general consensus that the political framing of financing for local production efforts is critical. The suggestion led by Nick Drager is that the effort should be framed in terms of National Health Security principally because this will bring in public finance which is necessary when it is more difficult to make the business case.

Transformational change entails engaging public finance. Incremental change requires building the business case.

Pharmaceutical production (including vaccines) should be aligned with energy, food and water as essential long-term infrastructure, among other reasons to permit long-term financing, 20 to 40 years, rather than short term.

Presumably one thing this group could do is encourage or advocate for a change in political perspective concerning where pharmaceutical production fits in the national or regional industrial policy and social welfare constellation. It is worth noting that public health, and health security, has typically played only an ancillary role when governments negotiate on matters such as trade agreements although the corporate security aspect (i.e., IP protection) receives significant attention. This has been a persistent feature of international relations.

Regional Approaches and Economies of Scale

There was an apparent second consensus that African local production efforts should be approached from a regional perspective, mainly because many African national markets are too small to support production facilities. Participants are aware that efforts to establish regional cooperation have historically been fraught with difficulty, not only in Africa. At the least, companies should be able to export.

It was pointed out that few local producers in Africa have good visibility into the regional market, and do not perceive it as a source of demand.

Not specifically discussed at the meeting was the potential for establishment of regional production zones or Pharma cities, something along the lines proposed and executed at least in part in India (see WHO India Study 2017). For small molecule chemical drugs, this likely means establishing nearby to existing petrochemical facilities to take advantage of energy supplies, raw material inputs, existing environmental controls, and other infrastructure.

As a thought experiment, would it be possible to designate some African territory as "de-nationalized" and subject to the jurisdiction of a regional governance body so that the problems associated with national competition would be minimized? Is there an example of that anywhere? Unfortunately, without some over-arching legal framework matters such as financing would become problematic. What law would govern? On many subject matters, there is a need for some type of basic legal infrastructure that would be difficult to accommodate in the absence of a full-blown regional governance framework, somewhat like the EU.

As an additional element, could African governments pool financial resources for regional production hubs, either through the African Development Bank or otherwise.

Elements of Finance

Regarding financing, there are various elements to consider:

1. The distinction between public and private finance;
2. The distinction between capital coming from outside and capital raised within country;
3. Outflows of capital from major fund-holders such as pension funds and sovereign wealth funds, and whether they are investing domestically or exporting capital;
4. Whether taking on debt, particularly debt arising from external sources and establishing restrictive terms and conditions creates longer-term risks, and whether those can be ameliorated;
5. The role that national central banks can play, such as by providing guarantees;
6. Restrictions on funding for foreign projects imposed by some national development banks, such as in Brazil, which do not permit regional funding;
7. Whether financing for pharmaceutical projects can be added to the list of long-term national infrastructure projects involving energy, food and water, thereby benefitting from lower long-term costs of capital.

From the standpoint of the project, the lesson may be that the map may require expanding to elevate sovereign wealth and pension funds that we have referenced but may not have been high on the list of targets. Also, consider for advocacy trying to persuade government money managers – and perhaps even the legislatures that establish the rules for government money managers -- that funds should be invested within a country, not exported. Query whether the issue raised by Jorge Bermudez – restrictions on the Brazilian development banks – might in fact inhibit regional development?

It is certainly worth observing that attempting to impose controls on capital movements almost certainly runs into resistance from the financial industry as a whole, which is then tied into the home countries of finance. Trade and investment agreements usually include provisions requiring that capital be able to move freely. Some of these treaties should be examined for their

potential to inhibit finance policy development. (Recall Malaysia where the 1MDB Fund scandal brought to light the corruption that underlies some large capital movements.)

We might also consider whether public and private finance streams may be more suitable to particular types of pharmaceutical production projects. What would be the differentiation line? Essential medicines versus other? API production versus formulation? Chronic versus acute treatments? Vaccine, diagnostic or therapeutic?

We recognize that part of the problem with pharmaceutical sector investment is that disruptive technologies can render a particular product obsolete fairly quickly. Even the paradigm example of long-term demand for HIV antiretrovirals would be disrupted by the discovery of a "cure" or vaccine. Is this different than petroleum-based energy which is currently disrupted by alternative energy demand?

Regarding the point that taking on private debt from foreign sources creates potential long-term problems, from the standpoint of a pharmaceutical business, what is the difference between defaulting on domestic debt and foreign debt? Domestic debt presumably can be discharged in bankruptcy, with business ownership potentially transferred. If debt originates overseas, and depending on agreement terms, the debt may be more difficult to discharge. But, unless the private owner has personally guaranteed the debt or secured with non-corporate assets, the net outcome likely is the same. It is different with bonds issued by governments where there is always a long-term capacity to repay, and the ability to discharge through bankruptcy or default it is not a remedy. The net is that a government may be wary of issuing an international bond to finance a pharmaceutical facility because it could not discharge the debt, whereas a private firm is in a different situation. This will also, of course, depend on the extent to which the private firm provides collateral outside the basic business being financed.

It would be interesting to see the terms under which the African Development Bank lends and/or guarantees in terms of securitization and remedies in the event of default.

Cooperation from/with African Development Bank (AfDB)

The African Development Bank is interested in financial instruments and related initiatives. In terms of cooperation with the private sector, the African Investment Forum has been used to attract large-scale corporate investments in major projects, as much as $80 billion in commitments in the past several years. The AfDB considers that a package involving the pharmaceutical sector might attract interest. The AfDB apparently provides some type of loan guarantees in this context.

The AfDB works closely with the African Union and national central banks and is interested in integrating this project in discussions with leaders in the AU and connecting the project with central bankers.

The AfDB also points to possible interest from the sovereign wealth funds, pension funds and diaspora financing.

We will be following up with the AfDB. An outcome of this project may be to recommend the format for a potential proposal to the AfDB regarding funding of production in Africa that advocates might use to generate interest among producers as a package for the African Investment Forum.

One of the constraints with respect to AfDB funding is the $15 million threshold for lending. Based on review of potential project costs, we may also consider advocating the creation of an AfDB funding mechanism for small and medium enterprises (SMEs) that will allow them to take advantage of AfDB financing facilities.

We should also inquire into how the AfDB assesses funding possibilities with respect to public versus private investments.

Here it is worth noting that the Asian Development Bank has previously expressed interest in funding pharmaceutical production projects in Africa, and similar investigation should be made with respect to the ABD.

Country Resources of Interest

It was noted that there are several countries from which potential financing or other forms of cooperation may be available, and may not yet have adequately been considered:

1. China – bearing in mind that there are both state-owned and private industry to consider. The Beijing office of WHO and UNDP may be helpful.
2. European Union - including the EIB, IMI and regulatory financing.
3. India - over the past couple of years has shown increasing interested in expanding its footprint in Africa, reversing previous policies.
4. Japan – DNDi in particular points to openness to initiatives in Africa (note that GHIT (Japan-sponsored PDP) also works with UNDP).

Appendix B. List of Interviewees

1. Alexandra Graham and Paul Lartey, LaGray Pharmaceuticals, Ghana and former President, SADC (PL)
2. Zydus-Cadilla Ethiopia
3. Julphar Pharmaceutical Industries, Ethiopia
4. Humanwell Pharmaceutical Ethiopia, plc
5. Bonds Pharmaceuticals
6. Emzor Pharmaceuticals
7. Neimeth Pharmaceuticals
8. May and Baker, Nigeria
9. Mobihealth Nigeria
10. Nazeem Mohammed, IPS Kenya
11. Nigerian Association of Industrial Pharmacists
12. Quality Chemicals, Uganda
13. Sanjay Advani, President, Federation of East African Pharma Manufacturers Association, and Aspen Pharma Kenya
14. Messay Wolde-Mariam, Deputy DG of Ministry Trade and Investment/Ethiopia
15. Andreas Seiter, Global Lead, Health, Nutrition & Population, World Bank Group
16. Subir Basak, Senior Industry Specialist, International Finance Corporation
17. Christophe Spennemann, Legal Officer and Officer-in-Charge, UNCTAD
18. Jude Nwokike, VP and Director; US Pharmacopeia, Promoting the Quality of Medicines (PQM+) Program.
19. Andre Kudlinski, former Pharmaceuticals Director at the South Africa Department of Trade and Industry (previously DTI; now dtic)
20. Bill & Melinda Gates Foundation (Melinda Moree, Senior Program Officer, Global Health R&D, Global Policy and Advocacy at Bill & Melinda Gates Foundation)
21. Aspen Pharmacare (Stavros Nicolaou, Group Senior Executive, Strategic Trade at Aspen Pharma)
22. Rockefeller Foundation (Jono Quick, Managing Director, Pandemic Response, Preparedness, and Prevention, Health Initiative, The Rockefeller Foundation)
23. Association for Savings and Investment South Africa (ASISA) (Gill Raine Senior Policy Advisor to ASISA)
24. Stephen Smith, Senior Policy Advisor to ASISA
25. Medicines Patent Pool (Chan Park, General Counsel)
26. Biovac Institute (Morena Makhoana)
27. Kahma Group (Selwyn and Martin Kahanowitz)
28. Ketlaphela/Pelchem (Petro Terblanche)