

LoMMiA RESEARCH REPORT — NOVEMBER 2022

THE LOCALISATION OF MEDICAL MANUFACTURING IN AFRICA



The Institute for Economic Justice

The IEJ is the commissioning party of this report which forms part of a broader project on the subject. The IEJ is a progressive economics think tank based in Johannesburg, South Africa. The IEJ's core objective is to provide policymakers and progressive social forces in South Africa and Africa with access to rigorous economic analysis, and well-thought-through policy options, as a basis for advancing systemic change. Interventions proposed by the IEJ must advance social justice, promote equitable economic development that realises socio-economic rights, and ensure a thriving, democratic, environmentally sustainable, and inclusive economy that places the needs of the majority at the centre.

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The LoMMiA Research Report

The Localisation of Medical Manufacturing in Africa (LoMMiA) project undertakes research into the expanded localisation of the production of medical products in Africa in a manner that is developmental, stimulates economic recovery, and challenges entrenched control over the industry. It uses this research to engage with a broad spectrum of partners in order to raise the importance of this issue and how it can be incorporated into Covid-19 recovery plans. This contributes to challenging existing relations of production, distribution, and power with medical supply chains and allocations.

The need for the localisation of drugs, vaccines, and medical technologies /devices in Africa is an active conversation. This project contributes in unique respects. It conducts a comprehensive cross-continental research review that provides a baseline for assessing the state of discussion and implementation and assesses different opportunities and obstacles while providing concrete policy proposals. Second, its findings bring together a wide range of stakeholders needed to ensure meaningful action in this regard, including development economists; public health experts/researchers; public health activists; policymakers, particularly industrial and macroeconomic policy; labour unions; and local medical manufacturing associations/representatives. The Report builds upon previous work done by members of the team and also gathers new evidence to address the aims and objectives of this timely and important study.

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EXECUTIVE SUMMARY

Background and context

The Covid-19 pandemic has once again revealed that it is untenable that, in the majority of African countries, more than 70% of health technology requirements are imported. This moment provides an opportunity for African countries to localise medical manufacturing capacity. The localisation challenge is not only technical but encompasses local and global power dynamics spanning the political, socio-technical and economic aspects. These challenges include catching-up countries having to navigate entrenched, hegemonic, global pharmaceutical value chains, especially in innovator products, which elicit strong backlashes from incumbent companies and their governments.

The African pharmaceutical sector is in dire need of restructuring and transition into a responsive and innovative sector that drives local health security and the social, economic, political, and industrial objectives enshrined in the African Union's Agenda 2063. In the aftermath of the Covid-19 pandemic, this study sought to contribute an evidential basis for such restructuring and transition. The focus is on mapping out and analysing the status of local pharmaceutical and medical-device manufacturing capabilities on the continent and on scoping out opportunities for transition to more complex technologies and their impact on economic development and strengthening local health security.

This report emanates from a study commissioned by the Institute for Economic Justice (IEJ), a South African-based think tank. It was carried out between August 2021 and September 2022. With the IEJ, the researchers sought to answer the following main research question:

How best can African countries harness and deploy lessons from the Covid-19 pandemic and from other relevant local manufacturing experience, to develop and enhance sustainable capabilities for local manufacturing of medical health products?

(See the full Report for methodology, conceptual underpinnings and how data was collected and analysed).

Findings

The research findings bear out that the Covid-19 pandemic starkly reaffirmed that African countries were neither self-sufficient nor agile enough to repurpose local pharmaceutical capabilities to manufacture medical health technologies at the scale required to expeditiously meet the challenges of the pandemic. There were shortages of ventilators, diagnostic kits, drugs and vaccines across the majority of, if not all, African countries. The study's critical examination of some regional, country and product-specific cases of innovative responses to pandemic shortages shows that successes arose from harnessing and deploying complementary regulatory, organisational, coordination, infrastructural and investment capabilities.

Building on earlier work, the report traces the genesis and status of local pharmaceutical manufacturing on the continent. The earliest industrial pharmaceutical manufacturer dates back 125 years to 1897, when Egypt established a state laboratory now called Vacsera. This history is at variance with contemporary depictions of a nascent industry on the continent, as routinely reported in the literature.

In the area of drug manufacturing capabilities, there are at least 649 manufacturing plants in Africa today. The countries with the highest number of manufacturing plants are South Africa (122), Egypt (120) and Nigeria (150). North Africa outranks all regions on the number and complexity of formulations and technological capabilities. The local industry in North Africa has actively leveraged joint ventures to facilitate technology transfer and move upstream in terms of drugs and biologics. Global pharmaceutical MNCs continue to invest in Africa, but Indian MNCs have sharply increased their investments in the last few decades.

There are four countries with vaccine manufacturing operations in Africa. These are Egypt (Vacsera), Senegal (Institut Pasteur de Dakar), South Africa (BioVac) and Tunisia (Institut Pasteur de Tunis). Morocco once had vaccine manufacturing plants, but they ceased operations in 2001. In the aftermath of Covid-19, Morocco is currently accelerating plans to re-establish local vaccine manufacturing. Other countries are also planning establishment of vaccine manufacturing activities, and these include Algeria, Ethiopia, Kenya, Uganda and Nigeria. In at least 28 countries, there are nascent or established medical manufacturing capabilities, especially for drugs (small molecules). During the Covid-19 pandemic, countries depended on these companies. There are huge opportunities for further technological upgrading and introduction of new business models to facilitate development and transition to more complex drugs, vaccines, and biosimilars.

There is very limited capacity for manufacturing active pharmaceutical ingredients (APIs) for drugs and active drug substances for vaccines in Africa. South Africa produces APIs for paracetamol, codeine and a cancer drug. There is some capacity for vaccine active drug substance production in other countries, while for medicines, the entire continent (and globe) is essentially dependent on APIs, mainly from China. This concentration risk is stark. Production of APIs in South Africa has survived because of policies that banned imports of finished paracetamol because it is locally manufactured. Without that support, paracetamol API manufacturing could have failed. Establishing API manufacturing plants requires profitable production economies of scale, strategic technology transfer from leading API manufacturers, incentives on land acquisition and energy costs amongst other things, and provision of treatment plants for effluent and water, ideally in specialised pharmaceutical parks. This calls for governance capabilities, coordinated learning, sustained effort, resource allocation, and monitoring and evaluation by the state to support the emergence of this sub-sector.

In the medical devices sector, which, like the vaccine manufacturing sector, is among the most under-studied on the continent, there is a high reliance on imports across different countries. Local production is patchy. In most African countries, more than 90% of the medical devices in public hospitals are imported, with very limited local production. Even in South Africa, a country with a well-established medical device sector in terms of companies registered to sell medical devices, few manufacturing firms are local. The sector faces technological, market, and regulatory hurdles, which stifle the emergence of SMEs and growth of the sector in Africa. Innovative procurement by the public health system could be used as active industrial policy to support this sector. Local standards bodies need to enhance their capabilities, build reference laboratories and become local notified bodies to regulate the local sector. Currently, medical devices companies depend on European notified bodies, and this significantly increases their regulatory compliance costs.

Business models in the sector may need to be rethought in order to enhance localisation efforts. Our study points to four business model types for the pharmaceutical industry on the continent, with the bulk based on the generic drug business model, which is premised on low-value products and therefore requires a low-cost base for competitive success and business sustainability. The business models sit on a continuum from generic to innovator drug models. In the middle of the continuum, business models focus on innovator drugs close to patent expiry which can receive marketing support to become recognised 'branded' generics for the innovator company. We also found that the business models are generally linked to ownership structures. Most generic medicines consumed in African countries are branded generics produced either locally or in India (see example data in the case studies), since branded originator drugs command much higher prices. The bulk of these generics can be split further into lower- and medium-priced generic drugs depending partly on when

they came off patent and the competition in the market. African generics producers brand their drugs, as do the MNC's based in the high-income countries (HICs) that brand their originator drugs as they come off patent. Technological complexity also increases with the business model typology.

Although drug regulatory capabilities are prevalent on the African continent, institutional capabilities and strengths of regulatory bodies vary across countries and this hampers the growth of the sector.

Regulation is important in order to assure the safety and efficacy of technologies used in the sector. According to the WHO, there are 54 National Medicines Regulatory Authorities (NMRAs) in Africa, though only 7% of these have the capacities to perform the core functions expected of NMRAs. Establishment of the African Medicines Agency (AMA) in 2018 is expected to strengthen drug regulatory capacities on the continent. Vaccine regulatory capabilities exist in the four countries that have historically manufactured vaccines (South Africa, Senegal, Tunisia, and Egypt). However, regulatory capabilities in cell therapies are not yet available, although there are capabilities in monoclonal antibodies' (MAbs') regulation in North Africa.

A series of historical and current structural barriers to sustainable localisation of manufacturing capabilities have been identified.

These include policy and regulation, institutions, norms and practices, knowledge systems and technology, innovation and entrepreneurship, finance, trade and procurement, and broader national development agendas. The pharmaceutical sector faces huge hard infrastructural challenges (good quality potable water, uninterrupted electricity supply, transport and communication networks, and access to ports) and soft infrastructural challenges (regulators and regulatory frameworks, tariff regimes and competition policy, laws and regulations, norms and cultures that drive generation of trust and social capital). This forces companies to invest in alternative infrastructure, which raises costs of production. These infrastructural challenges can be resolved, to some extent, by development of national-level technological capabilities (physical investment, human capital development, and technological effort) and incentives, and harnessing factor markets (preferential interest and exchange rates, credit provision and availability of foreign currency for importation of plant, equipment, and machinery). Political stability is a critical macroeconomic incentive. Institutions, as rules of the game, are critical for providing legal institutions and IP rights protection, and are important for inter-company linkages. Support institutions for knowledge generation and exchange are critical for emerging sectors.

In addition to production of essential medicines to enhance health security, the pharmaceutical industry and medical device manufacturers generate local incomes and employment.

There is a dearth of data on pharmaceutical sector employment in Africa, although globally, employment in the pharmaceutical sector is rising. African countries can therefore potentially generate more employment through both direct and indirect (supply chain) employment effects. Two important aspects for policy consideration are, firstly, the nature of the direct employment (for example, work conditions, training, safety, contractual conditions) and secondly, the generation of local supply chain employment and the conditions in those firms. Trade unions and local industry associations are important vehicles for the emergence of decent work and consolidation of opportunities for local manufacturers.

Conclusion and recommendations

The Covid-19 pandemic has revealed that fractures in global pharmaceutical and medical value chains can affect any country; what differs is how countries respond through harnessing or repurposing available capabilities.

The main issues emerging from this study point to the need for deliberate, holistic, agile and consistent policies that can stimulate and sustain local production of products for the medical sector. There is the need for dedicated investment to generate the required range and levels of competencies, capabilities, and skills for different points of the value chain, including abilities to scale up. There is also the need for leadership capabilities, which will limit the fragmentation that can be caused by external influences or agendas driven

from outside the countries or continent. External resources – financial, policy, and intellectual – are still required, but what is key are local structures and strategies for deployment of those resources. With poorly structured, poorly resourced and poorly functioning local structures, there will be limited prospects for sustainable local manufacturing, as has been the case.

Our findings and analysis revealed that Africa urgently needs to broaden and deepen its medical health technology manufacturing capabilities if it is to enhance local health security, become pandemic and epidemic ready, and contribute to global health security. In addition, there is great scope for using the medical device, drug and vaccine sectors to accelerate industry and economic development, as well as contributing to better availability of life-saving medicines and other technologies.

The development of the sectors is premised on careful consideration of the following:

- a. African governments must stress the urgency of building the necessary industrial capabilities in what are highly political projects.
- b. The continent urgently needs to build API manufacturing capabilities, with Covid-19 revealing the risk of being unable to access these. This calls for governance capabilities, coordinated learning, sustained effort, resource allocation, and monitoring and evaluations by the state to support the emergence of this sub-sector. These projects require vast sums of patient resources, profitable production economies of scale, strategic technology transfer, incentives for, for example, land acquisition and energy costs, and provision of treatment plants for effluent and water, ideally in specialised pharmaceutical parks.
- c. Existing business models need to be rethought and reconfigured in order to have the capability to solve technical, managerial and industrial challenges, and to possess an adequate scale of intervention to build resilient local health systems that are foundational for global health security and pandemic or epidemic preparedness.
- d. Industry, working with innovators and joint venture partners, needs to have foresight as to which drugs will soon come off patent and start development work. The industry also needs to upgrade and capacitate both local and lucrative export production, and to transition to newer technologies.
- e. Medical devices are a fledgling industry that requires urgent support, including finance, standards and institutional and infrastructural support. Local production eases foreign currency demand for imported finished products, carries lower regulatory hurdles, and has potential for concentrating production in SMEs to grow employment and GDP. This is low-hanging fruit for African governments and its development should be supported.
- f. Biologics is a sector with tremendous commercial and export opportunities because of its immediate and future utility and profitability. The appropriate business models, business prospecting skills, and international networks must be developed, so that the sector can transform the medical health technology sector on the continent, while simultaneously making Africa pandemic ready, especially if capabilities are developed with platform technologies such as mRNA technologies.
- g. Development of the medical health technologies sector requires that the state and local financial institutions, especially development banks, play a more significant role in providing patient capital to the sector. Innovative procurement is important for signalling to potential funders the viability of the local business operations, and public health system procurement needs to be leveraged to achieve this.
- h. Science technology and innovation systems are a critical component of localisation of medical health technology manufacturing, and of brokering technology transfer. SGCs need to be adequately funded to play a more prominent role in shaping the science, technology and innovation trajectories of countries.

- i. Regulation and governance issues are critical challenges for all sectors. For the medical device sector, the local standards bodies need to upgrade their capabilities and become notifying bodies to have a direct positive impact on entrepreneurship, cutting regulatory costs and supporting economic development. Biologics urgently require (local and regional) regulatory capabilities to be developed. This will be easier for countries with vaccine manufacturing capabilities, as developing these capabilities will be an incremental innovation, which will help shorten the learning curve.
- j. Specialised pharma and medical manufacturing parks with support infrastructure must be established, along with creating purposive alliances amongst industry, academia and the government in a triple helix approach to support technological change and transitions.
- k. Prioritising decent work includes support for training, health insurance provision, and other aspects of social protection; ensuring the health and safety of employees; support for union organising and negotiation within the industry; investigation of contracting processes; and support for improvements in conditions of contract workers.
- l. Hard pharmaceutical infrastructure includes the provision of critical knowledge bases and skills. Gaining an understanding at a local level of the labour skill requirements for certain functions in the pharmaceutical sector is vital. Foregrounding skills transfer and ongoing skills upgrading, as a non-negotiable aspect of direct foreign investment, should be a priority for the sector.
- m. Regional integration presents enormous opportunities for pharmaceutical planning that coordinates production for regional and international markets, with strategic access to preferential finance for industrial development. Both trade and non-trade barriers will need to be reduced, policy and regulation coordinated, and production planned through regional manufacturing associations. Crucial is the regional alignment of standards to facilitate an Africa-wide market and economies of scale.

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ABBREVIATIONS AND ACRONYMS

AUDA-NEPAD	African Union Development Agency
ACT	Artemisinin-based combination treatments
API	Active pharmaceutical ingredients
cGMP	Current good manufacturing practice
COMESA	Common Market for Eastern and Southern Africa
DFIs	Development financial institutions
EDA	Egyptian Drug Authority
EIPICO	Egyptian International Pharmaceutical Industries
GMP	WHO's Good Manufacturing Practices for Pharmaceutical Products
IP	Intellectual property
MNC	multinational corporation
NMRA	National medicines regulatory authorities
OTC	Over the counter
PPE	Personal protective equipment
PPP	Private-public partnership
R&D	Research and development
SEDICO	South Egyptian Drug Industries
SGCs	Science granting councils
SME	Small to medium enterprises
SSA	Sub-Saharan Africa
UNIDO	United Nations Industrial Development Organisation

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'The most important lesson learnt from this [Covid-19] crisis is – when you have a state of crisis, no matter how much I like you, and how much I want to support you, it's me first. Whether you say it outright or whether in your actions ... we have a proverb in my language [Wolof] that says, 'It's not that I hate you – but I love myself more!'

Former Global Health Practitioner (2021)

1

INTRODUCTION

The Covid-19 pandemic accelerated African governments' urgency to achieve the localisation of manufacturing medical health technologies (drugs, vaccines, medical devices, and diagnostics). As the pandemic rolled out, shortages of drugs and vaccines became widespread, and public outcry rose at the inability of African countries to secure the health of local people. Some governments – for example Ghana, South Africa and Senegal, amongst others – announced investments in vaccine manufacturing plants. Countries with local industrial and pharmaceutical capabilities were quick off the ground in producing health-related commodities for their countries. Others teamed up to combine resources and capabilities. South Africa, for example, was chosen as the centre for technology transfer and reverse engineering of a Covid mRNA vaccine (WHO, 2021). The WHO and COVAX are collaborating with a South African consortium composed of Biovac, Afrigen Biologics and Vaccines, a network of African universities and the Africa CDC (Centre for Disease Control). Their goal is scaling up production of and access to vaccines. Germany donated €20 million to the Institut Pasteur de Dakar in Senegal, for the construction of a vaccine manufacturing plant (Institut Pasteur de Dakar, 2021). These initiatives show that Covid-19 generated momentum that had been absent until then for localisation of medical health technology manufacture. However, the emphasis was highly skewed to vaccines at the expense of other critical life-saving medicines, diagnostics and medical devices for diseases such as cancer, diabetes, and hypertension.

Covid-19 demonstrated that the current African health-industry complex – comprising local health industrial structures, value chains, supply chains, and other industries that support the health sector – were woefully inadequate to rapidly address fast-moving public health emergencies. This situation is untenable, both now and in the long run. Current pharmaceutical industrial structures were shaped by historical industrial policies and under-investment in the sector. Globally, the last five decades saw a gradual shift of pharmaceutical activity to Asia, especially for active pharmaceutical ingredients (APIs), generics and biosimilars' manufacture. The shift in API manufacture has been so dramatic that India now imports up to 85% of its APIs from China (World Pharma Today, n.d.). China is the world's largest producer of APIs and constitutes 40% of global API production (MHRA, 2017). Consequently, all global pharmaceutical manufacturers are exposed to serious API supply concentration risk. The concentration risk is, however, more severe for African manufacturers who do not have local supplies of APIs and excipients. Only South Africa possesses API manufacturing capabilities for paracetamol, codeine and a single cancer drug.

Although African governments recently acknowledged the strategic importance of the pharmaceutical sector to local health security, their investment track-record in and design of science, technology and innovation policies to stimulate and sustain technological change in the pharmaceutical sector is poor. They have failed

to leverage this sector's potential to accelerate industrial and economic development whilst at the same time building local health security – a critical foundation for global health security (Banda et al., 2021a). Local production of medical health technologies has the potential to meet these multiple development and health security goals.

The project informing this report was commissioned by the Institute for Economic Justice (IEJ), a South Africa-based think tank with a special interest, among others, in the intersection of economic knowledge production and addressing public health concerns, as well as provision of policy proposals that promote development, economic recovery and equitable access to public goods. The IEJ was interested in understanding how Covid-19 could provide a trigger for reconceptualisation and action on 'the potential for the localisation of the production of medical products in Africa in a manner that is developmental, stimulates economic recovery, and challenges entrenched control over the industry'.

The project was guided by the following aims and objectives:

- a. Assessing the current landscape of medical product manufacturing in Africa;
- b. Identifying structural barriers and opportunities for local manufacturing;
- c. Developing a framework for assessing the normative elements of the project (that localisation is developmental, ensures better availability of drugs and other medical health technologies and challenges entrenched industrial dominance patterns); and
- d. Providing policy proposals that promote development, economic recovery, and improved availability of medical health technologies, understood broadly.

Consolidated and searchable peer-reviewed or grey literature on the African pharmaceutical sector is scarce. Consequently, we built on our ongoing and previous projects (Mackintosh et al., 2016, 2018; Russo and Banda, 2015; Banda, 2013) as well as networks in industry, academia and policy circles to continue to build the consolidated picture of African pharmaceutical capabilities and reflect on potential points of technological capability upgrading and transition to local manufacture of more complex drugs, vaccines, diagnostics, and medical devices. The focus is on how we get from import dependency to manufacturing, from simple formulations to complex ones, the stages and what is needed. Political economy issues, policy coordination and coherence, governance, and institutional capacity capabilities are all important facets to understand with regard to localisation of manufacture for the sector.

In order to contextualise the potential for localisation of production, we map the African medicines, medical device and vaccine manufacturing footprint and current technologies in use. This is important in understanding key policy, infrastructure, technology, and political economy issues that shaped the sector. Consequently, this informs strategies and policies that can imbue localisation of production with developmental, entrepreneurial and economic recovery attributes. Localisation of production has potential to improve availability of medicines for health systems, including during medical emergencies, through co-location and proximity (Mackintosh et al., 2018). Short supply chains are beneficial in health emergencies (Banda et al., 2021b).

The rest of the paper is set up as follows: Section 1.1 gives the background to Covid-19 and the new impetus it generated for local medical manufacturing in Africa. Section 2 covers the methodology used for the study, while Section 3 discusses the research context. We present the historical context for the medical manufacturing footprint on the continent in Section 4. Section 5 covers the local drugs sector; Section 6 presents the vaccine sector and Section 7 the medical devices sector. Section 8 discusses the structural and infrastructural barriers and normative issues in localisation of the production of medical health technologies. Policies to support local manufacture are covered in Section 9, and Section 10 presents the conclusion and recommendations.

1.1. Background

Prior to Covid-19, two other recent public health emergencies helped refocus and galvanise African governments and leaders to seriously consider local production. First, the 2009 H1N1 influenza pandemic highlighted the continent's lack of capacity to develop and manufacture products for the flu pandemic and other strategic vaccines for public health emergencies. This culminated in local vaccine manufacturers becoming members of the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI, launched at Davos in 2017, is a coalition of public, private, philanthropic, and civil society organisations whose goal is the development of vaccines that address future epidemics. Their mission, similar to product development partnership (PDP) initiatives, is to accelerate development of vaccines against infectious diseases and build equitable access to vaccines for all people. The second public health emergency was the 2014 Ebola outbreak in West Africa which led to strong recommendations from the African Union (AU) and others regarding support for accelerated local vaccine manufacturing. During the Covid-19 pandemic, the message re-echoed that Africa was neither self-sufficient nor agile enough to repurpose local pharmaceutical capabilities to manufacture medical health technologies at the scale required to expeditiously meet the challenges of the pandemic. There were shortages of ventilators, diagnostic kits, drugs and vaccines across many African countries.

A former global health procurement expert remarked that Covid-19 was a wake-up call for everybody to realise that Africa needs to do something. Covid-19 impacted medical stores' logistics in the early days because of global lockdowns. After Chinese and Indian manufacturers shut down plants, no commitments were being met as global freight movement halted. There was no production and delivery from traditional external suppliers, who went into a state of limbo because of the prevailing uncertainty. The expert further highlighted that nobody had a clue as to when they would receive their supplies. For central medical stores that put out annual tenders for replenishing supplies, if Covid-19 occurred at a time when they were expecting a huge delivery, they were faced with the reality of empty stores or warehouses. To compound the challenges, India placed limits on the export of 26 pharmaceutical ingredients as well as medicines and vitamins made from those ingredients. The Indian government also stopped exports of medicines such as paracetamol, Remdesivir used to treat Covid-19, hydroxychloroquine and formulations of malaria drugs, antibiotics such as tinidazole and erythromycin, the hormone progesterone (which is used in the contraceptive pill), and vitamins B1, B6 and B12. In addition, to the lack of availability, there was a dramatic increase in prices of many APIs supplied to African companies.

The respondent further noted that Covid-19 was a crisis that was affecting the whole world and remarked: 'Sentiment aside – your first responsibility is to your country and therefore, local production is important for Africa to be able to at least deal with part of what they need.' However, she argued that 100% self-sufficiency in medical health technologies in any part of the world is not realistic. There will always be trade. The critical question she posed was: 'How can African countries shift from being at the end of the queue to somewhere where equality is evident? Local production is key to achieving this.' Her argument was that the focus on local production should be on life-saving medicines. Some life-saving medicines require only low-technological capabilities, and can be ramped up quickly, while others need a transition to high-technology production systems. However, these technological capabilities need to be accompanied by complementary regulatory, organisational, coordination, infrastructural, and investment capabilities. These capabilities may reside in other companies, institutions and government.

The African medical health technology sector needs urgent restructuring and reshaping into a responsive and innovative tool that fosters economic and industrial development whilst building local health security and pandemic preparedness. It is also a potent tool for pursuing multiple social, economic, political, and industrial transition objectives enshrined in the African Union's Agenda 2063. In addition, with careful orchestration, the sector can be enhanced through backward and forward linkages. Backward and forward linkages create

opportunities for entrepreneurship and employment whilst reducing import dependence. These technological efforts would help reduce concentration risk amply demonstrated by Covid-19 supply chain disruptions.

Most approaches to localisation of production have distilled the challenge to purely technical and technological capability issues. This is problematic. These are highly political projects that are steeped in international trade, global value chains, and competition contestations. Their potential to disrupt contemporary power, commercial relations and value chains inherently generates international relations and commercial friction. Even at the local level, projects are subject to local politics.

International politics is not a new phenomenon. India, Sri Lanka and Bangladesh faced challenges more than 40 to 50 years ago when they embarked on drug manufacturing localisation. They were able to do this because the countries had local pharmaceutical capabilities. Peculiar to that period and the power dynamics in the drug industry, they faced backlash from multinational corporations who tried to influence government as well as the health professions' associations (Lall and Bibile, 1978; Reich, 1994). The political conditions in these three countries shaped how the local governments effectively challenged the multinational corporations (MNCs) and their governments at headquarters. For instance, in Sri Lanka, it was the emergence of a left-wing coalition (Lall and Bibile, 1978) that pushed for the industrial transition. Similarly, in Bangladesh, the new military head, General Ershad, introduced the National Drug Policy in 1982, with the support of leftist leaning intellectuals, notably, former freedom fighter and health advocate Zafarullah Chowdhury (Islam, 1999; Srinivasan, 1996). The policy was important for General Ershad to gain legitimacy and expand his support base to include rural and poor communities. Thus, local and international politics came into direct contestation in the localisation of pharmaceutical production in the three countries. Although there was a huge backlash from the international community, the governments had the support they needed from their most important constituency. This alignment was essential for the sustainability of their localisation projects (Kofon, forthcoming).

The situation is different for African players because the dynamics have shifted to an Asia–Africa nexus. Some of the dominant players on the African continent are Asian corporations, which have the dual advantage of access to cheap APIs and local incentives that support production of finished formulations and their exports to African countries. The continent uses mostly generics and the major players in this terrain are India and China. For modern vaccines and biologics, however, the power dynamics are different. North–South dynamics drive the interplay, as amply demonstrated in the resistance to the reverse engineering of the mRNA vaccine in South Africa. We will explore and unpack some of these issues further in Section 3 (the research context). Suffice to say that, whilst the power and trade dynamics have shifted to an Asia-Africa nexus, local technological and other capabilities such as governance and regulation, procurement, policy coherence and coordination, and incentives remain critical for localisation of production in African countries (Kofon, forthcoming).

We first conducted a two-week exploratory study to ascertain the utility of case studies based on selected countries, and in other instances on specific technologies. We also used data from concurrent projects that we are engaged in directly or as advisors.

2

METHODOLOGY

Conceptually, this study points to an interplay among policy, technology, governance, industrial, health and other factors that shaped how firms, sectors and countries responded (or did not) to the pandemic through local manufacturing capabilities. In diverse contexts at different levels of existing and embedded manufacturing capabilities, firms, sectors and countries had to repurpose their capabilities or welcome new players in response to the pandemic. System adjustments and co-learning had to happen in order to garner enough momentum for the required response. Looking at some of the issues above as analytical variables, our study's conceptual framework draws from and interrogates innovation systems and policy architectures, manufacturing and technological capability models to advance an empirically grounded and theoretically informed analysis of the African medical health-technologies manufacturing landscape during and beyond Covid-19.

The main question that guided this study was: **How best can African countries harness and deploy lessons from the Covid-19 pandemic and from other relevant local manufacturing experience, to develop and enhance sustainable capabilities for local manufacturing of medical health products?**

We used mixed methods that included case study approaches and gathering data from primary sources using online semi-structured interviews during the Covid-19 pandemic. We used a desk-top study approach to search for secondary sources (peer-reviewed and grey literature) on the web, as well as company and government websites. We supported the secondary data with online semi-structured interviews with key informants in the industry and policy sectors. Interviews were audio-recorded and archived. Informed consent was sought from interviewees and anonymity was preserved. We analysed qualitative data using thematic analysis, and for quantitative data sets, we used tabulation and simple statistical analysis.

We first conducted a two-week exploratory study to ascertain the utility of case studies based on selected countries, and in other instances on specific technologies. We also used data from concurrent projects that we are engaged in directly or as advisors. We used reflections from these studies and projects to enrich the understanding of local manufacture at continental level. For access, we leveraged our networks of key informants in the pharmaceutical industry and related industry associations, as well as policy actors. After the scoping work, we proceeded with data gathering and categorised the key contacts as illustrated in Table 1 below. The exercise, as reflected in the table, recognised the importance of economic and market aspects, specifically procurement, imports, exports and trade, which are important issues for manufacturing investment.

TABLE 1**Key categories used for interviews, subcategories and potential respondents.**

Category	Sub-categories	Respondents
Industry	· Firms – local and MNC manufacturers · Industry associations · Partnerships · Distributors/importers	For medicines, vaccines and medical devices: industry associations
Academia and government	· Science · Health/medical/pharma · Business/Finance/HR · Industrial/economic analysis of markets · Industrial/engineering · Policy/legal	Industry or other R&D institutions
Policy/regulatory	· Global, national, regional, local (health, industry, finance, infrastructure)	National research and science councils, drug and medicines regulatory authorities, competition authorities, and procurement bodies
Development partners	· International, continental and national	International development organisations
Civil society	· Local and international health and consumer action bodies	Managers and experts

We focused on the institutional, infrastructural, regulatory, technical and political barriers as well as opportunities for technological capability upgrading that promote local manufacture and, at the same time, introduce opportunities for transition to more complex manufacturing processes and technologies for the local health sector.

RESEARCH CONTEXT

As highlighted in the introduction and background sections, the Covid-19 pandemic, with its sudden, pervasive and inequity magnifying nature, raised a sense of urgency for promoting local manufacture in Africa. From the African Union, African Development Bank and regional economic communities, through to national publics, as well as private and not-for-profit actors, refocused and galvanised efforts towards local production were prominent in the past 24 months. This presents a timely and important context for an assessment to be made of whether and how the landscape for medical manufacturing is changing in Africa.

Among the contentions and evidence is the fact that the pandemic generated and exacerbated supply chain disruptions for African health systems, through a toxic combination of import dependence and low purchasing power for health commodities. We have argued in recent work that the pandemic exacerbated international inequality in health, as high-income countries dominated international procurement and vaccine development and deployment. Yet in the midst of all this, some African countries were able to leverage existing manufacturing capabilities to respond to the crisis through local production of sanitisers, personal protective equipment (PPE), test kits, oxygen delivery mechanisms, ventilators and more (Banda et al., 2021a; 2021b). According to one African manufacturer who participated in a webinar we convened in October 2020, some innovations were by ‘people who weren’t given the opportunity to innovate in a pre-Covid world’ (Banda et al., 2021b). It is therefore imperative and timely, as set out by the terms of reference for this study, for medical health-technologies manufacturing capabilities in African countries to be assessed, specifically with a view to understand how localisation of these capabilities can be achieved and enhanced and to what extent it can stimulate economic recovery and engender developmental thrusts.

The Covid-19 pandemic put a spotlight on the lack of sustainability and reliability of global production and distribution systems across many sectors, including the health sector, for equitable access to health technologies during pandemics. Arguments have been made consistently by many scholars as well as national, regional and global agencies that building strong local production and distribution capacities improves access to essential medicines through shortening supply chains and subsequent reduction of shortages and stock-outs of essential medicines (Mujinja et al., 2014; Mackintosh et al., 2016, 2018; Fatokun, 2020). The argument and evidence for improved access from local production sits alongside other key arguments for fostering local production, which include promotion of technology transfer and industrialisation, employment creation, reducing import bills and dependence on imported products, and decreasing the influx of substandard and falsified health products into African countries. The merits of these arguments have been made and exemplified with historical and contemporary evidence (Banda et al., 2016; Nwaka, 2021), in some ways helping to shift the narrative from ‘whether African countries should manufacture [medicines] locally’, to ‘how best can they do this?’ However, the questioning of the viability of local manufacturing still looms large in many academic, policy, and practice debates. Some of the antagonistic arguments still proffered are around limited technical expertise, infrastructural and policy deficiencies and low economies of scale.

Experiences from elsewhere show that appropriate combinations of fiscal and non-fiscal incentives can be used to transform the local pharmaceutical production landscape. For example, the United Nations Industrial Development Organisation (UNIDO) highlights that Nigeria, with a population of more than 200 million people, has a huge market potential and commercial prospects for local manufacture of health products (UNIDO, 2011). Local stakeholders in Nigeria have argued that if Bangladesh, a country with a population similar in size to that of Nigeria, could make progress with transformative policy initiatives, then there is potential for the same

In 1982, the government of Bangladesh introduced the National Drug Policy and the Drug Control Ordinance, which together proved to be a catalyst for increased investment and development of the local pharmaceutical sector.

effects in Nigeria. However, the configuration of power and technological capability preparedness that prevailed in Bangladesh to support the introduction and sustenance of its National Drug Policy has not yet emerged in Nigeria. The same argument can be extended to other African countries. Political economy plays a critical role in what succeeds and what fails. Nigeria, in 2005, introduced an import prohibition policy, which banned the import of certain medicines. This policy created domestic market protection in certain medicines; however, it failed in advancing productive capabilities beyond the medicines protected. In Bangladesh, the policy had the opposite effect. While it initially had granted indigenous pharmaceutical manufacturers domestic protection for certain medicines, in this context the firms did progress to complex medicines and to eventually export to stringently regulated markets. The combination of governance capabilities to incentivise and compel firms and the existing technological capabilities are important determinants of the effectiveness of policy (Kofon, forthcoming).

In fact, besides the highly-cited case of India, Bangladesh is a case in point for how low-and-middle-income countries (LMICs) can develop, deploy, and commit to policy objectives that can sustainably promote local pharmaceutical production and remove harmful or inefficient products from the market (Fatokun, 2020). In 1982, the government of Bangladesh introduced the National Drug Policy and the Drug Control Ordinance, which together proved to be a catalyst for increased investment and development of the local pharmaceutical sector. This was achieved through market incentives, setting prices, banning the sale of certain medicines and limiting pharmaceuticals from being imported if foreign firms did not have a manufacturing plant in Bangladesh or if the drug or its equivalent was already being produced in-country (US Pharmacopeia, 2019). MNCs were restricted to manufacturing complex medicines. Apart from reducing the cost of pharmaceuticals, these initiatives resulted in a significant drop in drug importation, with the Bangladeshi domestic industry now reported to be meeting 98% of local demand for essential medicines and exporting to more than 150 countries (US Pharmacopeia, 2019; Sultana, 2016). However, Bangladesh faced direct resistance from multinational corporations, foreign governments, and the Bangladesh Medical Association (BMA), who were vocal against the drug policy. Foreign governments argued that the drug policy would discourage private investors from entering the country, whereas the BMA, although it agreed with the policy's ultimate objectives, criticised the lack of consultation (Reich, 1994). Sri Lanka faced similar hurdles with arguments about the 'bogeyman' of low quality, and the threat of risks to patients (Lall and Bibile, 1978).

These two examples highlight that local production is not only a technical issue, but is also highly embedded in political systems and prone to resistance from incumbents who may not benefit from a restructuring of the pharmaceutical infrastructure on the African continent. It is important to understand how these political systems function – in particular the capacity to resist challenges to institutional reforms, and the differences in organisational power and technological capabilities across the organisations relevant to the successful delivery of policies. In domestic settings, economic institutions can be coupled with political institutions to perpetuate the status quo by excluding innovative entrepreneurs from disrupting incumbents. This can be done through skewed policy or regulatory ratcheting and non-access to incentives and finance. This power dynamic extends to importation versus local-manufacture contestations. If traders dominate policy prescriptions through political power and reach, then it becomes difficult to generate an innovation ecosystem that supports technological change and entrepreneurship that fosters industrial transitions to more complex technologies (Kofon, forthcoming).

3.1. New impetus for localising medical manufacturing

The on-going Covid-19 pandemic has been labelled a tipping point for local manufacturing in Africa, with some stakeholders labelling it a 'wake-up call', while others feel it is an opportunity for injecting new urgency and direction into the agenda. The pandemic has demonstrated the critical nature of local manufacturing for timeously tackling medical emergencies and generating local health security in African countries (Banda et al., 2021a, 2021b). The industrialisation agenda has indeed returned to being a priority for many African governments, reinforced by pandemic urgency, although as highlighted in our study, the knee-jerk reaction has diminished the focus on the critical role of life-saving medicines for diseases such as cancer, diabetes, hypertension, TB, and HIV/AIDS, which kill more people on the continent. The continent needs local production of all medical health technologies, not just vaccines, to build better access to healthcare and strengthen local health security.

There is ample evidence that a number of national, regional, and continental programmes have been championed to stimulate, accelerate and sustain local production of medicines with interrelated objectives coalescing around industrial and economic development, ensuring local health security and contributing to global health security. For detailed reviews, see Mackintosh et al. (2016; 2018), Chaudhuri and West (2016), and UNIDO (2019), among others. However, as will be explored further in this report, there is a need to locate local production in wider discourses of economic development, industrial and technological catching-up, power and hegemony, and the required agency and urgency – attributes that, worldwide, are possessed by the state, be they developmental or entrepreneurial states. For example, industrial policy has been put in the spotlight, going beyond setting directions and ecosystems for manufacturing capabilities, to deploying its integrative capabilities to use local health sector procurement as an industrial policy tool that supports both access to care and industrial employment.

If Covid-19 was a wake-up call, will the respective actors in the pharmaceutical innovation system stay awake? Did Covid-19 generate the momentum to galvanise the right mix of civil society, academics, government, the private sector, health NGOs and multinational organisations to cooperate and form advocacy coalitions that compel African governments and regional authorities to pay more attention to medicine production? The jury is still out on this.

A mural warning about Covid-19 in Ukunda, Kenya, September 2020.
(Picture: RZAF_Images / Alamy Stock Photo)



The countries with the highest number of manufacturing plants are South Africa (122), Egypt (120) and Nigeria (150), followed by the next strata – with 30 to 60 plants – composed of Algeria (55), Tunisia (39), Kenya (35), Morocco (33) and Ghana (30).

4

HISTORICAL AND CURRENT MEDICAL MANUFACTURING FOOTPRINT IN AFRICA

In this section, we present the historical and current manufacturing footprint for Africa, covering drugs, vaccines, and medical devices.

4.1. Analysis of pharmaceutical sector emergence in Africa

Pharmaceutical manufacturing on the continent is not a new phenomenon and the history of local pharmaceutical production is lengthy (Banda et al., 2016).¹ The earliest industrial genesis dates back to 1897, for Senegal's Institut Pasteur de Dakar, and 1896 for Egypt, on establishment of a state laboratory that is now Vacsera. This 126-year pharmaceutical production history is at variance with contemporary depictions of the continent as having a nascent industry, as is routinely reported in academic and grey literature.

Between 1896 and 1933, North Africa dominated establishment of local pharmaceutical firms: Vacsera in Egypt (1896), Memphis Pharmaceutical and Chemical Industries in Egypt (1930), and Cooper Maroc in Morocco (1933). According to our developing database, activity then spread to southern and West Africa with Mayer and Baker in Nigeria (1944), Novartis in South Africa (1946), and CAPS Pharmaceuticals (1952) and Datlabs (1954) in Zimbabwe. The 1980s and 1990s saw more countries establish local plants, as illustrated in Figure 1.

Many sub-Saharan African countries saw a wave of new investment in pharmaceutical production after independence, in the 1960s and 1970s, which aimed to serve the primary health sectors and hospital expansion instituted by independent governments (Figure 1). These included multinationals, local private firms and government investors. For example, in Ethiopia, the first pharmaceutical manufacturing plant, EPHARM, was founded in 1964 as a joint venture by the Ethiopian government and the British company, Smith & Nephew; this remained the sole manufacturer until 1993. In the 1960s and 1970s, Ayrton Drug Manufacturing, a local private company, opened in Ghana, and Nigerian-German Chemicals, a public limited company (Plc), and Ranbaxy Nigeria, an Indian company, opened in Nigeria (Banda et al. 2016). In Kenya, Lab & Allied, Dawa, and Elys were all opened by local capital in the 1960s and 1970s, while in Tanzania, two government firms, Keko and Tanzania Pharmaceutical Industries, joined Shelys and Masoor Daya, local private firms, in the expanding domestic market. In North Africa, Merinal in Algeria was established in 1969, and Sothema in Morocco was established in 1976. Figures 2, 3, 4, and 5 illustrate the genesis of the industry in North, West, East, and southern Africa respectively.

1. We have extended the local pharmaceutical manufacturing genesis and footprint, begun by Russo and Banda (2015). This is on-going work and what follows is by no means comprehensive.

The economic crises across sub-Saharan Africa (SSA) from the late 1970s and through the 1980s caused many multinational pharmaceutical manufacturers to disinvest, while some government firms, such as those in Tanzania, were bankrupted during this period of deindustrialisation. Local capital was instrumental in sustaining the pharmaceutical sector across SSA in these years; a high proportion of the firms that survived and (re)established production belonged to middle-sized locally-owned business networks and family conglomerates with diverse business interests (Wangwe et al., 2021). In the 1990s and 2000s, the pharmaceutical industry in SSA began to grow again and to diversify, with new investments by local and overseas investors. In South Africa, for example, local company Medpro Pharmaceutica was established in 1992; it listed on the Johannesburg Stock Exchange and grew fast. In Kenya, Universal, in Ghana, LaGray, in Uganda, Kampala Pharmaceutical Industries, and in Nigeria, Fidson Healthcare, are all examples of local investments in the 1990s. Fidson began as an import-trading organisation in 1995, and went into manufacturing in 2002.

At the same time, investment in SSA from Indian multinational pharmaceutical firms increased sharply, with Cipla being a prominent example. Other examples include Evans Therapeutics in Nigeria, incorporated as a joint venture between Evans Medical Plc (a local company) and Cipla Ltd in 2003; Cipla Medpro in South Africa, formed when Cipla India bought 100% of Medpro in 2013; and Quality Chemicals in Uganda, now CiplaQCIL, in which Cipla India took a 51% stake in 2013. Other recent Indian company investments in SSA have included Strides purchasing a majority stake in Universal in Kenya. Meanwhile, Aspen, the leading South African firm that has become one of the largest global generic manufacturers, has also been investing in other SSA countries, acquiring 100% of Shelys in Tanzania in 2012, and taking a majority shareholding in Kama Industries Limited (KIL) in Ghana in 2015.

Cipla has steadily invested in pharmaceutical manufacturing in sub-Saharan Africa.
(Photo: Timon Schneider / Alamy Stock Photo)



FIGURE 1

An illustrative presentation of the history of pharmaceutical companies set-up in Africa.

Source: Compiled by authors.



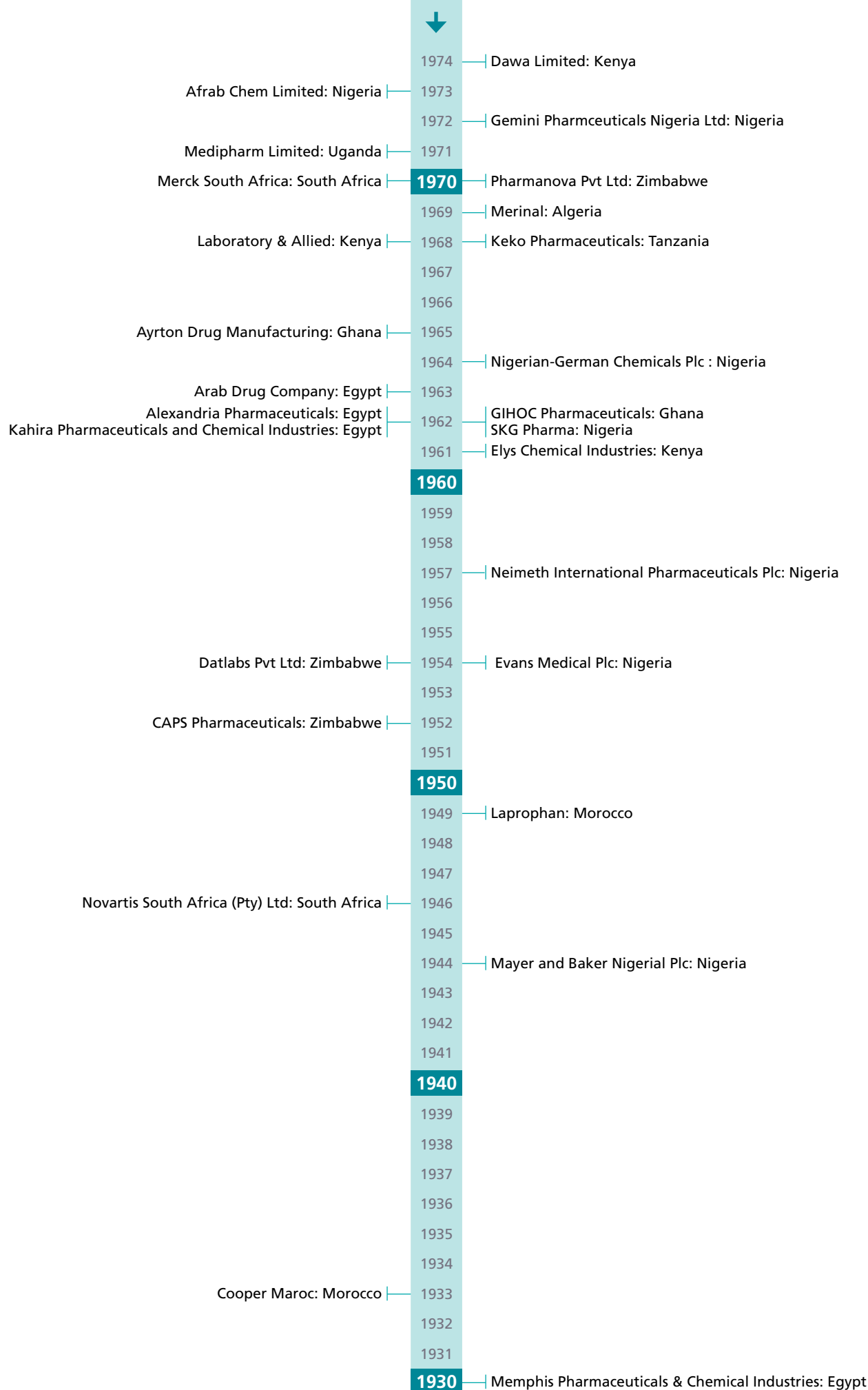


FIGURE 2

An illustration of when pharmaceutical manufacturing plants were set up in North Africa.

Source: Compiled by authors.



FIGURE 3

An illustration of when pharmaceutical manufacturing plants were set up in West Africa.

Source: Compiled by authors.

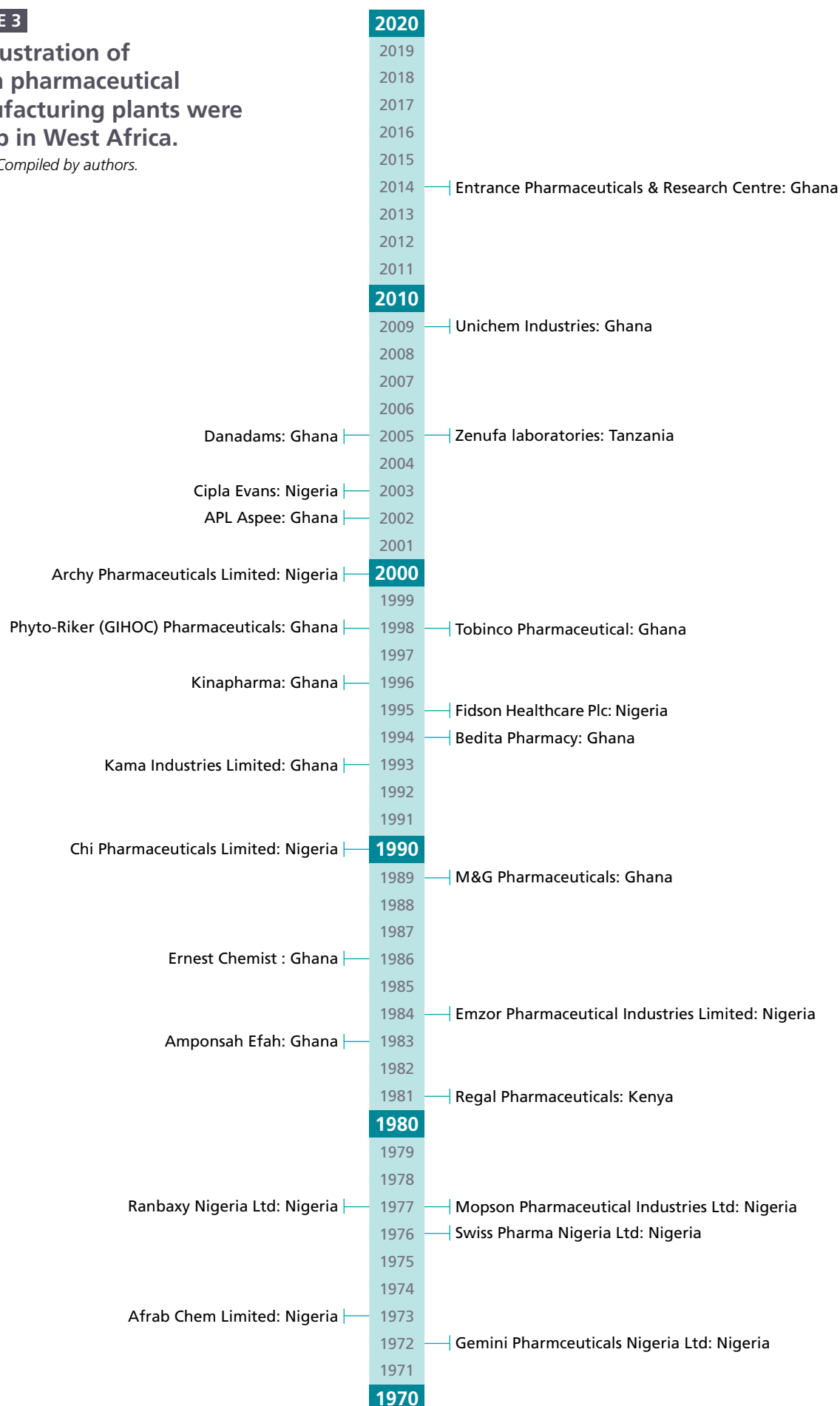


FIGURE 4

An illustration of when pharmaceutical manufacturing plants were set up in East Africa.

Source: Compiled by authors.

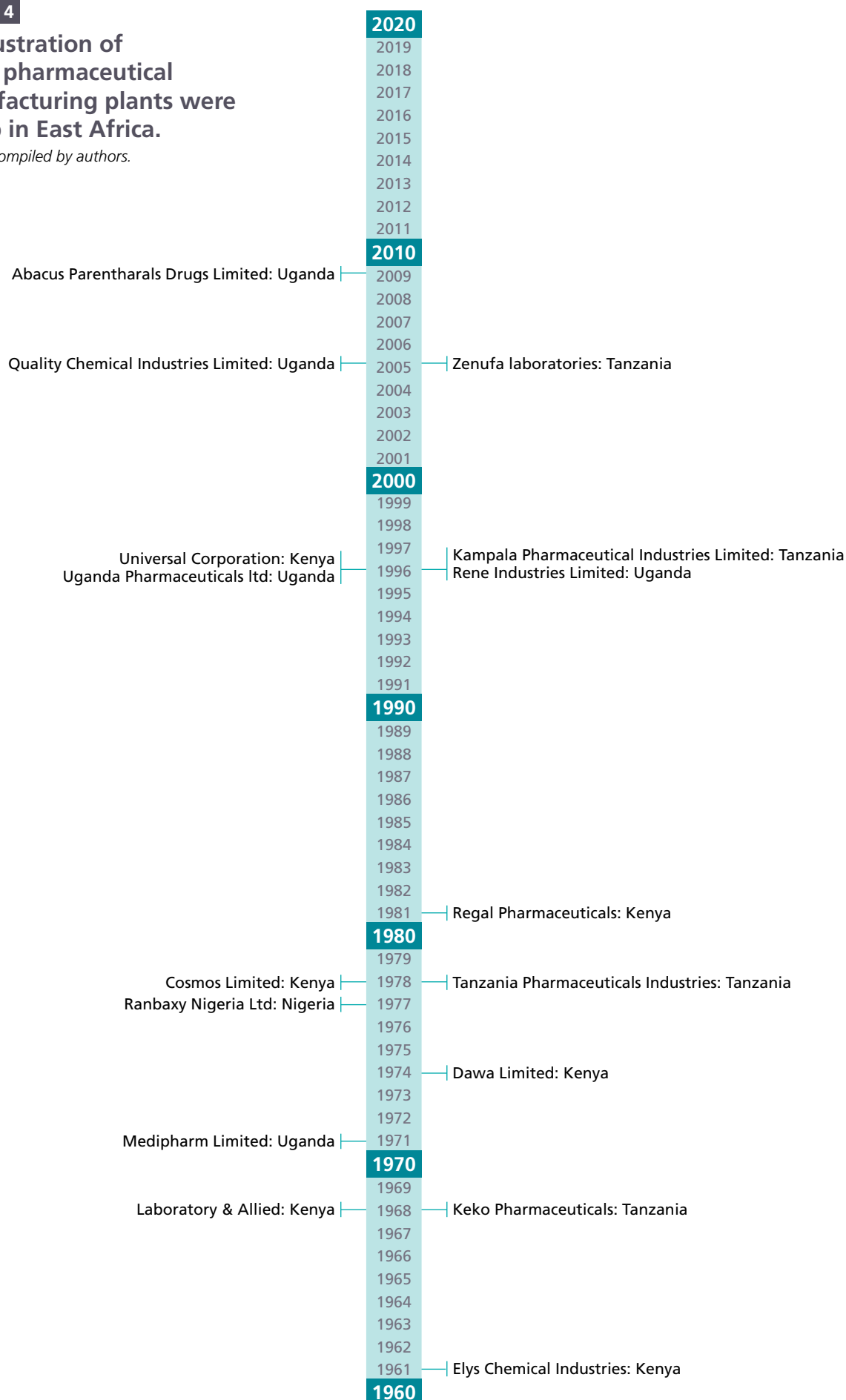
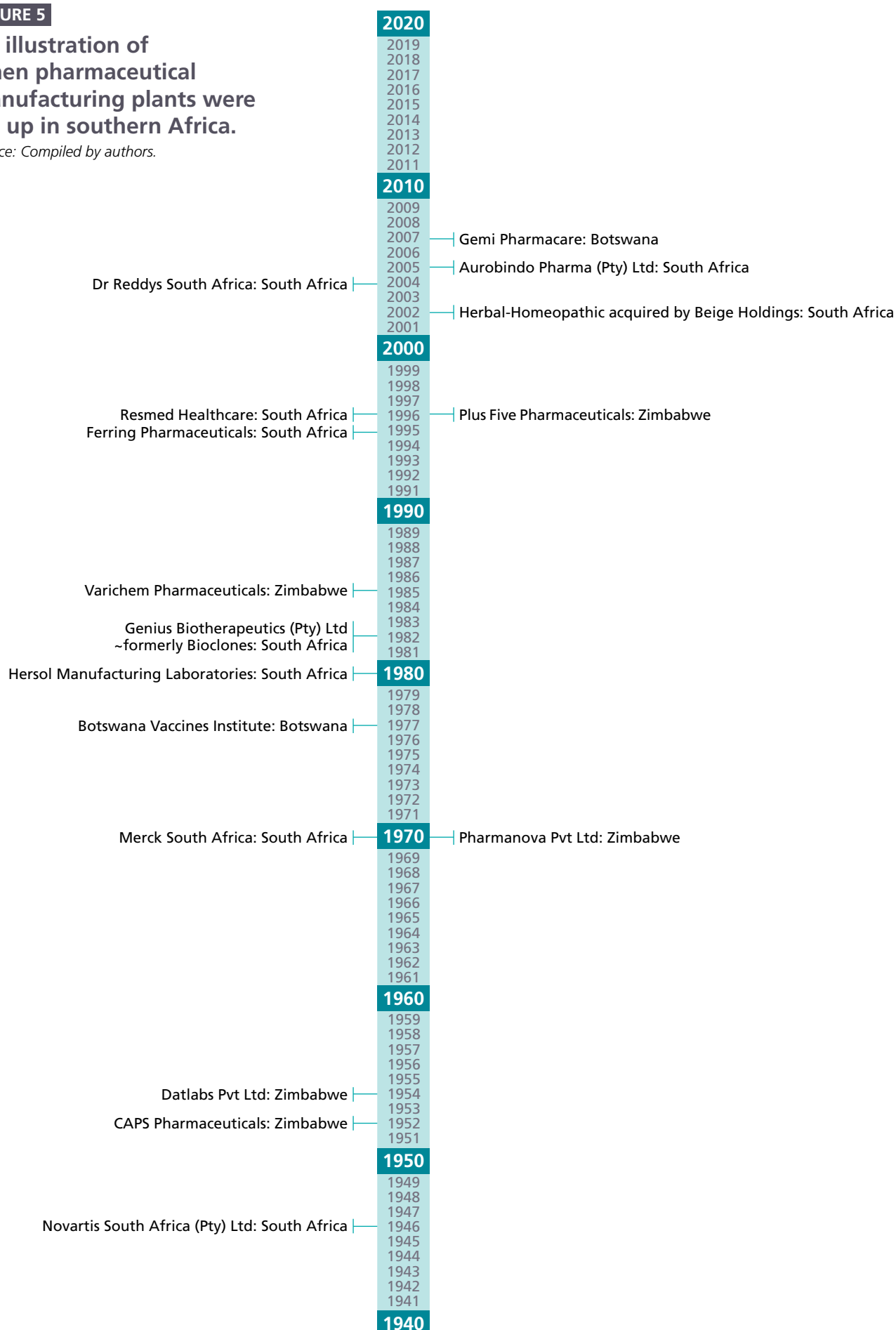


FIGURE 5

An illustration of when pharmaceutical manufacturing plants were set up in southern Africa.

Source: Compiled by authors.



4.2. Vaccines and drugs manufacturing footprint

In this study, we established that, currently, at least 29 countries have varying drug manufacturing capabilities, and of these, four countries (Egypt, Senegal, South Africa and Tunisia) have vaccine manufacturing capabilities (Figure 6).

- There are at least 649 manufacturing plants on the continent, with North Africa having the largest share at 272, followed by West Africa, which has 178 plants; southern Africa has 139 plants, and East Africa has at least 60 manufacturing plants (Table 2).²
- The countries with the highest number of manufacturing plants are South Africa (122), Egypt (120) and Nigeria (150), followed by the next strata – with 30 to 60 plants – composed of Algeria (55), Tunisia (39), Kenya (35), Morocco (33) and Ghana (30). The next strata, with fewer than 30 plants, includes Sudan (25), Cameroon (15), Ethiopia and Uganda (11), and the rest with fewer than 10 plants.
- Table 2 shows regional hubs for pharmaceutical production: Ghana and Nigeria for West Africa, and Kenya in East Africa, with Ethiopia and Uganda as key players. South Africa is the main hub for southern Africa, with Zimbabwe having been a key player in the past. North Africa shows a vibrant sector. In terms of numbers of plants, Egypt ranks first. North Africa outranks all regions on number and complexity of formulations and technological capabilities. The local industry in North Africa has leveraged joint ventures to facilitate technology transfer and move upstream in terms of drugs and biologics.

FIGURE 6
The African pharmaceutical manufacturing footprint



Source: Banda et al. (2022).

2. The numbers of plants may vary per country at any one time because some of the sources (governments, companies or international NGOs) that we used to get an estimate had contradicting numbers in some cases.

TABLE 2.

Number of manufacturing plants in each country shown by region

WEST AFRICA		EAST AFRICA		NORTH AFRICA		SOUTHERN AFRICA	
Benin	1	Burundi	2	Algeria	55	Angola	2
Burkina Faso	0	Djibouti	0	Egypt	120	Botswana	0
Cape Verde	1	Eritrea	2	Libya	No production ³	Lesotho	0
Côte D'Ivoire	5+	Ethiopia	11	Morocco	33	Malawi	3
Cameroon	15	Kenya	35	Sudan	25	Mozambique	2
Gabon	0	Rwanda	0	Tunisia	39	Namibia	0
Gambia	0	Somalia	0	Western Sahara	0	South Africa	122
Ghana	30	South Sudan	0			eSwatini	0
Guinea	1	Tanzania	4 ⁴			Zambia	5
Guinea-Bissau	0	Uganda	11			Zimbabwe	5
Liberia	No production						
Mauritania	0						
Mali	2						
Niger	Unknown						
Nigeria	150						
Senegal	5						
Togo	3						
Total	213+	Total	65+	Total	272+	Total	139+

Source: Compiled by authors including reference to Coulibaly (2018) and WAHO (2014).

Countries with high pharmaceutical manufacturing activities have actively supported the sector. In Morocco, for example, the pharmaceutical sector is the second largest after the phosphates industry and ranks second on the African continent (Ministère de l'Industrie et du Commerce, n.d.). The industry is composed of MNCs with local subsidiaries that manufacture originator brands and generics. Morocco is one of the success stories of local production. As far back as 2012/13, local pharmaceutical production met 70% of domestic demand.

Further details on the status of manufacturing capabilities are given in the case studies of Egypt, Ghana, Kenya and South Africa (Annexes 1-4).

3. All pharmaceutical manufacturers in Libya ceased operations because of the war – all healthcare demands are met by imports.

4. These are companies producing prescription drugs only; there are seven, including over the counter drug producers.

THE LOCAL PHARMACEUTICAL DRUGS SECTOR

The local drug industry on the continent is characterised by generics manufacturers. Most generic medicines consumed in African countries are branded generics produced either locally or in India (see example data in the case studies), since branded originator drugs command much higher prices. The bulk of these generics can be split further into lower- and medium-priced generic drugs depending partly on when they came off patent and the competition in the market. African generics producers brand their drugs, as do the MNC's based in the high-income countries (HICs) that brand their originator drugs as they come off patent.

There is minimal API production, except for South Africa where the APIs for paracetamol, codeine, and a cancer drug are produced. The local production of APIs in South Africa has survived because of policies that banned imports of finished paracetamol because it is locally manufactured. Without that support, a respondent reported that the paracetamol API manufacturing operations could have failed.

5.1. Technologies and therapy lines

There are varying technological capabilities for drugs, and prevalent technologies in use in pharmaceuticals include tablets, capsules, powders, injectables, suspensions, topical applications, parenterals, and sprays. Therapy lines span infectious and non-infectious diseases. The technologies and therapy lines present on the continent are shown in Table 3.

TABLE 3

Technologies, therapy lines, vaccines, biologics and other technologies produced across the African continent

Technologies	Therapy Lines
• Tablets • Gelatin capsules • Powders • Injectables • Granules • Ampoules and vials • Effervescent sachets • Syrups and suspensions • Topical preparation • IV fluids • Large-volume parenterals • Sprays • Fixed Dose Combinations • Slow release formulations	ANTI-INFECTIVES • Antibiotics • Antimalarials and other antiprotozoals • Antiretrovirals • Antifungals • Anti-tuberculosis OTHER MEDICATIONS • Antihistamine • Anthelmintics • Analgesics • Gastrointestinal medicines • Erectile dysfunction agents • Anti-hypertensives • Cardiovascular agents • Anti-diabetic • Cold and flu preparations • Asthma • Dermatologics • Anti-nausea • Anti-inflammatory • Antispasmodics • Cough suppressants • Antidepressants • Anti-psychotics • Ophthalmic • Haematology • Radiology • Musculoskeletal • Multivitamins

Source: Compiled by authors from company websites and interviews.

Reflective of the prevalence of infectious disease, a significant portion of therapy lines cover bacterial, fungal, and viral infections. There has been an acknowledgement of the demographic shift in diseases and the gradual rise of non-communicable diseases severely impacting health systems in recent decades. However, as revealed in a separate research project, there are still challenges of local production of critical life-saving drugs, especially in cancer care. These highly toxic drugs require particular modes of production, production staff health, and safety assurances, as well as environmental protection.

5.2. Business models and ownership in the African local pharmaceuticals sector

Drawing on previous work, we define business models as ‘frameworks of understanding the logic of an enterprise, that is, how it creates and appropriates value from unique product(s), and service(s) offering(s)’ (Banda et al., 2018). A business model explains how a firm, using a unique value proposition, can position itself in a market to appropriate that economic value through provision of products or services. In other words, a business model explains why and how the enterprise exists and continues to ensure its economic sustainability or longevity. There is, however, a lack of consensus on the theory of business models. Consequently, there are multiple interpretations and applications of the business model concept (Al-Debei and Avison, 2010; Chesbrough and Rosenbloom, 2002). Nonetheless, the concept of a business model is still a useful framework for understanding the logic of an enterprise, how it creates and appropriates (economic) value and how it assures sustainable revenue inflows and profitability (Banda et al., 2019).

There are four fundamental elements of business models: architecture/structure, value creation and extraction, networks and linkages, and governance. The business model approach of authors such as Osterwalder et al.

Eye drop production, Kikuyu Eye Unit, Kenya
(Photo: Ulrich Doering / Alamy Stock Photo)



The bulk of business models on the African continent are based on the generic-drug business model, which is premised on low-value products and therefore requires a low-cost base for competitive success and business sustainability.

(2005) focuses on cost structures and revenue streams as the ‘logical frame’ for organising cost and revenue drivers of a firm. How firms manage their revenue and cost structures determines how good they are at creating and extracting value (Banda et al., 2019). We distinguish here between the business models typical of production of basic essential generic medicines, and business models for the production of innovator drugs. The bulk of business models on the African continent are based on the generic-drug business model, which is premised on low-value products and therefore requires a low-cost base for competitive success and business sustainability. Pricing of generic drugs – that is, those which are off-patent – are generally constrained by open competition, and for African-based manufacturers, the main competitors are large Indian multinational firms with high technological capabilities which export from a high-volume, low-cost Indian base, often benefitting from substantial export incentives and organisational capabilities in India (Chaudhuri et al., 2010; Wangwe et al., 2021).

In many African countries, the industry is composed of small to medium enterprises (SMEs), with MNCs more prevalent in North Africa and South Africa. As a result of the low prevalence of MNCs, there is little influence of western MNCs on the continent. Indian MNCs are more prevalent in terms of establishing subsidiaries and trade with local SMEs with particular respect to APIs, excipients and finished formulations. These arrangements provide scope for technological learning in the local subsidiary through intra-company technology transfer. In South Africa, de-investment by MNCs and local acquisition of those entities has provided technology transfer and know-how that has helped the industry transition more easily to complex technologies.

Relatedly, the pharmaceutical industry in SSA, outside the protected South African market, is strongly characterised by family firms. In some sense, these form an African ‘mittelstand’, comparable to the German small- and middle-sized firms that are the backbone of much of German industry. These are famously characterised as stable, innovative firms with strong generational control, able to withstand economic headwinds. The African firms are survivors: they have sustained a life-saving industry through the economic turbulence of the 1980s and 1990s and are still the backbone of the industry. This is not a ‘new’ industry. Its product range is limited and its technology relatively low-level (Table 2 2 and Table 3). However, the firms are the bedrock of the industry and its basis for expansion. They have created the industrial clusters on which industrial policy and new entrants can build. These predominantly family-owned businesses should therefore not be underestimated, having carried the industry through severe economic crises and helped to mitigate the cost impacts of high-cost finance and poor local infrastructure.

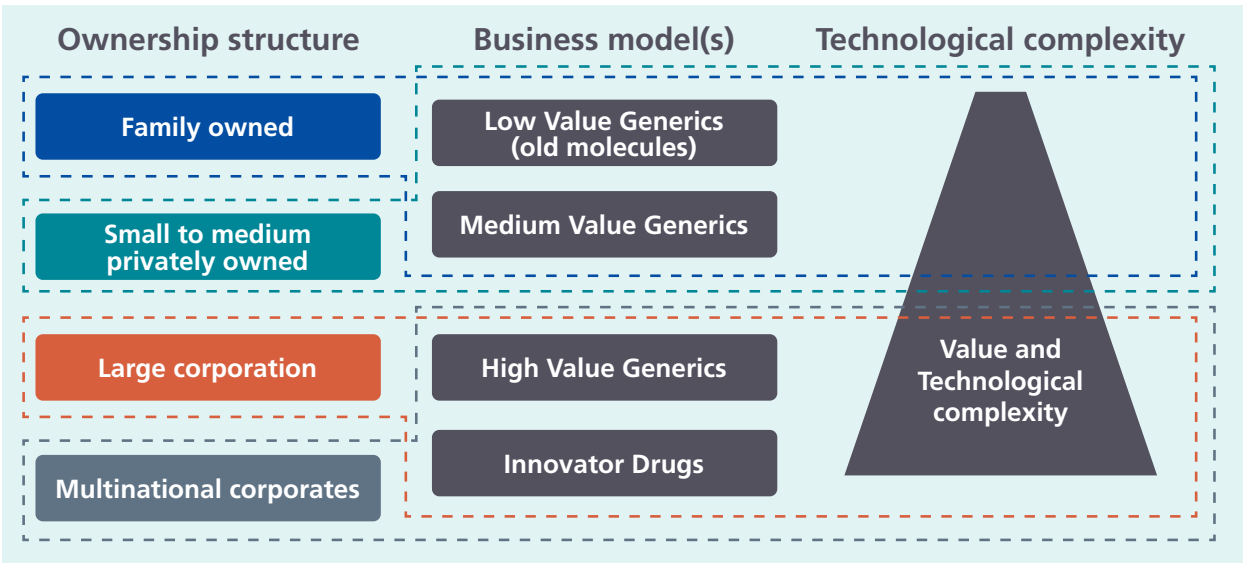
However, the business model of these family firms also has its limits, which are tested when firms need to upgrade their technological capabilities in order to survive intensifying competition, and to expand their range (Wangwe et al., 2021). While these family-owned, often conglomerate, businesses are resilient to economic shocks, their business model can restrict their appetite for new projects, thus losing out on technological upgrading and expansion. Family-owned businesses may fear loss of control and hence be reluctant to expand, as explained by agency theories in management where owners are reluctant to relinquish control to professional managers who may have no equity in the business. These firms now face important competitive challenges and substantial new opportunities, especially in the wake of Covid-19. Their key requirement is technology transfer to enable wider product ranges, larger scales, upstream investments and more complex, internationally accredited production systems. Can they adapt? What does the evidence suggest?

As technological complexity increases in pharmaceuticals, the number of competitors generally falls, so that, for example, the majority of essential oncology medicines, though long off-patent, are still produced and exported by relatively few firms in India, resulting in prices higher than would be expected relative to their costs of production (Chaudhuri 2021).

Pricing in innovator drugs – those under patent and hence subject to monopolised production – is high and constrained only by how much health systems⁵ are willing to pay for the patented drug. Thus, value creation and appropriation for the innovator drug is based on a legalised monopoly (a patent) that allows high prices on the back of claims of spending more than US\$1 billion in R&D to bring a drug to market. The large European and US-based MNCs thus focus on innovator drugs producing high profits per item, while the international generics market is dominated by Global Southern-based MNCs, mainly Indian-based but also including Aspen, a South African-based multinational that is one of the largest generics producers in the world.

These business models are linked to ownership structures in ways that pose a challenge for technological upgrading. Figure 7 summarises this patterning of business models and ownership in pharmaceuticals. The family-owned and privately-owned SMEs are active in the generic (lower- and medium-value) drug business model, whereas the large corporates and MNCs are active in the higher-value generics and innovator drugs. Public sector firms are active in the generics business model and in the area of vaccines, in the countries where there is vaccine production. There are few North American and European MNCs actively manufacturing in SSA, though there is some production under licence. These MNCs have a stronger presence in North Africa and South Africa. Elsewhere, their limited footprints are seen through importer-distributorships in East and West Africa. Joint ventures are common in countries such as Tunisia, which has 39 pharmaceutical manufacturing companies. Technological complexity also increases with the business model typology, as depicted in Figure 7. The third element of business models – networks and linkages – is evident especially amongst the family-owned and SME sector. For example, in East Africa, family-owned firms generally have extensive overseas partners, networks and associated firms, especially in India. These networks are important in value creation and appropriation, as well as for architecture/structure and governance.

FIGURE 7
Four business models and attendant ownership structures prevalent in the African pharmaceutical sector



5. Broadly defined, a health system ‘consist[s] of all organisations, people and actions whose primary intent is to promote, restore and maintain health’ (WHO, 2010).

It follows that, as firms attempt to move into more technologically complex products, the business models and ownership patterns in pharmaceuticals may change. Table 4 below summarises the evidence in this paper on the ownership structures in medical manufacturing more broadly in Africa; the cases of vaccines and medical devices are discussed further below. In basic generics, the dominant family-ownership pattern is being eroded by spin-off joint ventures with external Global South-based multinationals, by direct foreign investment in the form of partial and 100% buyouts, and by new greenfield investments. The multinational firms involved include large Indian, Chinese and Bangladeshi firms expanding into African production. A special case is Aspen, the only large African-based multinational in this industry, which is rapidly expanding its African footprint through investments outside South Africa, having previously concentrated on developing a multinational presence outside Africa. Other patterns are also emerging: rising investments from private equity; shifts to incorporation and quotation on local stock exchanges; and new public sector investments.

TABLE 4

Intersection of technological complexity, business model and ownership structure in African medical manufacturing

TECHNOLOGICAL COMPLEXITY	OWNERSHIP STRUCTURE						
BUSINESS MODEL	Family network /SME	Public sector	Private equity	Public-private partnership (PPP)	Publicly quoted MNC	Private joint venture	Overseas FDI
Basic generics	X	X	X	X		X	X
More complex molecules	X		X	X	X		X
Basic medical devices	X		X	X	X		
More complex medical devices	X					X	
Biotechnology/ vaccines		X		X		X	X

A wide range of business models and ownership structures can facilitate essential technology transfer critical for the technological transitions required to enable international competitive success. However, the essential element is international networks and linkages. Successful firms are building those networks and linkages, for technology transfer and exporting success, in a wide variety of models. Examples of how these linkages are developing in sub-Saharan Africa include:

- A wholly-owned *family firm*, in an export processing zone, producing a new product (single-use syringes) with support from an external foundation, with WHO prequalification, now successfully exporting to markets including Europe, Asia, other African countries and large UN procurement bodies;
- A *joint venture* between a local African distributor and a Chinese manufacturer to produce capsule shells for final formulations, now exported widely across Africa, including South Africa;
- A *joint venture*, established as a separate entity, between a local African producer and a Japanese technology owner, to produce WHO-prequalified insecticide-impregnated bed nets, sold largely to philanthropic procurement bodies;
- A buyout by an *African venture capital group* aiming to create a group of pharmaceutical companies in several countries that could share technology and raw materials procurement to keep down costs for generics;
- A *51% buyout by an Indian pharmaceutical MNC of an African family firm*, bringing new products and technology;

- A *100% buyout* of a previous joint venture by an Indian pharmaceutical MNC, aiming to widen the product range;
- *Foreign direct investment by a Bangladeshi MNC*, aiming to produce a wider product range, that includes cardiovascular and diabetes medicines, than the local firms.

In addition to these linkages, we are also seeing the emergence of more long-term government investment to support ambitious upgrading and development of complex products such as vaccines or APIs. There are, therefore, public-private joint ventures with similar aims, leveraging and enhancing existing capabilities to address supply gaps. The medium- to long-term impact and sustainability of these ventures would be important to investigate in future studies.

While international linkages are essential, not all work out well. Here are a few warnings from the evidence:

- Beware of venture capital with short-term aims, which can asset-strip companies that are potentially successful. The risk is that products that currently aren't profitable, but which have huge future potential are de-emphasised through portfolio-management strategies. One of the companies we interviewed had been working on locally producing APIs for azithromycin. This pilot project was shelved, yet when Covid-19 emerged, azithromycin was in high demand. Furthermore, local manufacturing of antibiotics on the continent has been in decline and de-emphasising local production of an antibiotic API was not the most strategic thing to do.
- Beware of overseas buyouts which aim to strip out less profitable, though lifesaving, lines to increase margins rather than upgrade. One of the companies studied in previous work had seen many basic essential generics removed from production by the new (Global South MNC) parent company since, although contributing to cash flow, they did not meet the profit objectives.

Business models, ownership structure and technological complexity thus form a critical triad for understanding the type of local production dynamics that have to be built to contribute to pandemic responses, addressing medical emergencies, and future-proofing African countries' health systems for access to medical health technologies and products. New business models and different or enhanced ownership structures that drive innovation and technological capability upgrading are required for building local health security on the continent.

5.3. Opportunities for technological capability upgrading

We argue for the continuing importance of valuing and protecting local capabilities to manufacture basic generics that save lives, including antibiotics, other anti-infectives, diuretics and antidiabetic medicines, while also expanding and developing more complex capabilities. One interviewee noted that the danger of the current Covid-19 pandemic response is to produce a knee-jerk reaction with a rather myopic focus on vaccines evident at the moment, whereas diseases that kill more people are ignored because they are neither in the public conscience nor do they receive widespread exposure in popular and social media.

In addition to sustaining the production of life-saving basic generic medicines, two aspects of technological upgrading in pharmaceuticals deserve careful attention: API manufacture and transitioning to technologies that are more complex.

API manufacture

Global production of APIs is concentrated in China. Covid-19 generated a very sharp rise in prices of APIs, and cut off imports of inputs for African manufacturers. This experience accelerated recognition of the need to have more distributed API production systems (Banda et al., 2021a). However, API manufacturing requires efficient waste management systems to avoid environmental contamination. It also requires high energy input, as well as a consistent supply of starter materials for fermentation and organic chemistry manufacturing processes.

Our analysis shows that there is an urgent need to transition to more complex technologies.

Sen (2020) details how China built its API manufacturing capabilities by offering attractive land deals, effluent treatment plants and cheap power to MNCs that could set up joint-venture API operations in-country. He argues that the fermentation processes required for producing bulk drugs was both power intensive and extremely polluting to the environment. By offering land deals and effluent and water treatment plants free of charge to MNCs, the Chinese attracted the Dutch (DSM NV) to move their API manufacturing to China. With time, more MNCs attracted by such incentives moved to China, and, over three decades, China built up its capabilities in API manufacture to become the dominant supplier to the world. It is important to note that there was a strong science-and-technology base in China that supported the rise of API manufacturing.

Establishing API manufacturing plants on the continent requires strategic technology transfer from leading API manufacturers, incentives on land acquisition and energy costs, and provision of treatment plants for effluent and water processing. Specialised pharmaceutical parks are one of the avenues that could be pursued. This calls for sustained effort and resource allocation by the state to support the emergence of this sub-sector. In the era of sustainable development goals, care should be taken to ensure sustainable industry development. Emzor in Nigeria has signed an MOU with an Indian manufacturer for API production in Nigeria. A respondent whose company had started a pilot project to produce APIs reported that there is an unnecessary mystification of API production, with the often-repeated message that it is (too) complex. The respondent said API manufacture for drugs is, on the contrary, 'simple organic chemistry', and there was a need to support the development of organic chemistry skills. They went on to report that what was needed was a 'can-do' attitude. Their company had successfully piloted the production of azithromycin APIs as proof of concept. They partnered with a company in India for technology transfer and engaged a consultant to localise the skills. However, to be sustainable given the low-value nature of the product, the manufacturer needs to produce huge quantities to achieve the scale required for profitability.

Localisation of API manufacture will also require governance capabilities, designing of appropriate industry development incentive schemes, coordination of learning, stimulating technological change and monitoring progress. South Africa launched the Ketlaphela project in 2011. Ketlaphela was set up to produce APIs for the most prevalent diseases in the country: TB, HIV/AIDS and malaria. Ketlaphela was established as a subsidiary of Pelchem SOC, which in turn was a subsidiary of NECSA (Nuclear Energy Corporation South Africa). Early plans focused on a public private partnership with the Swiss company Lonza, but Lonza later withdrew. The government could not find a new partner. Thereafter attention shifted to Ketlaphela to produce ARV and other drugs APIs (Sowetan, 2021). However, this government initiative has not taken off to date. This is important because it shows the complexities and difficulties of engaging in these highly political-technical projects.

Transitioning to newer and more complex technologies

Our analysis shows that there is an urgent need to transition to more complex technologies. Covid-19 demonstrated the need to manufacture new types of vaccines and, for clinical settings, advanced diagnostics and medical devices. In terms of addressing pressing medical challenges, there is a need to transition to newer drugs, for example, for HIV and cancer. In a separate research project, we found no local production of oncology drugs that are already off patent. We are aware that transitioning to local production of oncology drugs entails plant re-designs in order to address issues of toxicity to the workers and waste management. However, if the industry ventures into API production, they will still need to address environmental safety issues as well as health and safety for staff handling potentially carcinogenic or toxic starting or intermediate raw materials and finished products.

Transitioning to newer technologies will entail rethinking the precursor knowledge and technology systems, how they are nurtured to mature, and the governance, policy and operational environments in which they operate. Backward integration and transitions to more complex and newer technologies represent technological change that can lead to creative destruction. Incumbents, including local manufacturers entrenched in importing finished products, may feel threatened and block the rise of the new entrants. Policy and institutional mixes should anticipate incumbent resistance through political reach or regulatory ratcheting. Specific industrial development frameworks and incentives should be designed to support nascent and emerging innovative sectors.

The firms that engage in transition to new technologies need to develop firm-level technological capabilities, namely investment (pre-investment and project execution), process engineering, product engineering, industrial engineering and linkages within the economy, as discussed by Lall (1992). Companies may not have all these capabilities in-house. They can engage in learning efforts through joint ventures, collaborations with knowledge-development institutions, or acquisition of existing companies elsewhere, including offshore entities, to bring technological capabilities in-house.

Assured procurement of new technologies and fast reimbursement are important pull factors for technological transitions. Assured markets and commensurate compensation of innovators, including intellectual protection, is the bedrock of technology transitions, especially in the healthcare system. Demand for medicines is one of the drivers, and this, as well as other factors relating to pricing, sits at the interface of many factors, including but not limited to levels of competition in the market, mechanisms and incentives for controlling prices, and bargaining power between buyers (public health sectors) and sellers (manufacturers). Therefore, a sustainable well-funded health system including health insurance is important for the use of procurement as an active industrial policy tool and signalling mechanism for entrepreneurs and innovators to engage in risky technological change for the benefit of patients.

Leveraging intellectual property (IP) opportunities

Our ongoing research projects show that the vast majority of drugs required to meet health challenges on the African continent are off-patent. Patents do two things: they protect new innovations, but, by the nature of patents, they also reveal knowledge and pathways for producing a technology. We are aware that patents do not reveal anything; however, they are a source of learning for innovators who want to copy a technology. Many African companies have not taken advantage of this opportunity to grow their portfolios and start to target wealthy countries. India has taken advantage of this opportunity and has grown significant technological capabilities in reverse engineering generics and biosimilars.

Achieving the aforementioned capabilities, however, requires functional research and development ecosystems with linkages and collaborations with universities, standards and other regulatory bodies, and knowledge sharing across companies and countries. Some companies have used the licensing-in of new technologies and thus transitioned to more complex drugs or vaccines. Until such a time that local R&D has grown to engage in radical innovations, there are still opportunities in targeting soon-to-be off-patent drugs or vaccines and moving up to more lucrative products targeting exports. The profits generated from such activities can be channelled back into more R&D.

5.4. Infrastructural challenges

The pharmaceutical sector faces huge hard and soft infrastructural challenges. Under hard infrastructure, the key challenges pertain to access to good quality potable water, uninterrupted electricity supply, transport and communication networks, and access to ports for exports and imports. This forces companies to invest in

alternative infrastructure, which raises costs of production. A Zimbabwean company invested in a generator that used up to 200 litres of diesel a day, and this raised production costs. Some companies have had to sink boreholes because of unreliable municipal water supplies. For a more comprehensive discussion of hard infrastructural challenges, see Mackintosh et al. (2016).

The soft infrastructural challenges include economic and social infrastructure. Economic soft infrastructure includes regulators and regulatory frameworks (see Section 8), tariff regimes and competition policy, amongst others. The social infrastructure includes laws and regulations, as well as other norms and cultures that drive, for example, generation of trust and social capital.

These infrastructural challenges can be resolved to some extent by development of national-level technological capabilities. National-level technological capabilities can be broadly classified into three categories: capabilities, incentives and institutions (Lall, 1992). Under capabilities, national governments need to engage in physical investment, human capital development, and technological effort. These are supported by macroeconomic incentives and incentives for promoting competition, as well as harnessing factor markets. This category covers the soft infrastructure of interest rates, exchange rates, and credit provision, as well as availability of foreign currency for importation of plant, equipment and machinery. Political stability is a critical macroeconomic incentive. Institutions, as rules of the game, are critical for providing legal institutions, IP rights protection, and institutions important for inter-company linkages (Lall, 1992). Support institutions for knowledge generation and exchange are critical for emerging sectors.

Industry experts in interviews argued that the sector used old technologies, and there was no investment to upgrade the facilities to introduce new platforms for vaccine manufacture.

6

VACCINES

This study and our earlier work on making medicines in Africa confirm the importance of examining the sector's historical trajectory and footprint as a way of deepening understanding of the challenges and opportunities for the sector. According to the emerging data we have, vaccine manufacturing is the oldest pharmaceutical industry on the continent, and, after Covid-19, vaccine projects have assumed a hugely political-technical nature because of the situation African governments found themselves in when they could not procure vaccines. Institut Pasteur de Tunis, Vacsera in Egypt and Institut Pasteur de Dakar are the oldest entities which were established as state organisations in 1893, 1897 and 1896 respectively (Table 5). Although Aspen Pharmacare predates them (it was established in 1850), its earliest activities were as a druggist and the company only ventured into vaccines recently. Biovac, a joint venture-PPP between the South African government and the Biovac Consortium, was established in 2003. However, South African state-owned vaccine manufacturing institutions – the State Vaccine Institute established in 1965, the South African Institute of Medical Research (SAIMR) established in 1935, and the National Institute of Virology established in the 1950s, all predate Biovac. The State Vaccine Institute used to manufacture BCG, rabies and smallpox vaccines, whereas the SAIMR produced DPT, polio and cholera/typhoid vaccines. The National Institute of Virology used to produce oral polio vaccine (OPV) and yellow fever vaccine. These three institutions were all closed down in the early 1990s as a result of technological knowledge senescence. Industry experts in interviews argued that the sector used old technologies, and there was no investment to upgrade the facilities to introduce new platforms for vaccine manufacture.

6.1. Current capabilities

Table 5 on the next page shows current capabilities of vaccine manufacturers in the only four countries active in producing vaccines. Ampofo (2021) reported that there are fewer than ten African vaccine manufacturers in five countries: Egypt, Morocco, Senegal, South Africa and Tunisia. However, Morocco ceased operations in 2001. They are engaged in fill and finish and not upstream production processes. They focus on internal markets and rarely export, except for yellow fever vaccinations (AVMI VMPA, 2017). The VMPA study by the African Vaccine Manufacturing Initiative (AVMI) reported that setting up a vaccine manufacturing plant costs between US\$60 million and US\$300 million, with capital expenditure accounting for more than 60% of the costs. However, the report acknowledges that new technologies may not be as capital intensive and may be cheaper to set up. Algeria, Morocco, Ethiopia, Kenya (The East African, 2021 Kemri, 2021) Uganda and Nigeria are some of the countries planning establishment of vaccine manufacturing initiatives. Morocco, on the back of the Covid-19 pandemic, has accelerated plans for re-establishing local vaccine manufacture by engaging in agreements for technology transfer with Swedish contract development and manufacturing organisation Recipharm, as well as Chinese Sinopharm. Ethiopia, on the other hand, has capabilities to produce rabies vaccines using the Fermi technology, which was reported to be an old technology, and consequently the country is set to acquire cell-culture equipment for production of meningitis A, C, and W vaccines (AVMI VMPA, 2017).

TABLE 5

Vaccine manufacturers and the products manufactured locally

Country	Organisation	Established	Vaccines Manufactured
Egypt	Vacsera The only producer of vaccines and sera and one of the main blood banks.	1897	· Tetanus Toxoid Vaccine · Diphtheria and tetanus toxoid vaccine [paediatric and adult use] · Diphtheria, tetanus and pertussis · Meningococcal vaccine · Cholera vaccine · Typhoid vaccine <i>Planning to produce Sinovac vaccines.</i> <i>A new vaccine facility outside Cairo will have capacity for 1 billion doses per annum.</i>
Senegal	Institut Pasteur de Dakar 'A non-profit association for public utility' with more than 80 years of vaccine production.	1896	· Yellow fever – since 1930s <i>One of four WHO-approved manufacturers of yellow fever vaccine in the world.</i>
South Africa	Aspen	1850; went public in 1997	· Johnson & Johnson Covid-19 vaccine. First Covid vaccines manufactured (fill and finish) on the continent.
	Biovac	2003 as a PPP	· BCG for TB · Measles vaccine · Pneumococcal conjugate vaccine · Hepatitis B Vaccine · Hexavalent vaccine for diphtheria, tetanus, pertussis, poliomyelitis, haemophilus influenza B and hepatitis B · Tetanus toxoid vaccine <i>Agreement to produce Pfizer Covid-19 vaccine (fill and finish).</i> <i>Guillain-Barre syndrome (GBS) vaccine development.</i>
Tunisia	Institut Pasteur de Tunis	1893 commissioning of establishment	· BCG vaccines – intradermal BCG and fresh BCG for immunotherapy (bladder tumours) <i>Under development – rabies vaccines for human and veterinary use and bacterial vaccines for veterinary use (mixed anthrax and enterotoxemia).</i>

Source: Compiled by authors from company websites, Institut Pasteur de Dakar, Aspen, Mukherjee (2021), and other grey literature.

The only countries with drug substance manufacturing capabilities are Senegal and Egypt. The next two levels of capability – fill and finish and packaging and labelling – are operational in four countries: Senegal, Egypt, Tunisia and South Africa. Egypt, South Africa, Algeria, Morocco and Ethiopia import vaccines for distribution, although some of these countries have advanced plans for local manufacture (AVMI VMPA, 2017). Relatedly, Tunisia produces anti-scorpion serum, antiperin serum (an effective antiserum for the venom of two types of viper), and rabies serum. Egypt produces polyvalent anti-viper-venom serum, polyvalent anti-scorpion serum, and polyvalent snake venom antiserum. In addition, Egypt also produces human insulin, leucogen and bee venom for rheumatoid arthritis, as well as BCG-T, an immunotherapy against bladder cancer.

The platforms in use for development and production of vaccines include bacterial, viral and egg platforms. However, recently a number of initiatives by the Partnership for Vaccine Manufacturing in Africa (PAVM), led by the Africa CDC, AVMI and others, are lobbying for local production capabilities to be accelerated, and countries such as Ghana, Rwanda, Senegal and South Africa have announced funding for vaccine manufacturing infrastructure. However, the key challenges for expanded local vaccine manufacture are not only technical but also procurement and policy related. The AVMI VMP Study (2017) argues that, unless local procurement – that is, purchasing of locally-manufactured vaccines (assured market, see Section 5.3) – is resolved, local manufacture will remain a difficult business case to sell to funders. In 2017, 37 African countries were approved for pentavalent vaccine support by the Global Alliance for Vaccines and Immunisation (GAVI). However, a number of countries are graduating from GAVI support and will have to find ways of funding vaccine programmes. Kenya, for example, is discussing its ‘graduation’ from UNICEF support to more locally funded buying. We have argued previously that innovative procurement, as active industrial policy, is important for shaping the local health-industry complex (Chataway et al., 2016; Mackintosh et al., 2018) and providing a technological upgrading impetus to local companies based on assured markets for local products.

6.2. New vaccine technologies

The onset of Covid-19 resulted in more concerted efforts to rapidly upgrade technological capabilities in vaccine manufacture. For example, Egypt is the hub for production of the inactive virus vaccine, Sinovac, and has a production capacity of 200 million doses annually. Aspen in South Africa is producing (fill and finish) the Johnson & Johnson viral vector vaccine, and their annual production capacity is 200 million doses. Fill and finish is the process of filling vials with an already-manufactured vaccine (or medicine) and finishing the process of packaging for distribution. It is common practice in the pharmaceutical industry for this downstream, yet critical, part of the process to be subcontracted to third parties who have special capabilities for that. This stage, which serves to expand and shorten distribution chains, can also serve as a launch pad for development of upstream capabilities in bioprocessing and product formulation.

As of September 2021, South Africa, Egypt, Algeria, Morocco, Senegal and Nigeria were in patent or production agreement arrangements. In Egypt, Vacsera went into an arrangement with China to produce Sinovac. Minaparm and BioGeneric partnered with Russia to produce Sputnik V. Saidal in Algeria partnered with Russia and China to produce Sputnik V (15 million doses) and Sinovac (15 million doses) respectively. In Morocco, Sothema is producing Sinopharm (60 million doses), Galencia is reported to be in partnership to produce Sputnik V, and Recipharm has an unsigned vaccine patent agreement. In Senegal, there is an unsigned patent agreement with Foundation Institut Pasteur de Dakar for drug substance manufacturing and plans to build a Covid-19 vaccine facility. South Africa, on the other hand, has two entities: Aspen and Biovac Institute, producing 500 million doses for Johnson & Johnson and 100 million doses of the Pfizer-Biontech vaccines respectively (Usman and Ovadia, 2021). Recently, Afrigen Biologics, in conjunction with the WHO and other partners, reverse engineered an mRNA vaccine. These are fill and finish operations in South Africa, whereas Egypt has drug substance manufacturing as well as fill and finish. Algeria has both fill and finish and drug substance manufacturing capabilities. Morocco does fill and finish for Sinopharm. Countries with plans to build vaccine manufacturing facilities include Morocco, Nigeria, Ghana, Rwanda, Kenya and Senegal.

Overall, the recent activities signal some appetite for upgrading. However, as discussed earlier, institutional and infrastructural settings require rethinking and redesigning. Business as usual will not support the development of newer vaccine technologies. Joint ventures are a viable route for technology transfer, and regulatory capabilities need to be enhanced as well as procurement, and reimbursement systems.

7

MEDICAL DEVICES: IMPORTANT BUT NEGLECTED

The medical devices sector, like the vaccine manufacturing sector, is among the most under-studied on the continent. Generally, there is a high reliance on imports across different countries. Local production is patchy. However, given the underlying metal and plastic manufacturing capabilities on the continent, there are huge technological opportunities in the medical devices sector. Its rapid emergence and prevalence will depend on careful structuring of a technological innovation system that supports the seven component areas of entrepreneurial activity: knowledge development, knowledge diffusion, guidance of search, resource mobilisation, market formation, and legitimisation. As for other medical technologies, innovative procurement by the public health system is one of the industrial policy tools that can be used to support the sector.

7.1. Patchy production

In most African countries, more than 90% of the medical devices in public hospitals are imported, with very limited local production (Mkwashi, 2020). The high reliance on imports presents an appealing opportunity for domestic manufacturers. Moreover, most medical devices cannot be serviced and maintained locally, given the lack of local infrastructure (Lustick and Zaman, 2011). For example, the WHO (2016) conducted a detailed analysis of medical device policies from selected countries in Africa (Ethiopia, Nigeria, South Africa and Tanzania) to identify opportunities for the development of local medical devices. The study found that there was a limited local manufacturing capacity and design mechanism to incentivise manufacturers to engage in the production

Hospital equipment and medical devices in a modern operating room.
(Photo: JLBvdWOLF / Alamy Stock Photo)



Few domestic companies with manufacturing facilities in South Africa have successfully developed medical devices that are on par in terms of quality with existing products that require complex technical know-how to manufacture

of priority medical devices. The same study revealed that there was a lack of funds for R&D and support to bring products into the market and to final users that could be of high public health value. Another study by Maharaj and Sunjka (2019), on a strategic framework for start-up medical device manufacturers in South Africa, highlighted that local medical device manufacturers were not starting up in South Africa due to the high capital investment required, the prohibitive and unaligned regulatory framework, brand representation and the unwillingness of end users to switch to smaller brands, and cash flow and liquidity problems.

Evidence from our synthesis of survey data, interviews, case studies and literature highlighted the following as the key challenges faced by medical device manufacturers in their on-going quest for local production: MNCs' dominance in the medical device industry; lack of funding and incentives for manufacturers; high cost of regulatory compliance; import duties on components which are often higher than the price of finished goods; and unavailability and unreliability of raw materials from local suppliers. We will explore the first three issues in detail below, while positing here briefly that the last issue, availability of reliable local suppliers, is the broader and pervasive issue which has resulted from, and will be resolved through, consistent financial and policy support for a broad range of local actors who are key for the medical device ecosystem.

7.2. MNCs' dominance in the medical device industry

In South Africa, for example, the medical device market is well established in terms of the number of companies registered to sell medical devices, revenue generation and technology uptake, especially in the private sector (Mkwashi, 2020; Friderichs, 2012). However, the wide diversity of product availability does not match local manufacturing and R&D capacity (Knijn and Patel, 2012). Currently a significant proportion of firms that occupy the South African medical device industry are MNCs such as Johnson & Johnson, Medtronic, GE Healthcare, Siemens Healthcare and Philips Healthcare. Even though manufacturing remains limited to producing mainly low-technology products, few domestic companies with manufacturing facilities in South Africa have successfully developed medical devices that are on par in terms of quality with existing products that require complex technical know-how to manufacture (Mkwashi, 2020).

For example, Southern Implants (Pty) Ltd, a South African firm, develops and manufactures dental implants and associated prosthetic devices. Southern Implants has been one of the pioneers in this field, contributing extensively to enhancements with respect to osseo-integration of implant devices, surgical techniques, patient education, and options of treatment. Glycar (Pty) Ltd, an associated company, was established in 1994 to manufacture and develop the applications for cross-linked collagenous membranes. The firm's products include hernia repair patches, dural membranes and cardio-vascular patches. Southern Ear Nose and Throat (Pty) Ltd, formed in 2002, is another local company dedicated to the development and production of products for the ear, nose and throat (ENT) field. South African-based Lodox Systems (Pty) Ltd focuses explicitly on the production of full body x-ray imaging devices for medical use in trauma and forensic pathology centres. Lodox imaging devices are installed in centres globally. In 2010, CapeRay Medical (Pty) Ltd began to develop a new digital mammography system, incorporating the functions of a low-dose digital x-ray machine and breast ultrasound, for which a provisional patent was registered. Gabler Medical is a local company based in the Western Cape province, specialising in the production and wholesale of incubators for infants, suction units, sutures, drip stands and clamps. SSEM Mthembu Medical is a company based in Gauteng, with approximately 185 employees, which is involved in the wholesale, manufacture, import and export of medical consumables.

A study conducted by KPMG (2014) indicated that the average declared local sales revenue for medical device MNCs operating in South Africa was US\$20 million per annum per company, and US\$5 million per annum for local medical device companies. The difference in revenues between MNCs and local South African companies is commonly attributed to the high entry barriers for the high-end medical imaging market. Producing more technologically advanced devices for diagnosis (MRI or CT scanners), treatment (such as endoscopy, treatment rooms, radiotherapy equipment), or recovery (such as rehabilitation equipment) is capital-intensive, requires lots of technical knowledge, and generally takes a long time to reach the market. A majority of the MNCs would prefer entering into technical agreements with large and validated firms because of concerns about the inability to perform or meet the manufacturing obligations of smaller firms. There are market and technological possibilities for expansion of the medical device industry on the continent. African countries must develop and retain a stimulating innovation and entrepreneurial environment for increased local production of medical devices in the post-pandemic era. For this industry to have long-term prospects, long-term financial and policy support is required.

CASE STUDY

Kenya's steps towards increased local medical device manufacturing

Kenya is a promising market for medical devices and supplies, having been ranked as the fastest growing market in SSA by the International Trade Administration. The market has attracted investors and manufacturers due to the tax incentives and the readiness of the government to work with the private sector. Health system reforms are aided by international funding. The Covid-19 pandemic brought about the need for PPE and ventilators as the country tried to contain the spread of the virus. The domestic production of these products increased. Medical device companies in the region continued to benefit too as the domestic demand increased (MoFA, 2021). Under the umbrella of the Kenyan Association of Manufacturers, a prototype of an intensive care unit respirator has been developed in Nairobi and it is estimated that it will become available at a quarter of the cost of an imported device. Local production using 'context-aware design' through product development partnership initiatives (PDPs) is one of the solutions suggested for improving access to medical devices (Ayah et al 2020).

7.3. Lack of funding and incentives for medical device manufacturers

Access to finance is one of the key elements for business success for both start-ups and business expansion, especially in medical device manufacturing, due to the high capital intensity of the sector. In Africa, fewer than ten local medical device producers are able to boast revenues of more than US\$5 million per annum. Local producers lack both incentive from government to invest in production capacity, and regulatory control to root out a large number of defunct products finding their way onto medical device markets (Mkwashi, 2020). However, according to Mamo (2020), five sub-Saharan African countries – South Africa, Ethiopia, Kenya, Senegal and Ghana – are taking a lead in encouraging and incentivising repurposing of domestic manufacturing supply chains, production lines, and distributional channels to address shortages of essential medical equipment. In South Africa, the Department of Trade, Industry and Competition (dtic) is mobilising and assessing business proposals from local manufacturers to address shortages of essential medical equipment. There are some agreements in place between the Ethiopian Investment Commission and domestic manufacturers in and outside of industrial parks to produce some medical supplies to combat Covid-19. The Kenyan government, through business associations such as the Kenya Association for Manufacturers and the Kenya Private Sector Alliance, are mobilising and encouraging members to repurpose their manufacturing to produce critical medical supplies.

In Senegal, foreign manufacturers, development partners and the government worked together to produce and

distribute testing kits and PPE, in particular masks, surgical gowns and caps. For example, UKAID provided a grant of approximately £1 million to support a joint venture between Mologic, a UK diagnostics company, and Diatropix, a Senegalese manufacturer, to produce eight million diagnostic kits (10-minute tests) in Senegal. In Ghana, manufacturers were exempted from lockdowns and were allowed to produce sanitising products and PPE. The government engaged and supported local garment manufacturers to reorganise and reposition themselves by sewing fabrics such as scrubs, gowns and masks (Mamo, 2020).

7.4. Regulatory environment

The regulation of medical devices is still rudimentary in many African countries, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices (Mkwashi, 2020). These underdeveloped regulatory processes present challenges for manufacturers of new medical devices interested in entering the African market, as regulatory processes are country-dependent but generally modelled after the European Union framework. As a result, introducing a new medical device in the African region requires evaluating local laws and regulations on a country-by-country basis (Hubner et al., 2021). The regulatory approval process for medical devices in Africa is lengthy, opaque, and skewed towards controlling entry into the market of substandard imports, which pose a risk to health (McNerney and Peeling, 2015).

For example, in Kenya, the regulation of medical devices is the responsibility of the Pharmacy and Poisons Board, which is a regulatory authority established under the Pharmacy and Poisons Act, Chapter 244 (WHO, 2017). All imported medical devices are subject to pre-export verification of conformity to standards through a programme implemented by the Kenya Bureau of Standards (KEBS, 2017). The regulation of imports in Kenya is important, as the country relies heavily on products brought from other countries (Lilech, 2014). However, the Covid-19 pandemic has hindered importation of medical devices due to weaker economic performance and affordability constraints. Imports dropped by 8.7% to US\$104 million in the 12 months to June 2020 (MoFA, 2021).

South Africa now has an established, formal regulatory process for medical devices that includes all essential regulatory components as recommended by the WHO (Level 1). The Medicines and Related Substances Amendment Act 14 of 2015 regulates medical devices. South Africa is one of the countries in the SADC region that meets the WHO's standard of good manufacturing practice (GMP) through local firms that hold ISO 9000 and ISO 13458 certificates; thus the industry has ample opportunity to expand its manufacturing base for export. However, local device and diagnostic manufacturers all spend significant time and financial expenses to obtain the CE mark (European Economic Area) registration from European certified bodies. This is because South African medical device regulations have an affinity to European directives and their value for opening up the export market, despite the fact that the directives are particularly strict (De Maria et al, 2018). This places an increased burden of compliance cost, especially when it comes to bringing in auditors for CE certification purposes (Mkwashi, 2020). Thus, the compliance costs for a manufacturer are much higher than those of a distributor.

The regulatory environment, or lack thereof, is a key issue for manufacturers in Africa. It should be considered an issue of vital importance to be addressed for the development of the medical devices sector (Mkwashi, 2020). The WHO encourages the harmonisation of medical device regulation towards standardisation, to promote uniformity between national medical device bodies. In an era of globalisation, this facilitates cooperation among regulators and the industry, particularly with regard to audits, submission requirements, use of international standards and exchange of safety information, and also leverages experience gained over time (Saidi and Douglas, 2019).

In Ethiopia, Ghana, Kenya, and Tanzania, a WHO framework for local production and access to essential medical products is being implemented to stimulate innovation and provide appropriate technical assistance towards establishing a viable and competitive domestic medical device industry (Saidi and Douglas, 2019).

While there may be some convergence of regulatory objectives and substantive principles, the character of national regulatory institutions is still best understood within each jurisdiction's culture.

8

REGULATION

The health technologies manufacturing sector is subject to high levels of complex regulation compared to other manufacturing sectors that place their finished goods on the open market. The regulation is important in order to assure the safety and efficacy of technologies used in the sector. Consequently, regulatory capabilities can support or hinder innovation and local production.

The data summarised in Table 6 on the next page shows that drug regulatory capabilities are prevalent on the African continent, although regulatory institutional capabilities and strength vary across countries. According to the WHO, there are 54 national medicines regulatory authorities (NMRAs) in Africa, though only 7% of these have the capacities to perform the core functions expected of NMRAs (Ndomondo-Sigonda et al., 2017). This shows no significant improvement since the WHO (2005) report that showed that only 7% of the 46 sub-Saharan African countries had an adequate NMRA in place. Of the remaining countries, 63% had minimal medical device regulation and 30% had none. Some African countries' legislative frameworks are now adopting the International Medical Device Regulators Forum (IMDRF) philosophy of accelerating international medical device regulatory harmonisation and convergence. But while there may be some convergence of regulatory objectives and substantive principles, the character of national regulatory institutions is still best understood within each jurisdiction's culture (Mkwashi 2020). Establishment of the African Medicines Agency (AMA) is expected to strengthen drug regulatory capacities on the continent.

TABLE 6

Medical health technologies governance tools and state of capabilities in African countries

Type of Technology	Characteristics	Governance tools	Capabilities
Biologicals - Monoclonal antibodies (MAbs) - Cell therapies - Vaccines	Produced from living cells, high molecular weight, complex heterogeneous structure, very high process-dependency (the process is the product), propensity for heterogeneity, unstable and very sensitive to external environments, immunogenicity challenges.	- Legislation (law) - Guidelines - Standards	There are vaccine regulatory capabilities in South Africa, Senegal, Tunisia and Egypt. For MAbs, North Africa possesses some regulatory capabilities. No capabilities for cell therapies. The rest of the countries do not possess biologicals regulatory capabilities.
Drugs (small molecules)	Produced through chemical synthesis; low molecular weight, well defined structure, process-independent, stable and non-immunogenic.	- Legislation (law) - Guidelines - Standards	Regulatory capabilities are prevalent across Africa; however regulatory institutional strength varies.

Type of Technology	Characteristics	Governance tools	Capabilities
Medical devices	Medical devices constitute a huge field ranging from spatulas and thermometers to radiation machines and implantable devices. Standards are the general regulatory tool used in this sector.	• Acts • Regulations (law) • EU directives • Local legislation • Standards such as the ISO 13485 and ISO 14971, which provide a management environment that lays a foundation for firms to develop products. The use of harmonised standards can lead to CE mark approval through a notified body. • Guidance documents (which are not legally binding but promote a common approach to the implementation of the procedures). • Technical information reports. • Local and international bodies for radiation emitting medical devices. • Reference laboratories. • For new devices, such as invasive medical devices, expert panels work through the regulatory framework, which is later distilled into laws and directives of standards.	Regulatory capabilities for medical devices are scarce on the continent. Local institutions can carry out plant inspections for GMP; however, there is no notified body on the continent and companies depend on Europe for obtaining the CE mark.

Source: Adapted from Declerck (2012), Mkwashi (2020) and Tait et al. (2017).

Vaccine regulatory capabilities exist in the four countries that have historically manufactured vaccines: South Africa, Senegal, Tunisia and Egypt. However regulatory capabilities in cell therapies are not yet available, but there are capabilities in monoclonal antibodies (MAbs) regulation in North Africa. There is a need to enhance regulatory capabilities in both drugs and biologics. Current initiatives such as ZAZIBONA which brings together regulatory experts from Zambia, Zimbabwe, Botswana and Namibia, plus South Africa which recently joined the group, need to be expanded. ZAZIBONA pairs an experienced regulatory authority with an emerging regulator, and during joint inspections there is knowledge exchange and competency building (Sithole et al., 2022). This ensures intergenerational continuity and builds the stock of competent regulators.

Full spectrum regulatory capabilities in medical devices on the continent are the least developed. Plant inspection and adherence to GMP can be conducted by local regulators. However, certification that requires a notified body requires using European Standards Organisations as the notified bodies. This dramatically increases regulatory costs for companies. A key industrial development need is for local standards bodies becoming local notified bodies.

Regulatory capabilities and competencies are a key soft infrastructure that needs to be built in order to support technological change and radical innovation in the pharmaceutical sector. When new innovation comes, regulators may not know as much about the product or processes. However, the notion of the ‘fellow traveller’ used by the MHRA may be useful. The fellow traveller concept describes the joint learning of the technology and processes between the innovator and the regulator and adaptation of regulatory requirements to the new technologies (Banda et al., 2019). As a sector develops there is need to avoid regulatory ratcheting – unnecessary gold plating of standards and guidelines – that is unnecessarily putting up very high standards as a competitive strategy by incumbents. The notions of proportionality and adaptability are critical in supporting emerging sectors (Tait et al., 2017).

Our argument is that current structural and infrastructural settings were not designed to support the required industrial transition from the dominant generic drugs to innovator business models for drugs, biosimilars for the biologics sector, and reverse engineering for medical devices.

9

STRUCTURAL AND INFRASTRUCTURAL BARRIERS, AND NORMATIVE ISSUES IN LOCALISATION OF MEDICAL TECHNOLOGY PRODUCTION IN AFRICA

In this section, we discuss the structural and infrastructural barriers to local production in Africa.

Despite a key respondent reporting that international conversations about local production on the African continent started as far back as 1998, epitomised by a meeting organised by WHO AFRO (World Health Organisation Regional Office for Africa), the industry still faces structural and infrastructural barriers. For decades, there have been discussions about how African countries should be involved in local production. The respondent reported that Nigeria has been at the forefront of local production, at least within SSA and the West African Pharmaceutical Federation. Among the issues were harmonisation of regulation to encourage sub-regional imports and exports. Regulation and trade (regional or sub-regional) were identified as two key hurdles to scaling up local production. Small countries in the sub-region, such as Gambia, were excited that this would be good for them. However, 22 years later, not much traction has been achieved on the ground.

We group policies, practices, supporting entrepreneurship, financing innovation, finance policy, innovative procurement and the development agenda, and norms or institutions under the structural category. We also consider the normative issue of generating decent work. Infrastructural barriers can be hard or soft. Hard infrastructure includes consistent provision of electricity, potable water, transport routes and logistics, and provision of critical knowledge bases and skills. Infrastructural challenges also encompass systemic issues such as low value chain integration, non-integrated trade, and a financial institutional architecture set up to support trade and commerce and not industry development. Our argument is that current structural and infrastructural settings were not designed to support the required industrial transition from the dominant generic drugs to innovator business models for drugs, biosimilars for the biologics sector, and reverse engineering for medical devices. This section explores the challenges and the next section outlines policy responses.

9.1. The lack of industrial protection to support local production

History teaches us that a nascent industry needs protection in the early stages. Opening up to external competition is effective once the local industry has acquired enough capabilities to compete with forerunners. This approach has not been adopted for African countries. For many years, companies in SSA have worked in an environment of very low tariffs on imports and highly liberalised trade. In certain cases, raw material imports have been subjected to import duties and value added tax while competing finished products were exempt from import duties and taxes. This policy incoherence incentivised imports and worked against local production. Some manufacturers are also importers and can therefore resist policies that restrict importation and concentrate on local production. These are policy and practice issues that need to be resolved by governments in their industrial development strategies. The need for nascent industry protection is increasingly being recognised, with North African countries cited as examples. Tunisia promotes local production by restricting imports from China and India, as well as Europe. If a local company can demonstrate that it can locally manufacture an imported product at levels of quality, safety and efficacy equivalent to imports, they can apply to the government to become the local producer and supplier. However, the company needs to meet the condition of having six months' worth of product supply as a back-up.

By contrast, the rest of African countries do not protect their nascent pharmaceutical sector until it has become internationally competitive. An industrial expert highlighted the dire consequences for local companies that would have invested for local production. The expert remarked that 'country x pays [only] lip service to local manufacture' and because of such disincentives to manufacturing, companies only manufacture 10% of the local requirements and import the balance from India, China, and other countries. This import-or-manufacture-locally conundrum is caused by a clash between finance policy (revenue collections) and industrial policy. We have previously argued (Mackintosh et al., 2016) for industrial, health and finance policy coherence as important drivers for building a functional health-industry complex. An industrial expert highlighted the impact of finance policy on industrial operations as follows:

For as long as the economy of country X is dependent on the income taxes [duty and import taxes] that they get from imports from around the world, it [local pharmaceutical industry development] will never happen. (Pharmaceutical Executive, 2019)

Revenue targets for ministries of finance force them to maximise tax and duty collections, and import taxes and duties are a lucrative source. On the other hand, global and local health actors usually lobby government

Pharmaceutical factory workers pack medicine.
Photo: Medicshots / Alamy Stock Photo



for suspension of duties on finished products, but there is no commensurate relief on duties and taxes for raw materials for local production. In light of this, two industrial experts argued for better tax regimes on APIs, excipients and packaging materials to level the playing field between imported finished products and locally manufactured products. They asked, 'How can they compete with India where local industry has subsidies for exports?' Indian companies access subsidised finance and receive export incentives, making them more competitive than local producers. Local industry protection, however, should be for a defined period, during which the local industry acquires capabilities to compete internationally.

9.2. Business models and growth options

The family-owned SME business-model architectures, prevalent in SSA especially, largely produce lower-end generics and frequently depend on delivering to public health systems that may delay payment. Consequently, they will continue to face major growth hurdles. Industrial transition will require an effort to change current business models (business model innovations). Some of these changes may include adopting a portfolio approach to winning tenders instead of all manufacturers producing a similar range of products and not standing out from each other by developing greater specialisation (Interview with an industrial expert from West Africa). In a separate project, a respondent argued that the generics business model would not radically change pharmaceutical manufacturing on the continent. They argued that only focused entry into niche innovator drug markets would provide the IP and protected markets that drive higher earnings which can be ploughed back into more R&D. This may be possible for some entrepreneurs with extensive experience of taking molecules from R&D in the lab to market authorisation in MNCs in developed pharmaceutical markets.

A global health procurement expert decried the missing managerial capabilities of deal prospecting. She explained that Indian pharmaceutical industrialists do very well in this field compared to African industrialists. The former actively search for new medicines to be included in new treatment regimes. They forecast the new demand and gradually shift research and development priorities to those new therapies. They embark on reformulation activities for these generics and are quick to launch their affordable medicines when, for example, new treatment regimens are announced for ARVs. She contrasted this example with an African manufacturer who spent a lot of effort to pre-qualify their product, but by the time they had obtained pre-qualification, the product had been taken off the treatment guidelines by the WHO. 'Fore sighting' or prospecting skills are thus critical for long-term survival and need to be embedded in business strategies.

9.3. Access to finance

[N]o matter what a business is going through, whether it's a small mom and pop business, whether it's a huge multinational corporation, if you don't have the money to do business day to day, there is no way you can survive. (Pharmaceutical Executive, 2019)

Three different enterprise types – pre-revenue, early revenue and mature enterprises – face different structural challenges regarding access to patient, sustainable and affordable finance. The most affected are the first two which do not have the long performance track record that commercial banks, the most prominent financial institutions in African countries, use for their financial analysis. Pre-revenue⁶ and early revenue enterprises need to invest in capital expenditure (capex), training personnel, and achieving accreditation and regulatory approvals, and therefore require patient capital. This is likely to be the greatest challenge in the industrial transition to manufacturing more innovative medical technologies on the continent. The financial system architecture for funding these types of operations is not prevalent in most countries. Table 7 illustrates the type of funding required for different phases of development and the current potential sources of funding for the enterprises.

6. These are companies that have been set up but have not started generating revenues.

TABLE 7

Different types of finance required for the pharmaceutical sector in Africa

Project type	Activity	Funding type	Potential funder(s)
Greenfield project	Plant construction and commissioning, equipment and machinery acquisition	Long- and medium- term funding: <i>(patient capital)</i>	· Development banks · Enterprise development funds
Brownfield project	Product range development (R&D & translational activities)	· Bonds · Equity · Debt	· SME funding schemes · Mortgage firms – industrial property
	Upgrading production facilities	· Hybrid instruments · Grants	· Governments · Sovereign wealth funds
	Local, regional or WHO good manufacturing practice (GMP) qualifications	FDI	· Insurance firms · Venture capital
	Upgrading standards current GMP (cGMP) roadmaps	Joint ventures Syndicated term lending	· Impact investors
Day to day operations	Working capital requirements	Short to medium term funding · overdrafts, short term loans	· Commercial banks · Continental and regional trade banks
		Trade finance · Letters of credit · Guarantees · bid, Performance and maintenance bonds · Export credit guarantees	· Innovative procurement · Social funding · Impact investment
		Trade credit: in-kind finance	Suppliers
		Advance payments	Innovative procurement
		Core working capital	Long term funding

Source: Banda (2016).

The African pharmaceutical sector's greatest financing challenge is with building new plants (greenfield projects) or upgrading existing plants (brownfield projects) to comply with current good manufacturing practice (cGMP). Development financial institutions (DFIs) are the most appropriate providers of long-term patient capital required for these capex projects. Other funders include governments, through investments of sovereign wealth funds or specific SME funding mechanisms. Governments with windfall revenues or profits from, for example, the extractive sectors, can create sovereign wealth funds which they can use to restructure their economy. The sovereign wealth fund could take equity in companies, or avail funds for lending through local financial institutions.

In the last few years, most notably after Covid-19, DFIs have become active in availing funds for local manufacture. Their focus, though, has been on vaccine manufacturing. Table 7 illustrates the different financing instruments for capex projects, namely bonds, equity, debt, hybrid instruments and grants.

Day to day operations are the remit of commercial banks; however, industrialists have complained of very high interest rates and onerous lending conditions. As a result, the sector minimises borrowing to manage costs, and to some extent depends on in-kind finance provided by trade credit. Key players for financing day-to-day operations also include impact investors, regional trade banks and social funding. From a procurement perspective, advance payment by public health providers, as occurs in Ethiopia, reduces dependence on commercial bank funding for working capital requirements. Concerted efforts to support the sector could copy Indian policies on subsidised funding and export incentives to the sector.

From a procurement perspective of financing, the most vibrant regions in North and southern Africa have a milieu of MNCs and subsidiaries of MNCs, as well as local manufacturers.

Access to affordable finance for capex and working capital is critical for growth, but entrepreneurs need to carefully consider the source of funds, their motivation, and strategic thrusts. Access to banking finance has the least challenge to vision and strategic thrusts. A respondent from a Southern African pharmaceutical company reported that they are now able to compete against imports from India because they accessed loans from a regional DFI to import equipment. The new equipment, with improved levels of automation, resulted in a lower headcount but more efficient production. The appetite to borrow for growth was facilitated by this company not being closely held by family. Closely-owned family businesses are hesitant to seek external funding through joint ventures or venture capital, and for legitimate reasons. Two respondents from Ghana separately reported bad experiences with venture capitalists. The first respondent classified venture capitalists as 'vulture capitalists', as they did not understand the vision the founder had, and the direction they took was leading to 'grabbing the company' from the founders. The second example pertained to contrasting visions for the company. The external funders came in and changed the direction of the company, discontinuing vital R&D for local API manufacturing, and focusing on the cash cows to increase the short-term valuation of the company. However, API manufacture was important for the founders, as this was where the long-term value for the company would be generated. This tension between short- and long-term strategic goals and focus is one of the structural barriers to localisation of the pharmaceutical industry. The main challenges faced with venture capitalists have involved clashes of culture, business models and strategic vision between company founders and funders.

Thus, access to finance is a complex issue, as entrepreneurs need to be careful who they bring on board as partners. They also need to develop finance capabilities in their companies to be able to know the type of finance they need and the most appropriate source. At the same time, they need to be careful not to over-borrow but pace their growth with their market conditions – local or external. However, structuring the financial sector architecture to support local industry is the forte of government policy. In countries where the dominant financial institutions are commercial banks, governments need to encourage the development of institutions that cater for long-term lending. Commercial banks focus on short-term lending, focusing on trade and commerce, and not industrial development.

From a procurement perspective of financing, the most vibrant regions in North and southern Africa have a milieu of MNCs and subsidiaries of MNCs, as well as local manufacturers. They are sustained by huge markets buttressed by health insurance and high government spending on healthcare. The scale of insurance and government spending is a core reason that the financing arrangements in these countries are stronger. This could be steered towards local manufacturing.

9.4. Innovative procurement – public health and global health programmes

Danzon (2014) notes that developing country pharmaceutical markets differ from those of industrialised countries. Countries with extensive health insurance have larger pharmaceutical markets compared to those markets, characteristic of SSA, where patients depend on out-of-pocket expenditure. Given this challenge, innovative procurement – where the state uses public health procurement to shape the local industrial development trajectory – is important. In interviews, industrialists bemoaned the short-term procurement tendering system because it could not be used as proof of future income when seeking funding from banks. Long-term tenders for five years give some modicum of stability, and can allow companies to securitise their receivables for access

to working capital finance. This helps in medium-term planning to build capabilities, efficiencies, and access to finance. Another major drawback of the current arrangement is that governments delay paying for supplies and cause serious cash flow problems for companies.

Global health programmes can sometimes scuttle local production, especially in instances where governments are dependent on them for financing health systems. An example highlighted by a key respondent was about the new antimalarial ACT (Artemisinin-based combination treatments) and the Affordable Medicines Facility malaria (AMFm) (started in 2010), where the Global Fund subsidised prices of antimalarials. The local manufacturers argued that the Global Fund undermined their ability to sell the new ACT-antimalarial in the private sector, thus excluding them from getting the business. In addition, donor support for public sector provision of ACTs built barriers to market access by local manufacturers, because of the difficulty of meeting WHO prequalification requirements. Consequently, quality standards became a barrier for procurement for local manufacturers.

Some companies have invested in improving their quality standards to meet international requirements for access to donor-funded markets. Innovative procurement is not the forte of governments alone. Global Health programmes can use their procurement to support local industries. This is an area that needs to be looked at as it still has challenges. In Uganda, Quality Chemicals set up a new plant promoted by CIPLA. They started producing antimalarials, and once they overcame the quality issue, pricing became the next hurdle and they could not supply global health programmes. However, the company is now a fully owned Cipla subsidiary and supplies both ACTs and ARVs to the Global Fund.

A quandary that procurement experts face is the tension between supporting local manufacture and spreading resources to acquire as much product as they can, as illustrated in the quote below:

My responsibility as a procurement person is to stretch the money as much as possible in terms of how many people can be treated from that envelope. So we were in the business of saving lives and not in the business of subsidising manufacturing companies because the only way one could give them significant business was to subsidise them, because their prices were almost basically twice higher than the [Indian] generic manufacturers for the same tablets. (Pharmaceutical Sector Consultant – Former Procurement Specialist, 2019)

The Global Fund began conversations with local manufacturers to avoid procurement concentration risk. One example cited by a respondent was a meeting in India on ARVs, at which manufacturers were worried about the impact of a hurricane in one state where most of their plants were located. If the hurricane disrupted operations, then millions of HIV/AIDS patients in African countries would run out of medication because there were no alternative suppliers. China was only involved in APIs back then, but all the formulation and finishing of product was done in India. This example demonstrates that procurement concentration risk has existed for a very long time, and Covid-19 only accelerated the recognition of its impact, especially for epidemics and pandemics.

The Global Fund started working with manufacturers in Africa to try to improve their market access and diversify the Fund's sources of supply for tenders in an effort to mitigate the risk of concentrated supply sources. They developed a different approach to criteria for judging tenders: they '... started thinking, in terms of procurement, that cost was not the be-all and end-all. So whilst cost is very important, we started bringing in other technical elements that can support them [local suppliers]'. They shifted away from a sole focus on the Free on Board (FOB) unit cost of the product from the manufacturer and developed a metric for looking at total landed cost. Included in this consideration were the elements of costs, lead time and technical points. Manufacturers that are closer to home – that is, offering shorter supply chains – got extra points. This was a strategy to level the playing field for external tenders. It lowers barriers without applying the domestic preference that can be applied by national procurement bodies, which can offer local firms a pricing premium of as much as 15% higher than external bidders. After this shift, Uganda's Quality Chemicals

started getting business from the Global Fund because they became more competitive. This is an example of innovative procurement that embeds security of supply and advantages to point of use producers. The respondent called this procurement with 'social responsibility', and added:

That was when you started to see more and more of the international community getting engaged in local production. It was not a new thing [local production], but nobody was taking note, but now it became more [of] a social responsibility, you cannot just bring all that money into Africa to support people without engaging with the local manufacturers. (Pharmaceutical Sector Consultant – Former Procurement Specialist, 2019)

The link between procurement and social responsibility extends beyond global health players to national governments and local manufacturers. This is exemplified by the Biovac example. Biovac, a PPP in South Africa established in 2003 which procures and distributes vaccines for South Africa, faced uncertainty when the government thought of opening the vaccines tender to the cheapest supplier (Webinar Respondent, 2020), which would have severely impacted their cash flows. However, when Covid-19 severely disrupted medical supply chains, the policy makers realised how important it was to have local capabilities in public health emergencies and allocated resources to Biovac, which has since been chosen as one of the centres of excellence for developing Covid-19 vaccine manufacturing capabilities.

9.5. Labour issues: generating decent work

In addition to production of essential medicines to enhance health security, the biopharmaceutical industry and the medical device manufacturers generate local incomes and employment, which are important to explore.

Lack of pharmaceutical employment data

There is nearly no documentation of the extent and type of African employment in pharmaceuticals. Global estimates of employment generation in biopharmaceuticals take into account direct employment, casual employment and employment in supplier industries. The most recent estimates, for 2020, estimate 5.5 million employees (direct and casual or engaged as self-employed) worldwide, and a further 45.1 million employed in supply chains (WifOR, 2020).⁷ However, these data do not include any African countries' data (WifOR, 2020: 14). We therefore lack data on pharmaceutical employment in North or sub-Saharan Africa. Similarly, we have found no estimates for African medical-device industry employment but given the weakness of the industry in Africa (see above), this is likely to be quite small.

Conversely, the WifOR (2020) report states (but does not document in detail) that India is an outlier: India's indirect employment impact of its pharmaceutical industry is estimated to be particularly large, with the number of people working in the industrial supply chains being 23 times the number working directly in the industry.⁸ It appears that India's industry and its supply chains are markedly more labour intensive than those in high-income countries. This may also be true in African countries, but in the absence of data, we do not know. Assembling basic employment data for the sector, importantly including suppliers' and distributors' employment, should be a policy priority.

Qualitative evidence

There is some limited qualitative empirical evidence on labour issues that we have assembled from case studies and interviews. The pharmaceutical industry does provide a welcome and expanding source of skilled and

7. Based on ILO statistical data for industrial category C21 pharmaceutical industry; coverage of countries is incomplete (WifOR, 2020 Annex).

8. These effects are calculated using world input-output tables.

The [ILO decent work] agenda (2018) covers employment creation, rights at work, social protection for workers and families, organising, dialogue, and gender equality.

stable employment in African countries. In East Africa, data from the Kenyan case study (see Annex 2) showed that direct employment of about 5700 people in the pharmaceutical industry in 2018 was split between a small majority of permanent employees, while the rest were contract and casual staff. In Tanzania, earlier data found that approximately 1300 people were employed in the smaller pharmaceutical industry in that country (Mackintosh and Tibandebage, 2016). In neither country do we have estimates for supply chain employment.

Interviewing for other projects by the authors and their colleagues in both countries confirmed that permanent employees were particularly skilled, as were managerial staff and direct production workers. Still, local manufacturers noted that they faced severe shortages of industrial pharmacists and laboratory staff with relevant experience and capability. In both countries, it was noted that academic pharmaceutical education insufficiently prepared pharmacists for the option of industrial work. In both countries, internal training is key to upgrading staff skills, and highly skilled industrial staff are frequently poached amongst firms. There is need for clear understanding, at a local level, of the labour skill requirements for certain functions in the pharmaceutical sector. There are many roles for which skills can be appropriately honed through in-house training (for example, manufacturing machine operations, some quality assurance functions, and some roles where either a chemist or pharmacist can be effective) (IFPMA, 2021).

The Kenyan case study (see Annex 2) shows that a large minority of pharmaceutical employees are women. In Tanzania, it was found that some production staff were women with nursing experience, who were appreciated by employers for their understanding of hygiene and the importance of product quality for health. Contract and casual employees included, for example, packaging and logistics staff, male or female, who might be laid off and rehired as required by the firms, thus generating precarious employment.

Employment structure and policy concerns

Globally, employment in the pharmaceutical sector is rising, and African countries can potentially generate more employment through both direct and indirect (supply chain) employment effects.

An ILO report on Bangladesh (Gregg and von Uexkull, 2011) usefully points out the diversity of employment in larger pharmaceutical firms. They list:

- operatives in formulating and tableting, and in filling and packaging;
- technicians and similar roles;
- chemists and pharmacists in high level jobs; and
- sales and marketing workers.

The ILO has used its Decent Work Agenda to explore the employment challenges within the pharmaceutical industry world-wide. The agenda (2018) covers employment creation, rights at work, social protection for workers and families, organising, dialogue, and gender equality. The ILO investigation into employment in pharmaceuticals (ILO, 2018: 16-17a) identified a number of concerns. They found shortages of workers with the scientific, technical and productive skills required, demanding investment in vocational education and training, including training and upskilling for employers and workers in SMEs. There was a lack of social protection, with discriminatory dependence on contractual status and enterprise size, and a notable lack of manageable guidelines and training for SMEs to meet occupational health and safety obligations.

The ILO found that female participation rates were improving, but gender equality and work-life balance still

needed promotion. They found a lack of good practice in the use of contract and agency labour and other flexible working practices, which should be created to meet international labour standards. Furthermore, corruption still needed elimination in promoting decent and productive work.

Policy makers can and should focus on areas of intervention that can strengthen and expand decent work. The focus should be on employment structure in both manufacturing firms and their local suppliers and distributors. Key aspects for attention include:

- Contract structure – increasing the stability of the workforce and the working conditions in the contract, and strengthening the position of what is likely to be a large pool of quite skilled staff on casual contracts;
- Working conditions, including health and safety, shift structure and length;
- Hiring and training, including external and in-house training support, support for female employment, and equal pay initiatives;
- Local content rules that encourage local employment in supply chains; and
- Industry governance, scope for worker organisation, and effective employment regulation.

These areas can all be explored locally to promote decent work in health industries. Priorities may include support for training for industrial work for both men and women; investigation of health insurance provision and other aspects of social protection in the industry; ensuring that GMP inspections by regulators pay attention to health and safety of employees; support for union organising and negotiation within the industry; investigation of contracting processes; and support for improvements in conditions of contract workers. The level of unionisation in the pharmaceutical industries in Africa is generally low. However, South African unions are active in the sector, and employers have formed regional African pharmaceutical manufacturing associations. Strengthening both trade unions and employers' associations can potentially contribute to improved employment and working conditions.

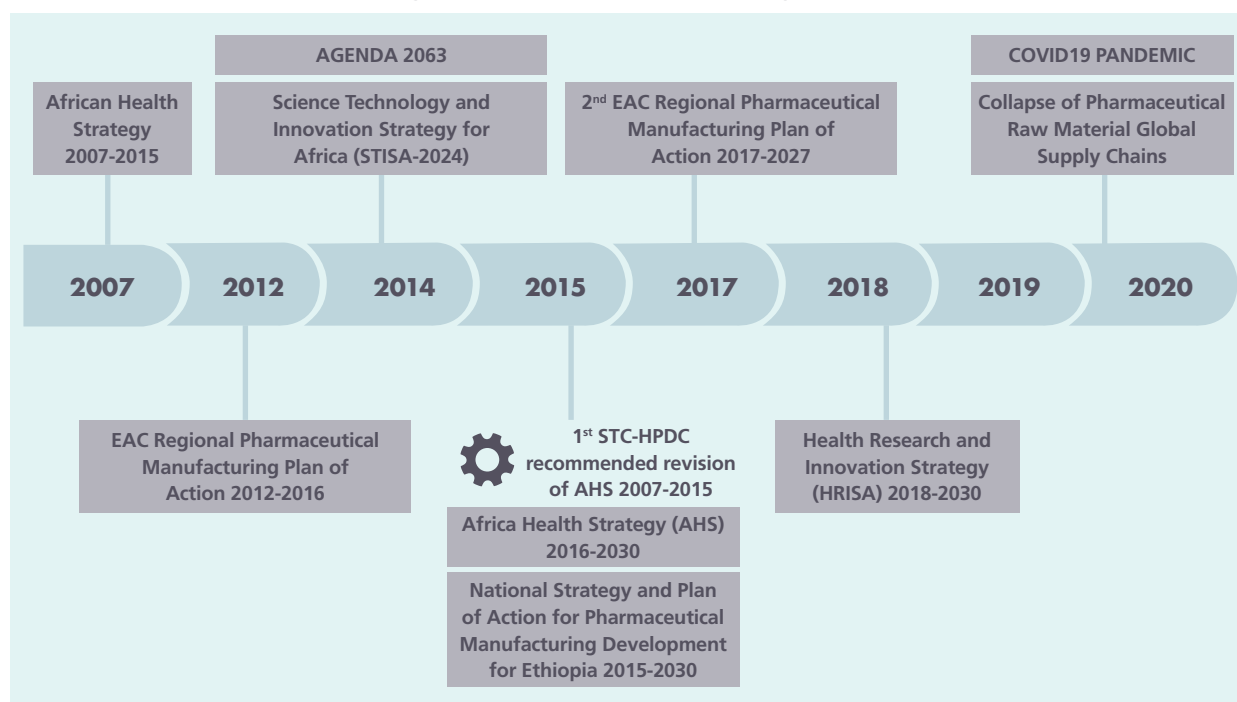
POLICIES TO SUPPORT LOCAL MEDICAL HEALTH TECHNOLOGY MANUFACTURING

The development of the medical health technology sector requires synchronisation of cross-sectoral policies in industry as well as the health sector. At a supranational level, the African Union and their technical implementing agent, the African Union Development Agency (AUDA-NEPAD), have, since the early 2000s been working with development agencies such as the WHO, GIZ (German development agency), and UNIDO on promoting local pharmaceutical manufacture.

In 2007, the African Union (AU) produced the Africa Health Strategy (AHS) 2007-2015; this was replaced by the AHS 2016-2030 in 2015. The AHS is important because the Pharmaceutical Manufacturing Plan of Action (PMPA) builds on it. The Science Technology and Innovation Strategy for Africa (STISA 2024) was produced in 2012 and, in conjunction with the Health Research and Innovation Strategy for Africa (HRISA 2018-2030), forms the other element of the policy cocktails at supranational level relevant for local medical health technology manufacturing. Other policy and strategy documents include the SADC Pharmaceutical Business Plan 2015-2019 and the ECOWAS Regional Pharmaceutical Plan. There are national pharmaceutical sector development strategies for Kenya, Ghana, Uganda and Zimbabwe, for example.

FIGURE 8

Various continental and regional policies supporting local manufacture



Source: Banda (2022).

We highlight these supranational policies as well as the regional policies (Figure 8) to show that, for the last two or more decades, there have been voices on the continent calling for more localisation of medical health technology manufacturing. However, they have found it difficult to generate the scale or magnitude required to jolt policy makers into action. Covid-19 was the incident that disrupted the complacency.

It is important to point out that the strategy that the AU and AUDA-NEPAD were pursuing was to develop 'model policies' which countries could modify to structure local policies. It was recognised that not all countries had the resources or ability to bring together specialist resource persons to individually develop national policies. The AU and AUDA-NEPAD have, over the decades, developed networks with key local manufacturers and have collaborated with the industry associations purposely to design the model policies. However, what is apparent is this approach takes a long time to generate momentum – and Covid-19 was the disruptor that generated great urgency and forced governments to exercise immediate agency on developing public policy interventions, a key component of which was industrial capabilities.

10.1. Covid-19 policy awakenings – how can they be leveraged?

The pandemic revealed fractures in global pharmaceutical and medical value chains. More importantly, supply chain disruptions and shortages affected all countries. What differed was how countries bounced back by harnessing or repurposing available capabilities. One respondent highlighted what they called a culture and policies that imbue a 'can-do' attitude, as seen in countries that led in developing technologies for Covid-19, from ventilators to diagnostic equipment and protective equipment to vaccines (Webinar Attendee 2, September 2021).

In a 2021 webinar that brought together industry and policy experts from India and African countries, respondents remarked that the pandemic was a wake-up call, and there was a need to shift from short-termism to embrace long-term views on investments in medical health technology manufacturing capabilities. One respondent noted:

...there is need to ask different questions regarding local manufacturing. Even if the products will be more expensive now, and the scale economies may be unfavourable, concerted efforts need to be sustained so as to hone in capabilities. There is need to rethink models and political visions. Equally, the pandemic has taught us the importance of public resources in incentivising the public sector ... e.g. advanced market commitments (AMCs) to vaccines. (Respondent Webinar Attendee 1, Sept 2021)

This quote reveals the cross-sectoral nature of local medical health technology manufacturing projects. Industrial efforts are interlinked with procurement policies and at the same time linked with competency building and technological capability upgrading. However, political vision is important in resource allocation for long-term projects that require collective envisioning of desirable technological futures.

10.2. The importance of policy coherence

Thus, policy coherence and mutual reinforcement between policies is critical. This encompasses the deliberate crafting and deployment of policies and operational mechanisms that are not in conflict with each other. For example, in some countries, trade and import policies favour importation of medicines because of quick and ready access to products, and contributions to tax revenues, while on the other hand, industrial policy focuses on stimulating or supporting local production. As one respondent noted, 'there is need to go beyond lip-service in commitments to transformative policies'. Similarly, in related work, we have argued for the importance of close collaboration between industry and health policy makers (Mackintosh et al., 2018).

There is a range of other inputs that could be produced in African countries, which are currently imported: examples include excipients for medicines production, some APIs, and services such as maintenance of equipment.

Related to the above, there is a need to commit financial resources and appropriate institutional mechanisms, including incentives, to policy objectives. Tailor-making incentives to specific contexts could be a good option. For example, in Ghana, a pharmaceutical manufacturer that exports 70% of their product qualifies to be part of a tax-free zone – that is, tax exempt. One respondent wondered if preferential taxes could be applied to the pharma sector – for example, 30% as an incentive to expand local production.

Policy coherence is also a regional matter. While regional programmes such as ECOWAS in West Africa or the AfCFTA (African Continental Free Trade Area) advocate for removal of trade and goods mobility barriers, including lowering medicines registration and marketing barriers, the reality on the ground is different. There are multiple barriers still in place, embedded in national preferences for products and historical geopolitical relationships. These and other key policy issues are elaborated in the case studies of Egypt, Ghana, Kenya and South Africa.

10.3. Deepening local supply chains

Pharmaceuticals generate very large up-stream demands for inputs, and downstream employment in distribution. Data from India and elsewhere suggests that, potentially, local employment numbers in these supply chains dwarf direct employment in the industry. This is in part because many of these supplying firms can be labour intensive and relatively lower skilled. Examples of firms that could readily expand their employment in African countries include packaging, handling, transport and storage firms. There is a range of other inputs that could be produced in African countries, which are currently imported: examples include excipients for medicines production, some APIs, and services such as maintenance of equipment. A shift to higher levels of purchase from local suppliers requires active support for local firms to upgrade to pharmaceutical quality, for example, in packaging. Development of supplier capabilities can, in turn, improve local manufacturer competitiveness by reducing costs (Wangwe et al., 2021).

Government policy can do a great deal to deepen local supply chains in this way, both to increase industrial output and to support improving quality and working conditions. Local content policies can be a useful tool, but require associated active support for supplying firms to meet quality targets. Industrial protection of medical industry suppliers can be associated with incentives for large lead firms to actively develop local contractors. This support can be allied to guidelines for health and safety protection and contractual conditions for supply chain workers, suitable for SMEs.

10.4. Sectoral development policy clashes

We argued earlier that medical health technology local manufacture is a political project. Politics, political decisions, political contestations and political tensions are an extra dimension that needs consideration in developing this sector. However, from a development perspective, it is difficult to balance health, agriculture, economic and industrial development. Scholars' approaches forget the long-term nature of infrastructural accumulation that industrialisers need to go through. Latecomer industrialisers have to invest in soft and hard infrastructure, and these activities are resource-hungry. Consequently, policy makers must trade off competing needs that include social, technological and industrial development. This is encapsulated in the following quote about trade-offs, as seen by an industrial expert.

I still remember sitting and watching the previous president of Tanzania [Jakaya Kikwete] ... and he was very frank, he said you have a budget, and it's a limited budget. You have roads to build, you have hospitals to build and you have schools to build; they are all competing important things. What do I do, how do I allocate it? If I allocate for roads, they will say education is failing, if I give it for health ..., which is more important? They are all important, we need our health, we need the education, we need the roads, we need the agriculture to feed the people. You need the roads to transport the food. (Pharmaceutical Executive, 2019)

These competing sectoral development priorities are real. It is a difficult balancing act and this sheds some light on the political economy of pharmaceutical production and industrial development in some countries, as well as the challenges in progressive public policy crafting during 'normal times'.

Thus, political contestations will play out in choices that countries make on which sector to prioritise, especially for countries that are not endowed with financial resources. However, localisation of health production helps meet multiple objectives – in local health security, economic development, employment and pandemic/epidemic preparedness.

10.5. Science, technology and innovation policies

Purposive rebuilding of the medical health technology manufacturing sector requires that governments play multiple roles, including policy formulation, funding and coordination. We have argued elsewhere that medical health technology sectors are not purely technical projects but are political projects, characterised by trade issues and potential backlash at commercial or international relations levels when the interests of incumbent players are threatened. In addition, for some of the particular sub-sectors, there is a need to support entrepreneurship, managerial capabilities and market formation. The public health sector has potency as a purposive industrial policy arena to support the emergence of the sub-sectors and build broad industrial capabilities. In addition, one respondent remarked that:

While manufacturing capabilities are necessary, they should not be considered, and would not be sustainable outside capabilities at other levels. There is a need to build local capabilities across the value chain, including R&D. Further, there is need to respect and utilise local capabilities – sometimes there is too much emphasis on building capacities at the expense of utilising and optimising use of available capacities. (Respondent Webinar Attendee 1, September 2021)

The capabilities at other levels span other sectors that are backward- and forward-linked into medical health technologies. Packaging, distribution, logistics, research and development, translational actors, contract research organisations, clinical trial organisations and tertiary education institutions are part of the innovation ecosystem that needs to be carefully put together and managed.

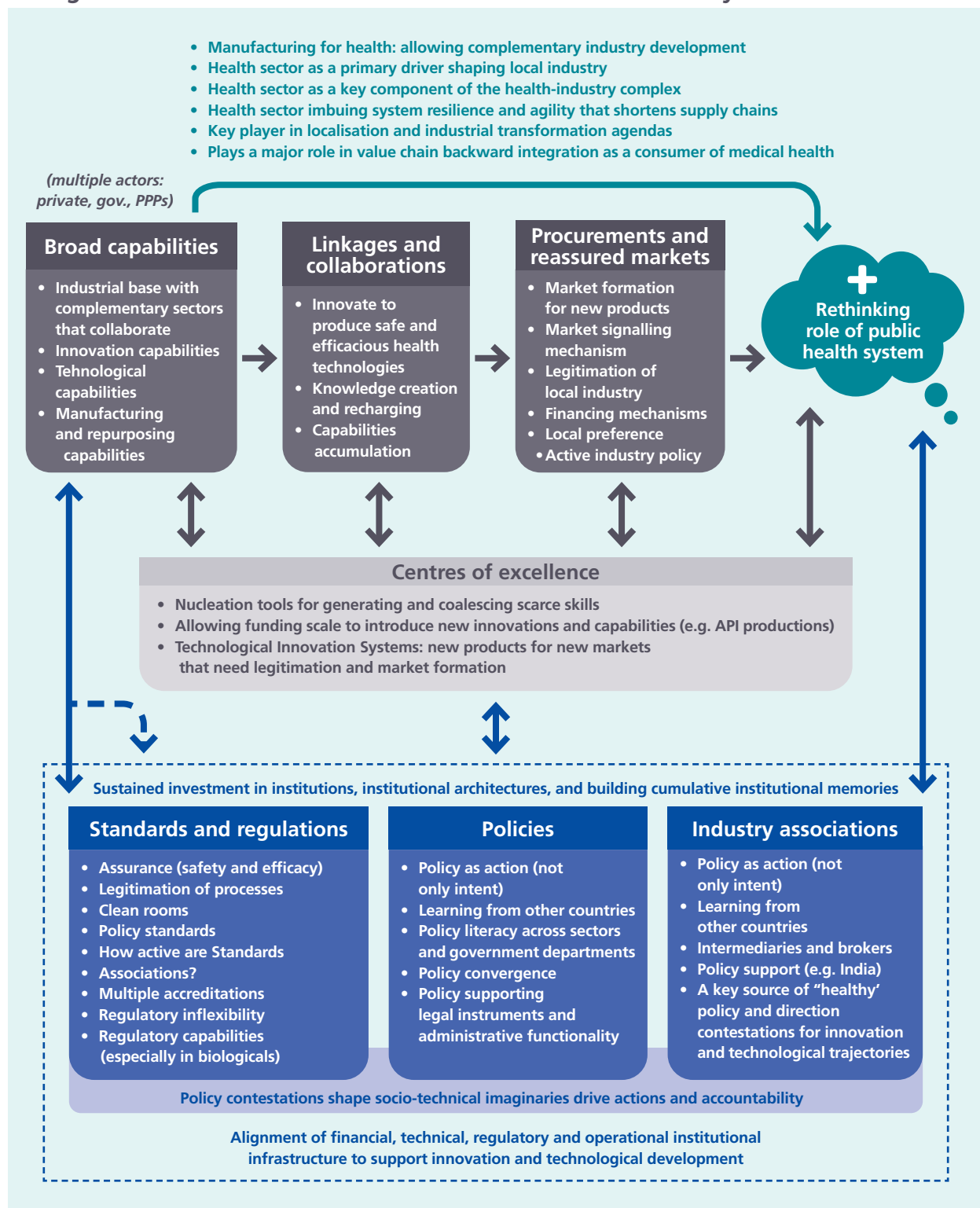
Science granting councils (SGCs) are an often forgotten component of science, technology and innovation policies. SGCs are important for shaping the research and innovation trajectory, midwifing emerging technologies and acting as brokers between industry and academia in particular. In many countries, the SGCs have not played a significant role because of underfunding and under-resourcing of skilled staff. Investing in SGCs promotes multiple sectors in an economy, including the medical health technology sub-sectors.

10.6. Health-industry-complex ecosystem supporting policies

We have previously proposed that the health-industry complex is an important conceptual framework to understand how strategic investment and co-building of health and industry capabilities can promote economic development, industrial development and enhanced local health security (Mackintosh et al., 2016).

FIGURE 9

The interlinkage between public health systems and industrial systems and how linkages and collaborations can reinforce local health security.



Source: Banda et al. (2021a).

The public health system is a potent industrial policy arena that can be used to support building broad industrial capabilities in the medical health technology sector. Procurement and assured markets for locally manufactured products serve as market-signalling mechanisms to entrepreneurship. However, the local industry needs to develop linkages and collaborations with upstream and downstream actors. This requires policy convergence and coherence. Industry associations play an important role in articulating the demands and challenges faced by the sector, and this helps to design policy learning and resolve contestations that may arise (Banda et al., 2021b).

10.7. Policies that enhance institutions for standards and regulation

Governance of the medical devices sector is mostly through standards. The greatest hurdle for local SMEs is the absence of notifying bodies on the continent. Standards organisations currently do not serve as notifying bodies. Local SMEs have to use notifying bodies in Western countries, and at the same time have their facilities inspected by local regulators. This results in multiple regulatory compliance systems that raise compliance costs and increase turnaround times. Medical devices firms we interviewed argued that the emergence of local notifying bodies would be advantageous to the sector. This shortcoming was especially demonstrated during Covid-19. Local innovators produced medical devices, but there were no standards bodies with the authority or capability to validate or certify them.

Skills in biologics are especially scarce on the continent. This was also evident during the Covid-19 pandemic. Local regulatory agencies struggled to handle challenges with Covid-19 vaccines. If greater biologics manufacturing capabilities are to expand on the continent, there is a huge need to establish biologics regulatory capabilities, especially in countries without vaccine manufacturing capabilities.

The pharmaceutical sector has historically had better regulatory capabilities compared to medical devices and biologics on the continent. This is a function of history and experience with the local pharmaceutical sector. Initiatives such as ZAZIBONA have contributed to enhancing local drug regulatory capabilities. Regulatory capabilities are an important foundation for the health-industry complex (see Figure 9).

CONCLUSION

Covid-19 exposed the urgency of localising medical health technology manufacturing. Localisation of manufacturing requires strategic use of policy, incentives and industrial development agendas. Covid-19 and other epidemics revealed fractures in global pharmaceutical and medical supply chains and that they can affect every country. What differed was how countries responded in harnessing or repurposing available industrial capabilities. Africa, however, was exposed. Our study has shown that there is a need for deliberate, holistic, agile and consistent policies that stimulate and sustain local production. This entails deliberate and dedicated investments in competency, capabilities and skills upgrading for medical devices, biologics (including vaccines), and drugs.

Going back to our overarching question:

'How best can African countries harness and deploy lessons from the Covid-19 pandemic and from other relevant local manufacturing experience, to develop and enhance sustainable capabilities for local manufacturing of medical health products?'

Our findings and analysis revealed that Africa urgently needs to broaden and deepen its medical health technology manufacturing capabilities if it is to enhance local health security, become pandemic and epidemic ready, and contribute to global health security. In addition, there is great scope for using the medical devices, drugs and vaccines sectors to accelerate industry and economic development as well as to contribute to better availability of life saving medicines and other technologies.

The development of the sectors is premised on careful consideration of the following:

- a. The current status of medical devices, drugs and vaccine manufacturing capabilities is not tenable. Urgent action is needed to build commensurate industrial capabilities. The state is the only actor with the political legitimacy, control of resources and incentives, and ability to exercise immediate agency through public policy, to create the urgency to accelerate rolling out these highly political projects.
- b. The greatest shortcoming during Covid-19 was the inability to access APIs. The continent urgently needs to build API manufacturing capabilities. This may entail offering incentives through science parks, supporting construction and running of waste management plants, and affordable energy provision for API production. The benefits of skills development will accrue through joint ventures with leading API manufacturers in India, China, Europe, and North America. These projects require vast sums of patient resources.
- c. SMEs have served African countries for more than a century, but these business models are not adequate for the scale of intervention required to build resilient local health systems that are foundational for global health security and pandemic or epidemic preparedness. Existing business models need to be rethought and reconfigured so that they are geared to solve the technical, managerial and industrial challenges.
- d. There is an urgent need for the local drugs manufacturing sector to transition to newer technologies. The industry, working with innovators and joint venture partners, needs to foresight which drugs will soon come off patent, and start development work. The industry also needs to upgrade and not only focus on local markets but also on penetrating lucrative export markets.
- e. Medical devices are a fledgling industry that requires urgent support, which includes availability of finance,

standards, and other institutional as well as infrastructural support. This sector includes micro-enterprises and SMEs which possess great potential. The regulatory hurdles are not as expensive as for drugs and biologics because they are standards based. This is low-hanging fruit that African governments can and should support. Localisation of medical device manufacture will decrease the demand for foreign currency for imported finished devices. Supporting micro-enterprises and SMEs also has direct positive impacts on employment and gross domestic product (GDP).

- f. Biologics is a fledgling industry in terms of vaccines and other products such as MAbs. This is a sector with tremendous commercial opportunities because of its immediate and future utility. Those firms that can develop capabilities in biologics and assure safety and efficacy can easily export their products to regional and international markets. Profitability is likely to be higher in this sector compared to the generic drugs sector. If the appropriate business models, business prospecting skills, and international trade networks can be developed, this sector can transform the medical health technologies sector on the continent, while at the same time making the continent pandemic-ready, especially if capabilities are developed with platform technologies such as mRNA technologies.
- g. Development of the medical health technologies sector is long-term in nature and requires patient capital as well as innovative procurement from public health systems as a market signalling mechanism. The state and local financial institutions, especially development banks, need to play a more significant role in providing patient capital to the sector. Innovative procurement is important for signalling to potential funders the viability of the local business operations, and public health system procurement needs to be leveraged to achieve this.
- h. Science technology and innovation systems are a critical component of localisation of medical health technologies manufacturing. SGCs need to play a more prominent role in shaping the science, technology and innovation trajectories of countries. SGCs are critical midwifing and brokerage agents in local science systems. They need to be adequately funded to support science, technology and innovation systems. Due to their international and regional collaborative nature, they can easily broker technology transfer deals between local industry and international partners.
- i. Regulation and governance issues were one of the critical challenges mentioned by all sectors.
 - For the medical devices sector, the local standards bodies need to upgrade their capabilities and become notifying bodies. Their inability to serve as notifying bodies imposes huge compliance costs on microenterprises and SMEs that can least afford them. Local capabilities building for standards bodies will have a direct positive impact on entrepreneurship, and will cut regulatory costs and support economic development.
 - For biologics, there is an urgent need to develop biologicals regulatory capabilities. It will be easier for countries with vaccine manufacturing capabilities as this will be an incremental innovation for them. However, a regional regulatory training initiative such as ZAZIBONA can help shorten the learning curve.
- j. Promoting establishment of support infrastructure, such as specialised pharma and medical manufacturing parks with reliable quality power supply, common effluent treatment plants, and co-location of support industry such as logistics, packaging, advanced analytical services, formulation laboratories, and regulatory and statutory compliance support actors is necessary.
- k. Purposively bringing together industry, academia, and the government in a triple helix approach to support technological change and transitions is needed.
- l. Prioritising decent work priorities may include support for training for industrial work for both men and women; investigation of health insurance provision and other aspects of social protection in the industry; ensuring that GMP inspections by regulators pay attention to health and safety of employees; support for union organising and negotiation within the industry; investigation of contracting processes; and support for improvements in conditions of contract workers.

- m. Hard pharmaceutical infrastructure includes the provision of critical knowledge bases and skills. Gaining an understanding at a local level of the labour skill requirements for certain functions in the pharmaceutical sector is vital. There are many roles for which skills can be appropriately honed through in-house training. Foregrounding skills transfer and ongoing skills upgrading as a non-negotiable aspect of direct foreign investment, should be a priority for the sector.
- n. Regional integration presents enormous opportunities for pharmaceutical planning that coordinates production for regional and international markets, with strategic access to preferential finance for industrial development. This will require a reduction in both trade and non-trade barriers and coherent and coordinated policy and regulation, along with planned production through regional manufacturing associations. Of crucial importance is the regional alignment of standards to facilitate an Africa-wide market that makes economies of scale more likely.

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APPENDICES

ANNEX 1

Egypt Case Study

(NB: These are not comparative case studies. Each is an illustrative case of some of the key issues in localisation of medical manufacturing in the case study country.)

Pharmaceuticals

Egypt has a large pharmaceutical industry, but nearly all ingredients for local manufacturing need to be imported. One of the key drivers behind Egypt's pharmaceutical market growth is the rapidly growing chronic disease burden that has accompanied an ageing and fast-growing population. The emergence of respiratory illness, heart disease, and cardiovascular diseases in particular are driving the growth of higher-value prescription medicines in Egypt (Fitch Solutions, 2019). According to the Arab Republic of Egypt General Authority for Investment and Free Zones (2021), the Egyptian pharmaceutical market is divided into two main partners: state-owned companies and private-sector partners, represented by multinational companies, in addition to local companies.

Multinational drug makers hold the greatest market share in value terms, with notable players including GlaxoSmithKline, Novartis, Sanofi, Pfizer and Merck. Egypt's domestic pharmaceutical manufacturing industry is strong, with the main players being Egyptian International Pharmaceutical Industries (EIPICO),⁹ South Egyptian Drug Industries (SEDICO),¹⁰ Medical Union Pharmaceuticals (MUP), VACSERA, and Amoun Pharmaceuticals, recently acquired by Canada-based Valeant. Domestic producers are mainly small to medium-sized firms that manufacture generic drugs, with many being copies of patent-protected drugs owing to the country's weak patent law.

Egypt imports about US\$600 million in finished medicines per year and US\$1.8 billion in active ingredients. Egypt is part of the Common Market for Eastern and Southern Africa (COMESA) and part of the African Medicines Regulatory Harmonisation scheme. Egypt is also part of the Arab Union of the Manufacturers of Pharmaceuticals & Medical Appliances (AUPAM), a sub-organization of the Arab League, which has begun the development of a regional drug registration process in the region. Egypt has adopted the WHO Good Manufacturing Practices for Pharmaceutical Products (GMP) as the Egyptian guide for good manufacturing standards. In terms of foreign ownership, the Egyptian law allows 100% foreign ownership of investment projects and guarantees the right to remit income earned in Egypt, and to repatriate capital. Local manufacturing is encouraged through tax incentives.

Strong policy support

The government is aggressively trying to reduce importing medicines, in favour of giving more support to local production and tackling the trade deficit. For example, Pharco has signed a deal with the government to build

9. EIPICO is, currently, one of the leading Egyptian pharmaceutical companies, in terms of production and sales, in the local market. It is the leading Egyptian company in pharmaceutical exports, capturing a 26% share of the total Egyptian pharmaceutical export market.

10. SEDICO was the first pioneer Egyptian company to produce human insulin in 2002 as a new era of production of biotechnology products in collaboration with Akzo Nobel Corporation to be the first Egyptian company that formulates human insulin among the very few multinational companies producing insulin. Its production line expanded to reach more than 180 products in 14 drug groups and the products are exported to 30 countries worldwide.

the country's first factory producing medicines for the treatment of tumours at affordable prices and drugs will be produced in partnership with state-owned Holding Company for Biological Products and Vaccines (Vacsera). Egypt's exports from medical and pharmaceutical industries grew 14% in May 2018, recording US\$41 million, compared to \$35 million in the same month of 2017. The Egyptian government has previously offered research grants for innovative projects that result in the development of pharmaceutical products using domestic expertise, production of pharmaceutical raw materials, manufacture of interferon and insulin, and early identification of viral ailments such as hepatitis. The Egyptian Drug Authority (EDA) is currently giving a high priority to plasma component manufacturing.

In July 2017, Egypt's Export Council of Medical Industries announced the establishment of EGYCOPP Company, which serves as a launch base for Egyptian pharmaceutical products into Africa. The company works alongside Egyptian pharmaceutical firms and local African drugmakers to form contract manufacturing agreements so as to save on transportation costs. Domestic drugmakers in Egypt have focused mainly on generic and over-the-counter (OTC) medicines, and therefore contribute a limited amount to the patented product list. As a result, patented products from abroad are more expensive owing to import costs, especially given the local currency's weakness and patented protection status (Fitch Solutions, 2019).

The country aims for pharmaceutical manufacturers to expand and increase production in order to target more lucrative markets where drug prices are rising. This would reduce import dependence and costs for manufacturers, increase production capacity, achieve economies of scale, and lower drug prices to the consumer in the long run. However, most exports will continue to target other markets in the MENA region, with a focus on Saudi Arabia, the United Arab Emirates, Iraq, Sudan and Jordan. Romania has also emerged as an important destination for Egyptian pharmaceutical exports, and the Ministry of Health has signed an agreement with Egyptian companies to supply public hospitals in Romania with locally produced medicines (Arab Republic of Egypt General Authority for Investment and Free Zones, 2021).

Some of the biggest challenges to local production of drugs in Egypt include red tape and a lengthy registration processes, unclear market regulations, and fixed price structures.

Biosimilar products

Biosimilars are comparable to their reference products; they give similar results at a relatively lower cost (10% to 30% below reference product) and present an interesting value proposition for all the stakeholders in the healthcare systems (Vogler and Schneider, 2017). Thus, low cost is the main reason for using biosimilar products in developing countries. In Egypt, the Central Administration of Pharmaceutical Affairs (CAPA) prices the first five biosimilars 35% below the originator, and subsequent biosimilars are priced 40% below the originator. SEDICO and EIPICO have been manufacturing biosimilars such as erythropoietin locally. Generally, the active substance is imported in bulk as raw material from China. Biosimilars started accessing the Egyptian market a long time before the government established a proper regulatory structure or pathway to regulate such products. Regulatory guidelines for biosimilars were implemented since 2009 and released as a final draft in 2015.

Vaccines

Egypt has a long-established existing vaccine manufacturer, Vacsera. It is the only producer of vaccines and sera in Egypt and is one of the main blood banks. It is the oldest manufacturer of vaccines in Africa and the Middle East. The country has strong existing facilities and knowledge; recently Vacsera has succeeded in local manufacture of the Sinovac-VACSERA Covid-19 vaccine. The start of the manufacture of the 'Sinovac' vaccine by Vacsera in May 2021 was highlighted as a historic step for Egypt to become a centre for the African continent for vaccine production, as the surplus of vaccines is exported to African countries once domestic supply quotas are met.

Medical devices

Until recently, there have been no production facilities operated by international medical device manufacturers in Egypt. Local production is negligible with just one Egyptian company producing a limited range of ultrasound scanners. Specialised medical equipment such as radiography and ultrasound apparatus, vital statistics monitors, and dialysis machines are imported and distributed by a handful of companies that benefit from low import tariffs, the biggest of which, El Gomhoureya, is wholly owned by the government. In April 2021, however, Egypt unveiled its first 100% locally manufactured ventilator. The design, implementation, production, and certification of the first Egyptian ventilator was developed in cooperation with the ministries of Health and Scientific Research, and the Ministry of Military Production, which was in charge of the manufacturing process. The Unified Purchase Authority was contracted to supply the first 50 devices to kickstart production, which we hope will grow substantially.

Regulatory oversight

The EDA is the pharmaceutical regulatory body of the Egyptian Ministry of Health. The EDA includes three sub-organisations that work and cooperate together to ensure the achievement of the Authority's objectives: the Central Administration for Pharmaceutical Affairs (CAPA), the National Authority for Drug Control and Research (NODCAR), and the National Authority for Research and Control of Biological Preparations (NORCB). EDA is continuously trying to update its regulations and to support local manufacturers, especially those who intend to manufacture medical devices or drugs used in the management of Covid-19. As an example, the EDA supports the local manufacturers of ventilators.

Areas of opportunity for local medical manufacturing in Egypt

- i. In general, the ability of Egyptian medical device manufacturers to gain the CE and ISO 13485 certificates will allow them to export their products worldwide. Thus, working closely with European accredited notifying bodies is a great opportunity. Cardiology and orthopaedics products are some of the main areas of opportunity for local medical manufacturing in Egypt.
- ii. Manufacturing according to GMP will allow Egyptian (and other African) manufacturers to register and export their drugs. Biological pharmaceuticals (including vaccine and plasma products) present strong prospects for expanding export production.
- iii. The ability of local pharmaceutical manufacturers to carry out authenticated and approved randomised clinical trials in Egypt and in the region is another big opportunity that will not only identify the efficacy of innovative drugs on African population samples, but will also help the manufacturers to estimate the available market. The production of oncology medications presents another substantial opportunity.

ANNEX 2

Kenya Case Study

Essential medicines production in Kenya

Kenya is the dominant East African pharmaceutical producer. Local production of medicines dates back to the 1940s (Banda et al., 2016). The pre-independence firms of the 1940s and 1950s were overseas investments by US, UK and Australian companies. After independence in 1963, the Kenyan industry saw a wave of import-substituting investments, benefitting from industrial protection, government support for technological upgrading, and active policy encouragement of FDI (Simonetti Clark and Wamae, 2016). In the 1970s, there was diversification into upstream investments such as plastics, active promotion of investment by local capital and local-overseas joint ventures through development finance, and technical assistance via the government's Industrial and Commercial Development Corporation. This period of import substitution policies built the industrial base in pharmaceuticals that exists to this day, including the capabilities of local firms such as Lab & Allied and Dawa, both established in this period (Simonetti Clark and Wamae, 2016).

The 1980s were a policy turning point in Kenya as they were across much of SSA. A shortage of foreign exchange led to Kenya's first World Bank loan in 1980 and the imposition of conditions, including trade liberalisation. The liberalisation and impact of increasing competitive pressure was implemented more slowly in Kenya than in other countries in the region such as Tanzania, with a less dramatic de-industrialisation impact. The majority of multinational firms left Kenya during the 1980s and 1990s. However new local firms entered the market in this period, including Regal and Universal, both important producers of essential medicines to this day. Kenya joined COMESA, opening up its market to more competition, but the government also implemented a 'buy local' policy to support local firms (Wamae and Kariuki Kungu, 2014). The establishment of export processing zones (EPZs) helped local firms to adapt to international competition, notably from India.

Pharmaceuticals have been recognised as an important strategic sector in Kenya since 2010. Kenya has an essential medicines list, and promotes generic medicines use. Local production of tablets, capsules, creams and syrups grew steadily from 2010 to 2013 (Simonetti Clark and Wamae, 2016: 30). Two firms were also producing injectables. Between the two most recent manufacturing surveys, 2010 and 2018, pharmaceutical production in Kenya has risen alongside an expanding market, and the market share of local producers appears to have expanded a little (Table 8). A varying but important share of Kenyan exports are re-exports of imported goods to the wider region (21% of exports in 2018; data only available for some years). Capacity utilisation in pharmaceutical production in 2018 averaged 62% (KNBS, 2019:35).

TABLE 8

Kenyan pharmaceutical production and trade, and local market share, 2013 and 2018

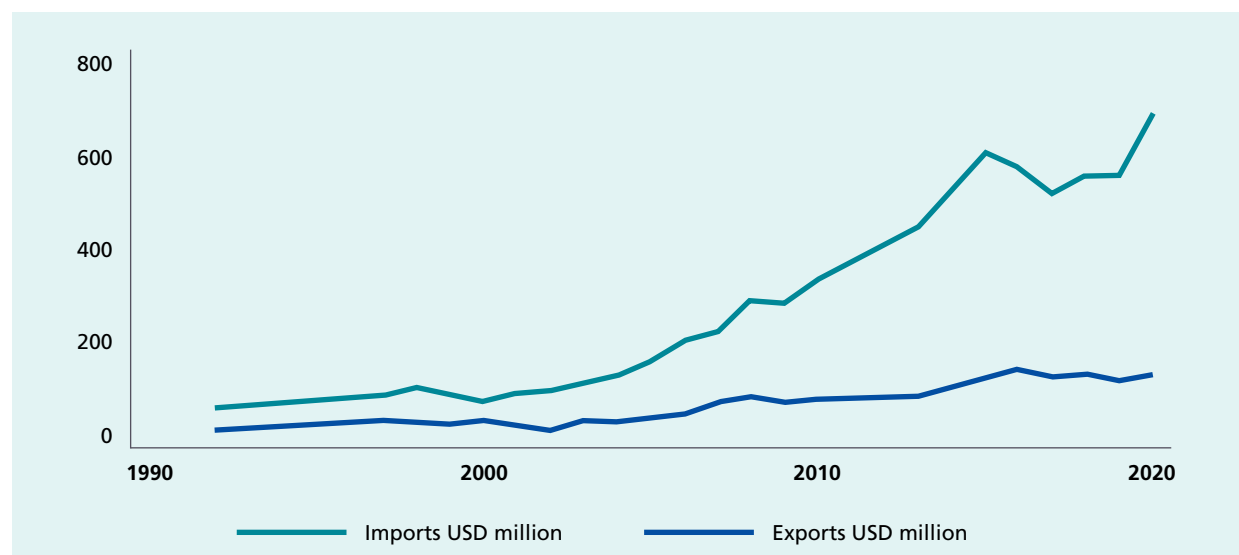
Kenyan pharmaceuticals	2010	2018
Local production value (current US\$ mn)	96.13	208.85
Exports (current US\$ mn)	74.95	130.16
Imports (current US\$ mn)	332.48	558.60
Market value (current US\$ mn)	353.66	637.29
Local market share (%) ¹¹	27.18%	32.8%

Sources: Trade values: Comtrade database, data accessed 08/09/21; Production values: Kenya National Bureau of Statistics, Census of Manufacturing Production 2010-2011 (KNBS 2013) and 2018 (KNBS 2019). KShs historical exchange rates with US\$ from [XE.com](https://www.xe.com) historical currency converter.

11. Market share calculated as Local production/(imports + local production – exports) (%)

Meanwhile Kenya's pharmaceutical trade gap has been widening sharply (Figure 10). Kenya is the main East African exporter, but exports have stagnated since 2015.

FIGURE 10
Kenya's pharmaceutical trade gap, 1990 to 2020



The dominant source of Kenyan pharmaceutical imports is India. In 2018, 46% of all pharmaceutical imports came from India. By category, India supplied 51% of finished formulations (which in turn made up 83% of all pharmaceutical imports) and 28% of human vaccines (which form 9% of Kenya's total imports). China is a relatively small supplier of Kenya's pharmaceutical imports, except for dressings of all kinds where it is recorded as supplying 70% of imports. Furthermore, China is an important source of the APIs for pharmaceutical manufacture.

Social justice and inclusion: Kenyan issues

The pharmaceutical industry is a locus of training and employment of skilled labour. It does, however, typically also rely, in African contexts, on fixed-term contracts and casual employment structures. The most recent Kenyan manufacturing census (NBS CIP, 2018) provides insight into labour force and employment structures (Table 7).

TABLE 9
Employment patterns in Kenyan pharmaceutical manufacturing, 2018

Pharmaceutical manufacturing employment	Number of employees
All pharmaceutical manufacturing	5 714
Large enterprises: 500+ employees	2 264
Medium enterprises: 100-499 employees	2 166
Male employees	3 712
Female employees	2 002
Permanent employees	3 144
Contract employees	1 415
Casual employees	1 045
Apprentices, interns etc.	108

Source: KNBS (2019).

Pharmaceutical firms in Kenya recorded 5714 employees in 2018, up from 3535 in 2010. A large majority of employees are in larger firms, and a slight majority are permanent employees. The percentage of casuals

(18%) may raise eyebrows in an industry where adherence to strict protocols is essential. While all firms record in-house training, this does not appear in apprentice numbers. Women make up a substantial but minority share of employment (35%). The data do not record their breakdown into categories such as type of contract or level of employment. However, interviewing elsewhere in East Africa (Tanzania) has found employment of women with nursing backgrounds as production workers, where their understanding of the need for hygiene and importance of the product are valued.¹² In general, this industry offers relatively good jobs in a labour market dominated by low-paid casual employment, and it is likely that more could be done to ensure access to health and safety, training and career prospects, especially in smaller firms.

Other aspects of justice and inclusion relate, as noted in the section on generic medicines, to the nature of the product. Kenyan local industry is producing a wide range of essential medicines, many of them lifesaving, and could produce more. Examples include antibiotics: Kenya-based firms produce a proportion of the beta-lactam (penicillin-type) antibiotics which are on the WHO list of essential antibiotics that should be widely available. Conversely, there is little production in the whole of East Africa of saline drips, an item which is heavy to import (it is mainly water), relatively cheap, and which can lead to death when unavailable. Covid-19 has stimulated discussion of the importance of local capability to provide a much wider range of affordable life-saving medicines, essential for more inclusive health care.

Kenya has recently seen considerable new investment in local pharmaceutical production, associated with ambitions to greatly widen the scope of production of essential medicines. New investors include Aspen, based in South Africa (through its purchase of Shelys, Tanzania, which also owned a Kenyan plant; Strides, an Indian multinational that has bought a controlling stake in Universal; and Square, a large Bangladeshi pharmaceutical firm building its first African plant. With rising recorded incidence of non-communicable diseases (NCDs), including diabetes, hypertension and cancer in Kenya, expansion of local sources of affordable treatments makes an important contribution to more inclusive health care, alongside Kenya's commitment to universal health coverage (UHC), currently operating in a number of pilot counties.

12. Source: authors' and colleagues' interviews.

South Africa Case Study

Background

The South African pharmaceutical market was valued at US\$3.2 billion in 2017 (Mothobi and Oliver, 2019) and was forecast to rise to US\$4.15 billion in 2021 and fall to just under US\$3.92 billion in 2022 (Table 10). It is the largest pharmaceutical market in Africa ahead of Nigeria, Egypt and Kenya. However, the Department of Trade, Industry and Competition (dtic), according to Mothobi and Oliver (2019), reported that pharmaceutical import penetration was a high 65%. In 2015, pharmaceutical imports accounted for 85% of total pharmaceutical trade, with most imports coming from Asia and Europe (CGI, 2020). The pharmaceutical trade deficit between the 1990s and early 2000s was US\$15.35 billion, and consequently the sector was the fifth biggest driver of the national trade deficit (CGI, 2020).

TABLE 10

Pharmaceutical and health forecasts for South Africa (2016-2022)

	2016	2017	2018	2019	2020	2021	2022
Sales – US\$ billions	2.85	3.26	3.90	4.53	4.53	4.15	3.92
Sales as % of GDP	0.96	0.93	0.91	0.89	0.87	0.86	0.85
Health spending in US\$ billions	26.23	31.14	38.26	45.39	46.18	42.77	40.67
Sales as % of health expenditure	10.8	10.5	10.2	10.0	9.8	9.7	9.6

Source: Consulate General of India, Johannesburg (CGI, 2020).

Sales of pharmaceuticals as a percentage of GDP have been under 1%. Health spending rose from US\$26.23 billion in 2016, building to a high of US\$45.49 billion in 2019, but it is forecast to reduce to US\$40.67 billion in 2022. Sales of pharmaceuticals as a proportion of health expenditure have revolved around the 10% mark and are forecast to fall to 9.6% in 2022 (Table 10).

South African health sector spending is amongst the most disproportionate. Despite the constitutional changes that declared access to adequate healthcare, including medicines, to be a human right (Mothobi and Oliver, 2019), 16% of the population accounts for 63% of (private) healthcare resources, whereas 84% of the population accounts for only 38% of (public) healthcare resources. Healthcare spend for the top 16% is US\$1300 per person per annum, and for the rest of the population it is an average of US\$220 per person per annum – a 6-fold differential (CGI, 2020).

Although there are only 122 local manufacturing plants in South Africa, the Department of Health and the local regulator have registered 276 companies to manufacture, import or export, as well as to distribute pharmaceuticals.

TABLE 11

Market share for the top ten pharmaceutical companies in South Africa

Market Players	Market Share (%)
Adcock Ingram	12.1%
Novartis	11.5%
Merck & Co.	9.7%
Johnson & Johnson	8.8%
Pfizer	8.8%
Sanofi	7.4%
Bayer	7.1%
Roche	6.9%
Aspen	5.21%
Cipla	5.0%

Source: Goldstein Market Intelligence (2020).

Case study of a medical device manufacturing SME

We interviewed a South African Medical Device SME that produces minimally invasive surgical devices, and medicines delivery and treatment devices. Some of the key issues that arose from the interview are briefly discussed below. Multinationals are the dominant players at least in South Africa, however there are many medical device importers and distributors.

Regulation and regulatory barriers to market entry

Local medical devices companies use European-based notified bodies to get the CE mark¹³. African companies are thus regulated from, for example, the UK, which makes regulation very expensive. The general cost for regulation is between ZAR600 000 to ZAR700 000, but it costs ZAR1.5 million per product to get the CE marking and production standards accreditation. It would be cheaper, and more convenient, if African countries had their own notifying bodies. The South African Bureau of Standards (SABS) should have the capability to regulate local companies and reduce the barriers to entry in the field. Given that compliance is critical, regulatory standards are a competition tool and having multiple regulators for different services is a huge cost to business.

The lack of notifying bodies in African countries is a serious impediment. There are multiple governing bodies that form the comprehensive regulatory framework for medical devices in South Africa: SABS, South African Health Products Regulatory Authority (SAHPRA), South African National Accreditation System (SANAS) and European bodies. SAHPRA inspects and licences premises, and SABS handles some equivalent standards but they do not have the full capabilities to regulate medical device manufacturing. SANAS regulates the sector to a certain degree – for example they can regulate x-ray equipment, but they do not have much capability to regulate technologies related to surgery. This forces local companies to comply with locally available standards first, and for standards that are not locally available, they have to access external notifying bodies. The regulatory barriers vary from one product category to another. Some capabilities are driven by the local development of technologies and innovations – for example, CapeRay which produces equipment to detect breast cancer, influenced the growth of regulatory capabilities in that sector.

Funding

Working capital requirements are high because there is a need to buy brand new machines and, as the medical devices respondent noted, ‘No company in Europe will send their machines around the world on a leasing agreement.’ However, there is limited to no funding in Africa for medical device manufacturing enterprises because of the capital-intensive nature of the business (expensive machinery is used in production). The respondent reported that when pre-revenue enterprises, in particular, approached commercial banks, the answer from several banks was, ‘When you are post revenue come back for money.’ This is not surprising, given that the financial system architecture in South Africa and many African countries was set up to finance trade and commerce and not industrial development. To make matters worse, in many countries there are no specialised venture capitalists or enterprise incubators for medical device businesses. Moreover, there is no interest in supporting manufacturing industries that are not yet commonplace on the continent, such as metal additive manufacturing (MAM), which is likely to be critical for the medical devices sector.

Networks and linkages

Prior clinical and pharmaceutical manufacturing experience is vital in identifying suppliers of plant and equipment for local entrepreneurs in European and Asian markets. The entrepreneurs cultivated these relationships with external companies manufacturing medical devices in order to bring their technologies to market. The feasibility

13. A CE mark ‘indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements’.

study of suppliers of machinery and equipment and other projections took two years, and they realised that no companies could produce the machines locally. Although the plastics industry is prominent (buckets, tanks, chairs), there are few suppliers of medical grade plastic; however, there is an appetite from local manufacturers to shift to producing medical grade plastic.

Local sourcing of medical grade polymers required local cooperation with companies which already produced medical grade polymers, and the critical step was incorporating standards for medical devices. It took some time for the collaborating company to come on board. The respondent reported that supportive policy at a level that drives rapid local industrial development is still lacking for the fledgling industry. The respondent argued that, although the sector is contributing marginally to GDP, the industry has great potential.

Some areas of opportunity for South Africa and Africa as a whole

- The biggest killers in Africa, and increasingly so, are diabetes and hypertension, linked to changing lifestyles over the years. Products that come into the market must be prioritised around those that address non-communicable diseases.
- Gastro-bypass surgery in the UK, US and China are quite prominent. Products exist to deliver this treatment, yet to date none are manufactured in Africa.

Ghana Case Study

Universal health coverage – a driver for the pharmaceutical sector in Ghana

Ghana's pharmaceutical market, which stood at US\$86m in 2019 and was projected to grow to about US\$20m in 2020, is seen as one of the most attractive markets in West Africa. Among the reasons for this are the support for a local pharmaceutical sector by the government, and the existence of the National Health Insurance Scheme (NHIS), which provides basic care to the majority of the population (Pharmexcil, 2020). The Ghanaian government's plans to attain universal health coverage in the next few years is likely to see the sector grow further, though issues such as low incomes and limited out-of-pocket spending power (which the NHIS is trying to address), dominance of branded generics, and dependence on pharmaceutical imports, will need to be resolved.

As with most emerging African countries, Ghana has a negative trade balance. According to the Ghanaian health service, only 30% of the national requirements for pharmaceutical products are produced in Ghana, while the remaining 70% are imported. However, the Ghanaian government has emphasised the need to manufacture more locally produced medicines over the next decade, an ambition it shares with many African governments.

According to Ghana's Food and Drug Administration, there were 126 foreign pharmaceutical manufacturing facilities with valid licences to export to Ghana. Of this total, the majority were from India (62), followed by Bangladesh (3), France (2), Germany (2), Nigeria (2), the US (2), Egypt (1), Belgium (1), Sweden (1), Thailand (1), and China (1).

Domestic producers in Ghana chiefly manufacture generic drugs. Although multinational drug makers operate in Ghana, the market is increasingly shifting in favour of generic medicines, thus favouring domestic production. Foreign generic drug makers in India and China have a growing influence.

There are currently 38 local pharmaceutical manufacturing units in Ghana, of which about 20 are actively involved in manufacturing formulations. These local manufacturers experience major challenges, including higher costs of production and absence of manufacturing facilities compliant with WHO GMP standards. Factors resulting in the relatively higher cost of production in Ghana include the inflated costs of raw materials, utilities, transport, equipment maintenance, financing and technical capacity (UNIDO, 2015), as highlighted in sections 8 and 9 on some of the value-chain and broader contextual issues that need attention for sustainable pharmaceutical production.

European and US multinational pharmaceutical companies dominate the innovator drugs market still, and these companies also participate, with limited competition, at the higher end of the market for patent-expired products and continue to charge high prices for their products. Generic manufacturers, particularly from India, have been able to exploit this strategy by charging lower prices for patent-expired products (UNIDO, 2015).

Policy support

The Ghanaian government has, over the years, initiated a number of policies to help local manufacturers gain a foothold in the local pharmaceutical industry. For example, the government developed a health policy in 1989 that would promote local pharmaceutical production and reduce reliance on imports. The key features of the policy were price preference for locally produced products and tax incentives (Zakari and Boly, 2013).

The impact of the policy is evidenced by a rise of pharmaceutical manufacturers from 9 in 1989 to 55 in 2014 (Frost and Sullivan, 2014), upgrading of the 39 manufacturing facilities towards international cGMP standards, partnerships with multinational companies, and one manufacturer, LaGray, engaging in primary production (UNDP, 2016). Other important policy initiatives include the following:

- The decade-long (2006-2015) Global UNIDO Project, 'Strengthening the local production of essential medicines in developing countries through advisory and capacity building support' launched in Ghana (UNIDO, 2015).
- In March 2020, Ghana's parliament passed the Narcotics Control Commission Bill, 2019, to treat drug dependence as a public health issue rather than focusing on law enforcement, incarceration, punishment, and repression.
- In September 2020, the Ghana National Chamber of Pharmacy (GNCP) signed a Memorandum of Understanding (MOU) with a construction firm for the creation of a pharmaceutical industrial park for pharmaceutical companies to establish large-scale operations.
- In November 2020, Ghana's president tasked the Pharmaceutical Society of Ghana (PSGH) to position the country to become the centre of generic drugs production across SSA. As Ghana is one of only two countries in SSA which produce APIs, we believe these initiatives will significantly help to bolster pharmaceutical growth.

Meanwhile, one of the most important recent steps taken by the Ghanaian government to promote the local pharmaceutical industry was to ban the imports of finished formulations of 14 widely used products that could be produced locally, including ampicillin, tetracycline, chlorthalidone, indometacin, paracetamol, aspirin and diazepam.

However, the VAT exemption for materials imported for local pharmaceutical manufacturing was withdrawn, probably due to revenue-generation considerations. Stakeholders involved directly in promoting local industry, including local manufacturers and the Ministry of Trade and Industry, have indicated their desire for VAT to be rolled back for locally produced medicines. The potential loss in revenue generation from the 10% import duty as a result of a reduced need for imported products may dampen the support for local manufacturing; this perception will need to be addressed.

Other support

The Ghana-UK Business Council (UKGBC) was launched in 2018, and since its inception, it has overseen millions of pounds of new UK investment in Ghana, supported a targeted development assistance programme and built and strengthened partnerships between UK and Ghanaian institutions. The pharmaceutical sector is one of the key areas of focus for the UKGBC.

In October 2020, the UK government pledged a £450 000 support package to Ghana's pharmaceutical sector, to help it adapt and 'build back better' in the wake of Covid-19. This new support is expected to:

- i. Strengthen vaccine production and delivery by building private sector capacity and creating new partnerships;
- ii. Help firms to address vulnerabilities in their supply chains and undertake R&D for new medicines, but in support of fighting Covid-19 and other common diseases;
- iii. Improve manufacturing practices making sure they are in line with global requirements for the industry; and
- iv. Support and improve pharmaceutical policy and regulations.

Generics market

Generic drugs comprise the majority of pharmaceutical sales in Ghana, although their share of the overall market is projected to decrease slightly. European and US-branded OTC and prescription drugs remain popular among the middle class as they are the 'trusted' option when compared with unbranded generics. One respondent, a pharmaceutical industry expert, highlighted that Ghanaians generally preferred imported products, not just pharmaceutical products, and this may be an issue that needs addressing at a broader societal level, especially given that branded medicines are often more expensive than unbranded generics. One of recent efforts to boost domestic consumption of locally produced goods was the 'Made-in-Ghana' campaign inaugurated in 2014. As part of the campaign, President Mahama encouraged public institutions to procure from local industries

in order to 'mainstream the patronage of Made-in-Ghana goods and services in their procurement practices' (National Development Planning Commission, 2016).

In 2019, Ghana had a US\$376 million generic drug market, representing 63.8% of the total market value and 86.6% of the prescription drug market. By 2020, the generic drug market was expected to reach US\$395 million. Generic drug sales will grow at a compound annual growth rate of 9.6%, to reach a value of US\$595 million by 2024, making up a 63.2% share of the pharmaceutical market in Ghana by this time (Pharmexcil, 2020). This almost double-digit growth rate in drug sales is characteristic of many pharmaceutical markets in SSA, where robust growth in medicine sales will be driven mainly by increased volume consumption within the generic medicines sub-sector. Across the region, generic drug makers will increase production to meet rising demand and will be further helped by cost-containment measures encouraged by governments. Per capita spending on medicines in Ghana is projected to increase from US\$20 in 2019 to US\$41 by 2029, remaining low by global standards (Pharmexcil, 2020).

Local manufacturing case studies

Among the local manufacturers are Ayrton Drug Manufacturing, which was set up in 1969, and is still operational, and LaGray Chemical Company, set up in 2009, but which ceased operations in 2016 because of lack of working capital and changes in investment commitments on the part of investors. Despite their contrasting fortunes, the two cases in many ways capture the challenges faced by local manufacturers in Ghana, especially relating to cost, personnel, and regulatory and market hurdles.

The following, gleaned from interviews and literature (UNDP, 2016) are among the major reasons why production costs are higher for pharmaceutical manufacturers in Ghana than for foreign pharmaceutical manufacturers:

- lack of technically-qualified people (though some innovative approaches have been tried in the past to upskill and deploy available personnel);
- higher unit costs of raw materials due to purchasing in smaller amounts and higher transport costs;
- requirement for higher inventories of materials and spare parts due to difficulties arranging supplies at short notice;
- higher costs of imported machinery;
- higher interest charges on loans (financiers do not understand the pharmaceutical sectors, while actors in the sector do not seem to understand how to develop fundable proposals; see Banda (2013) concerning the pharmaceutical sector in Zimbabwe;
- higher electricity and other utility charges (there is a need to think broadly about pharmaceutical sector requirements, including these infrastructural issues, when investment in this sector is being considered); and
- local manufacturing is not R&D based, and there is little or no interface between local research institutions and manufacturers.

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