



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



PHARMACEUTICAL INDUSTRY

IN SUB-SAHARAN AFRICA

A GUIDE FOR PROMOTING
PHARMACEUTICAL
PRODUCTION
IN AFRICA

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The lead author was Simon White. Nadine Vohrer, Industrial Development Expert, UNIDO led and coordinated the completion of the document. The overall management of the project rested with Juergen Reinhardt, Senior Industrial Development Officer, Investment Promotion Division, Department of Trade, Investment and Innovation, UNIDO. The intervention formed part of UNIDO’s long-time support for promoting local pharmaceutical production in developing and least developed countries, with a focus on sub-Saharan Africa. For more information see:

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LIST OF ABBREVIATIONS

ACT	Artemisinin-based combination therapy	PMPA BP	Business Plan for the accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa
API	Active pharmaceutical ingredient	QMS	Quality management system
AIDA	Accelerated Industrial Development of Africa	R&D	Research and development
AIDS	Acquired Immune Deficiency Syndrome	RPMPOA	EAC Regional Pharmaceutical Manufacturing Plan of Action
AMRH	African Medicines Regulatory Harmonization	SDGs	Sustainable Development Goals
ARV	Antiretroviral (drug)	SME	Small and medium enterprise
AU	African Union	SSA	Sub-Sahara Africa
CTD	Common technical document	TRIPS	Trade-related intellectual property rights
DFI	Development finance institution	UN	United Nations
EAC	East African Community	UNAIDS	Joint United Nations Programme on HIV/AIDS
EBITDA	Earnings before interest tax depreciation and amortization	UNCTAD	United Nations Conference on Trade and Development
ECOWAS	Economic Community of West African States	UNICEF	United Nations International Children's Emergency Fund
ERPP	ECOWAS Regional Pharmaceutical Plan	UNIDO	United National Industrial Development Organization
FDI	Foreign direct investment	USD	United States Dollar
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit	VAT	Value Added Tax
GMP	Good manufacturing practice	VC	Venture Capital
HIV	Human immunodeficiency virus	WHO	World Health Organization
IDDA	Industrial Development Decade for Africa	WTO	World Trade Organization
MCF	Medical Credit Fund		
NEPAD	New Partnership for Africa's Development		
NMRA	National medicines regulatory authority		
PE	Private equity		
PMPA	Pharmaceutical Manufacturing Plan for Africa (African Union)		

EXECUTIVE SUMMARY

There is now a wide-ranging consensus that local pharmaceutical production in sub-Saharan Africa in close proximity to where medicines are needed can reduce dependence and improve health outcomes for the population. Many African governments, regional economic communities and the African Union have recognized the need for active support to the development of the sector if these benefits are to be realized. However, concrete action on the ground has remained hesitant and piecemeal to date.

This document contains advice for government policy makers, the private sector especially pharmaceutical manufacturers in sub-Saharan African countries, development partners and (development) finance institutions on how to promote pharmaceutical production. The guide focuses on the key areas competitiveness, market access, technology and access to finance. It further proposes a path of how governments could embark on and steer a policy development process as well as giving guidance on policy interventions. The document especially emphasizes the interconnectedness of key intervention areas and recommends that promotional measures from key areas should be combined to increase impact.

OVERVIEW OF GUIDANCE

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- 4.2.2 Build strong political leadership for a common vision
- 4.2.3 Integrate vertical and horizontal policy approaches
- 4.2.4 Formulate a coordinated plan of action
- 4.2.5 Lead through consultation and partnership
- 4.2.6 Adopt a flexible approach

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OVERVIEW OF GUIDANCE

6

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TO NEW AND MORE
PROFITABLE MARKETS

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- 6.2.2 Balance short-term protection with long-term capacity building
- 6.2.3 Prevent medicine dumping and sub-standard imports
- 6.2.4 Publish medical items for local supply
- 6.2.5 Use public procurement to drive competition and investment
- 6.2.6 Align public procurement with quality improvements
- 6.2.7 Improve access to international markets
- 6.2.8 Build economies of scale through regional market harmonization
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HOW TO IMPROVE
QUALITY
AND DEVELOP THE PRODUCT
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- 7.2.1 Strengthen the enforcement of regulations on sub-standard products
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- 7.2.3 Link quality improvements with increased access to markets
- 7.2.4 Support dossier purchase and provide clear guidelines to facilitate approvals
- 7.2.5 Improve access to foreign expertise
- 7.2.6 Create a business case for technology-based partnerships
- 7.2.7 Foster collaboration between industry, academia and research institutes
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HOW TO STIMULATE
ACCESS TO FINANCE
FOR THE PHARMACEUTICAL
INDUSTRY

- 8.2.1 Use time-bound subsidies to lower the cost and risk of commercial finance
- 8.2.2 Support the development of more diverse financial products
- 8.2.3 Create sector funding mechanisms
- 8.2.4 Improve the financial competencies of local manufacturers
- 8.2.5 Improve the financial brokerage in the pharmaceutical sector
- 8.2.6 Improve corporate governance to attract investment
- 8.2.7 Build partnerships with the financial sector
- 8.2.8 Encourage foreign investment in the sector
- 8.2.9 Adapt procurement practices esp. improve payment terms for local suppliers
- 8.2.10 Encourage investment in upgrading to WHO GMP

The successful implementation of pharmaceutical sector development support measures requires coordinated action to tackle the main challenges simultaneously as well as cooperation between different departments within governments. It will also be contingent upon partnerships between public and private sector actors. The willingness and ability to fund key activities and to adopt a medium to long-term perspective are also decisive factors for success.

1

INTRODUCTION

**CHALLENGES AND
OPPORTUNITIES**

FOR PHARMACEUTICAL PRODUCTION

IN AFRICA

1. INTRODUCTION

1.1 CHALLENGES AND OPPORTUNITIES FOR PHARMACEUTICAL PRODUCTION IN AFRICA

The global market for pharmaceuticals was worth USD 934.8 billion in 2017 and is projected to reach USD 1.17 trillion in 2021 growing at 5.8% per annum^[1].

Emerging markets display highest growth rates in pharmaceuticals because population and consumption growth are among the major drivers of growth in the pharmaceutical sector. Spending on health care is growing disproportionately with rising household income (McKinsey 2018). The pharmaceutical market in Africa is estimated to be worth between USD 40 and 65 billion annually by 2020.

Despite high growth rates access to medicines remains a problem in sub-Saharan Africa (SSA). To address the high disease burden^[2] all sub-Saharan African countries largely depend on imports for the supply of essential medicines. In Africa, WHO reports that half the population lack regular access to essential medicines and 90% of medicines are imported (Chaudhuri and West 2014). In countries with pharmaceutical manufacturing in the region the share of local production lies between 10 and 30%. This varies among countries with a more substantial pharmaceutical sector, such as Ghana, Kenya, Nigeria and South Africa, and those with no manufacturing at all.

The ten largest drug companies in the world control over one-third of the market, several with sales exceeding USD 10 billion a year and profit margins of about 30%. Six are based in the United States and four in Europe. In the generics segment of the market, however, India has become a significant player with five out of the 15 largest generics producers headquartered in India^[3]. Most sub-Saharan African countries rely on India for the supply of generic medicines.

Congruently, African pharmaceutical manufacturers mainly import active pharmaceutical ingredients (APIs) and excipients from India and China. At the same time a large share of the medicines supply especially for HIV/AIDS, malaria and tuberculosis is provided by international agencies at a level that will not be sustainable in the long term. Some countries are graduating from international donor support and have to build reliable and sustainable supply systems.

[1]<https://www.pharmamirror.com/pharmaceutical-articles/growth-in-the-pharmaceuticals-market-a-market-research-report/>

[2]It is estimated that Africa accounts for 25% of the global disease burden, more than 50% of the global deaths of children under five. Only three per cent of the world's healthcare workers are deployed in Africa and the continent consumes only one per cent of global healthcare expenditure (International Finance Corporation 2007). The share of Africa in producing medicines is at a similarly low level.

[3]<https://www.thebalance.com/top-generic-drug-companies-2663110> or <https://www.fiercepharma.com/special-report/top-15-generic-drugmakers-2016>

In line with a real dependence on these imports African governments are increasingly considering medicines supply as a national security issue. Indeed, the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA) endeavours to ‘facilitate the development of a competitive pharmaceutical industry in Africa to ensure self-reliance’, while envisioning that the ‘African people have access to essential, quality, safe and effective medical products and technologies’ (AU 2007).

1.2 PURPOSE OF THE GUIDE

This guide focuses on how to improve pharmaceutical production in sub-Saharan Africa to strengthen local health systems and promote industrial development and job creation in a technology intensive sector. This includes advice on improving the policy and regulatory environment, stimulating competitiveness of local firms and innovation, improving quality standards, and increasing the access of sub-Saharan African pharmaceutical producers to national and regional markets.

This guide presents pragmatic perspectives on the challenges faced by local pharmaceutical firms and provides advice on how these can be addressed by governments, industry and development partners.

1.3 INTENDED READERS

This guide is a resource for African policymakers south of the Sahara, business owners and managers, industry associations, donor and development agencies with an interest in promoting greater levels of investment in African pharmaceutical production and improving the competitiveness of local firms while strengthening national health systems. It supports the efforts of sub-Saharan African policymakers and reformers, regional economic communities, and national and sub-national government ministries, departments and agencies.

1.4 ORGANIZATION OF THE DOCUMENT

Part 1 describes the context for African pharmaceutical manufacturing and identifies the key challenges for policymakers, industry, and international donor and development agencies.

Part 2 addresses a series of challenges facing the African pharmaceutical sector and provides pragmatic recommendations for policymakers, private sector and the development community.

PART 1

THE CONTEXT AND FRAMEWORK FOR PHARMACEUTICAL PRODUCTION -IN AFRICA-

The first part of this guide locates the challenges for pharmaceutical production in Africa in the broader challenges facing Africa's social and economic development. This includes the need for economic growth and job creation, as well as the priorities for health security and, more broadly, the achievement of the United Nations' Sustainable Development Goals (SDGs).

2

PHARMACEUTICAL

PRODUCTION

IN SUB-SAHARAN AFRICA

2. PHARMACEUTICAL PRODUCTION IN SUB-SAHARAN AFRICA

2.1 AFRICA'S DEVELOPMENT CHALLENGE

'To achieve the Sustainable Development Goals, including ending the AIDS epidemic as a public health threat by 2030, African countries need to secure sustained access to affordable, quality-assured medicines and other health commodities. This is a health and development priority.'

Michel Sidibé, Executive Director UNAIDS (UNAIDS 2016)

Africa faces a range of economic, social, health, and environmental challenges that underpin and inform its development strategies at continental, regional, national and local levels. Many of these challenges are reflected in the Sustainable Development Goals (SDGs). Supporting the development of a more competitive and sustainable pharmaceutical industry in sub-Saharan Africa is a powerful contribution to the achievement of the SDGs.

SDG 3 aims to 'ensure healthy lives and promote well-being for all at all ages.' There are many opportunities for action in this field, including support for collaboration across the healthcare industry and with research organizations, governments and other stakeholders to develop innovative low cost preventative and curative treatments for communicable and non-communicable diseases in low and middle-income countries. Other opportunities include the adoption of low price, high volume pricing models to expand access to vaccines, diagnostic tests, pharmaceuticals, supplements and family planning in low and middle-income countries (United Nations Global Compact and KPMG International 2016).

SDG 8 aims to 'promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all'. Opportunities here include increasing local sourcing and manufacturing of vaccines, pharmaceuticals, diagnostic tests, medical supplies and medical devices in low and middle-income countries. In addition, there are opportunities to integrate small-scale producers into value chains and provide them with support such as training, connections to supplier networks for lower cost joint procurement, and access to finance (United Nations Global Compact and KPMG International 2016).

SDG 9 aims to 'build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation'. This goal recognises the centrality of inclusive and sustainable industrialisation for development and is consistent with the African leaders' statement towards inclusive growth and sustainable development in the Common African Position on the post-2015 development agenda and the African Union's 50th Anniversary Solemn Declaration, culminating in the Africa Agenda 2063, and its First Ten-

Year Implementation Plan. Many African countries have already proceeded to formulate national strategies to take advantage of the current global momentum for fostering inclusive and sustainable industrial development.

2.2 HEALTH SECURITY AND PHARMACEUTICAL PRODUCTION IN AFRICA

‘Local production is essential for improved access to affordable medical products, and therefore to ensure a strong linkage between local production and improved access, there is need to bring coherence between health, industrial development and trade policies in the pharmaceutical sector.’

Cleopa Mailu, Cabinet Secretary Ministry of Health Kenya (UNAIDS 2016)

Development of the pharmaceutical industry in Africa contributes to building more robust and sustainable national health systems. Local production broadens supplier base, reduces foreign currency expenditure and helps local producers to improve their response to local needs. A stronger local pharmaceutical industry improves a country’s capacity to respond to local health priorities and creates synergies and linkages between industrial and health system investments. By developing the local pharmaceutical industry, African governments increase local value addition through better backward and forward linkages (e.g., packaging, excipients and distribution services).

The issues surrounding public health provide an important perspective on the local production of medicines in Africa. This requires the alignment of industrial development and public health objectives. The development of local medicine production is a priority for local consumers (Sidibé, et al., 2014).

African leaders have laid down the importance of the promotion of the pharmaceutical sector in the AU Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Business Plan for the accelerated implementation (AU 2012). The pharmaceutical sector has been identified as a priority sector in industrial development initiatives such as the Third Industrial Development Decade for Africa (IDDA III) and the Accelerated Industrial Development of Africa (AIDA). At the regional level development plans for the sector have been formulated like the 2nd East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) 2017-2027 and the ECOWAS Regional Pharmaceutical Plan (ERPP) 2014-2020. At the national level many governments are considering to prioritize the sector which can bring potential benefits in the health and industrial development spheres.

AFRICAN INDUSTRIAL DEVELOPMENT IN PHARMACEUTICALS

CAN SUPPORT HEALTH SYSTEM STRENGTHENING THROUGH :

(Mackintosh, et al., 2017)



INCREASED NATIONAL GOVERNMENT COMMITMENT

to funding of medicines from domestic taxes, improving medicines access;



IMPROVED PHARMACEUTICAL SKILLS AND TRAINING

benefitting health system management and procurement as well as industrial development;



LINKED PUBLIC AND NON-PROFIT PROCUREMENT

becoming more responsive to local needs, by building linkages to close-to-market suppliers;



IMPROVED RURAL ACCESS TO MEDICINES,

as local firms respond to incentives to expand domestic distribution networks;



COMPETITIVE FALLING COSTS AND PRICES

as domestic industrial investment and market competition increase;



SHORTENED SUPPLY CHAINS

and hence faster response to emergency supply shortages;



REDUCED INCIDENCE OF SUB- STANDARD MEDICINES

as proximity improves regulatory oversight and the share of public and non-profit procurement rises.

2.3 INDUSTRIAL DEVELOPMENT AND PHARMACEUTICAL PRODUCTION IN SUB-SAHARAN AFRICA

The development of an indigenous pharmaceutical production industry in sub-Saharan Africa is hampered by several critical challenges.

MARKET ACCESS

Over the years, local pharmaceutical manufacturers in Africa have learned to do business and grow in difficult market conditions. The market share of local production is low and declining in some African countries. Existing supply systems often favour imports as taxes and tariffs are often charged on inputs to pharmaceutical production and not on the importation of finished products. While donors supply a significant share of the medicines consumed in some countries, procurement is performed through international competitive bidding normally restricted to manufacturers with WHO prequalification. Only a handful of prequalified products come from manufacturers in Africa.^[4] Being caught between branded products from multinationals, which are perceived as superior quality and low price imported products, which sometimes fail quality requirements African manufacturers are forced to accept very low margins. This makes it hard to invest in the company for quality upgrading or portfolio expansion. Despite this, local producers are becoming more innovative and are responding to market changes.

COST OF PRODUCTION

African manufacturers suffer from several cost disadvantages including: higher unit costs associated with manufacturing, materials and machinery, finance and utility services. The small scale of most SSA producers also tends to increase the unit costs of production. Foreign firms with large manufacturing plants serving bigger markets can economise on costs with larger production batch sizes and can 'afford' dedicated facilities for particular formulations, which saves costs of change over between products. A firm with a larger plant producing larger volumes can also buy materials at lower prices. Unit labour costs in Africa are generally higher due to lower productivity and higher cost for hiring technically qualified people and experts from abroad. African manufacturers rely on imported sources for most of their requirements of APIs, excipients, primary packaging materials, machinery and equipment. Import duties and value added tax (VAT) on these materials and equipment increase the cost in many countries while imported medicines are often exempt from duties and taxes.

.....
[4]. WHO prequalification is a scheme run by the WHO, which certifies (i.e., prequalifies) products for a limited number of diseases including HIV/AIDS, malaria, tuberculosis, neglected tropical diseases, diarrhoea, influenza and reproductive health. The assessment consists of a dossier assessment for the specific product and a site inspection against international GMP standards. UN Organizations and other major international entities involved in purchasing medicines for consumption in Africa require WHO prequalification when procuring all of the products in the categories covered.

ACCESS TO AFFORDABLE FINANCE

Access to long-term credit and working capital is limited in Africa due to the high cost of finance. While the cost of borrowing varies the rate of interest is often in the range of 15-25 % per annum in local currency and in some cases even higher. For example, Beck and Cull (2016) report that private enterprises in Africa are less likely to obtain a commercial loan than in other developing regions of the world. Problems accessing finance prevent most local companies from investing in improvements, diversification and expansion.

INFRASTRUCTURE

The unreliable, insufficient supply and high cost of electricity and water not only substantially increase operating costs, but also act as barriers against effective use of installed production capacity. The poor conditions of roads are also a major challenge, often causing long delays in clearing the imports of raw materials and delivery to manufacturers. There is often limited availability of land that is connected to utilities and suitable for pharmaceutical production.

TECHNICAL CAPABILITIES

The pharmaceutical industry is a technologically intensive industry. Medicines must be manufactured under close technical supervision and by technically qualified people to ensure the safety, efficacy and quality of the products. This requires skilled technicians to set up and run good manufacturing practice (GMP) plants, to develop products to meet the regulatory requirements for marketing approvals. GMP comprises of a set of safeguards and procedures in the production process to ensure manufactured products are effective and safe. This requires not only qualified industrial pharmacists, but workers who are educated and trained in chemistry, biochemistry, engineering, and related sciences. While most local manufacturers currently produce a limited range of products, there are signs of innovation. Skills in developing new products to expand the portfolio of generics that are produced are often missing. The problem is not only the lack of adequate in-house competencies, but the insufficient opportunities to access pharmaceutical-specific technical assistance from local universities and research and training institutions. There is a big gap between what the industry requires and what is being taught in universities. In terms of scientific infrastructure there are very few clinical research organizations and bioequivalence centres in sub-Saharan Africa.

2.4 THE STATE OF THE PHARMACEUTICAL INDUSTRY IN AFRICA

The pharmaceutical industry across Africa varies, with some countries producing highly sophisticated products that they sell across the region and other countries with no or very little production relying completely on imports. More broadly, African pharmaceutical

production falls within a highly integrated global market in which developing economies and firms are struggling to compete. McKinsey & Company estimates the African pharmaceutical market will be worth between USD 40 and USD 60 billion by 2020.^[5] Ten countries represent 70 percent of Africa's pharma market: Algeria, Egypt, Kenya, Ivory Coast, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia (McKinsey & Company 2015). Increasingly, pharmaceutical companies from high-income countries are strategically expanding their hold in developing and emerging markets (Chaudhuri, et al., 2010). Developing country firms have been under increased pressure, which has led to increasing mergers and acquisitions (WHO 2011).

More than 300 companies are active in pharmaceuticals production across the African continent, among them multinationals such as Johnson & Johnson in South Africa and Sanofi in Algeria. The genesis of African pharmaceutical manufacturing was in countries such as Nigeria, South Africa and Zimbabwe. This was created during the latter part of the 1930s by European firms establishing subsidiaries in colonies and onwards. Later, local entrepreneurs with experience in the multinational pharmaceutical companies set up their own production facilities (Russo and Banda 2015) mirroring the pharmaceutical development trajectory in India. Therefore many sub-Saharan African manufacturers are small privately-owned firms that serve national markets. However, there are also some publicly listed companies (e.g., Dannex in Ghana and CiplaQCIL Uganda).

Increasingly, large African producers are owned, in full or in part, by foreign firms. Some companies have invested in facilities using international equity finance (e.g., Universal Corporation Ltd. in Kenya). A few Indian and Chinese multinationals are also active in the African market (e.g., CiplaQCIL in Uganda, Humanwell Healthcare Group in Mali and Sansheng Pharmaceuticals PLC in Ethiopia). Aspen in South Africa operates as one of the top ten largest generic manufacturers in the world.

Medicines can be classified as patented products and generics. Pharmaceutical manufacturing in Africa focusses on generics. In many African countries, generic drugs are rapidly gaining market share. In Algeria, Egypt, Kenya, Morocco, Nigeria, and South Africa generics experienced an average compound annual growth rate of 22.3% between 2004 and 2011, faster than the 13.4% for the whole pharmaceuticals sector. This is due to a greater preparedness by physicians and pharmacists to prescribe generic drugs, the expansion and increased demand on national insurance programs that encourages use of low cost generics and greater support by governments for the use of generics. For instance, pharmacists in South Africa are required by law to inform and offer private patients generic alternatives (McKinsey & Company 2015).

Pharmaceutical production for both originator products and generics can be divided into three linked activities: the manufacture of APIs and intermediates, the production of finished dosage forms from APIs and excipients, and the packaging of finished dosage

[5]. This growth is expected in all market segments, from prescription drugs (expected to increase by six per cent from 2013 to 2020), generic drugs (nine per cent), over the counter drugs (six per cent) and medical devices (11%). (McKinsey & Company 2015).

forms or repackaging of bulk finished products. A high proportion of local pharmaceutical production is the manufacturing of finished dosage forms especially in the field of essential medicines.^[6]

Sub-Saharan African manufacturers mostly produce a limited range of products, restricted to over the counter formulations and basic prescription medicines covering cough and cold preparations, vitamins, analgesics, basic sedatives, anti-malarial, anti-helminthic, older generation antibiotics, first generation anti-hypertensives, anti-diabetics, first-line and second-line antiretroviral medicines, etc. Many of these are produced in simple dosage forms, such as plain tablets, capsules, lotions, and suspensions. However, there are some examples of local companies producing more advanced formulations, such as sustained release tablets, and complex products, such as immune sera and immunoglobulins, sterile products and vaccines.^[7] Expensive innovative medicines such as anticancer drugs, immunosuppressive drugs, and blood components, are not manufactured by local producers.^[8] Local producers have similar product portfolios and mainly compete against each other in the same market (East African Community, 2017, pp. 21-22).

To be competitive and sustainable, local producers need to diversify into the higher value products in the prescription drug market, especially where health systems financing is underwritten by medical health insurance institutions or governments adhering to the Abuja agreement and allocating ten per cent of national budget to health.

African pharmaceutical manufacturers mainly import APIs and excipients from India and China.^[9] They also import plant equipment and machinery from these countries, while analytical equipment is typically obtained from Europe. As mentioned above, there is an extensive range of pharmaceutical technologies used in Africa. In addition, there is a concerted effort to move into products for non-communicable diseases such as hypertension and diabetes that are on the rise, implying a growing market (Banda, et. al., 2016).

The generic market consists of private and public (i.e., government procured) as well as non-governmental organizations and donor markets. In the private generics market, local manufacturers operate with various disadvantages. Local producers compete against multinational pharmaceutical companies and well-known foreign generic companies

.....
 [6]. The WHO defines essential medicines as 'those drugs that satisfy the health care needs of the majority of the population'. Essential medicines are selected based on disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. They are 'intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford' (WHO 2015b). WHO publishes a model list of essential medicines and each country is encouraged to prepare its own list considering local priorities. Over 150 countries have published an official essential medicines list. This allows health authorities, especially in developing countries, to optimise pharmaceutical resources. The list forms the basis of a national health policy.

[7]. The leading countries producing vaccines are Egypt (VacSera), Tunisia (Institut Pasteur de Tunis), Senegal (Institut Pasteur de Dakar), and South Africa (Biovac).

[8]. Blood and blood products are usually processed in Africa by national blood transfusion organizations. This is similar to the arrangements overseen by the National Health Systems Blood Transfusion in England.

[9]. APIs are the therapeutic component of the drug, while excipients are pharmacologically inactive substances used as a carrier for the active ingredients of a medication or as lubricants during the manufacturing process.

selling branded products. Reputed foreign firms can afford to sell at higher prices due to the perception among consumers that their quality is better. They also spend more on marketing and branding their products compared to local firms. To withstand such competition, local producers are often forced to charge lower prices, resulting in very low profit margins. At the same time, local producers compete on price against less quality-conscious foreign suppliers charging very low prices. Strained regulatory authorities often do not manage to keep all substandard products out of the market. As a result, local firms operate with low profit margins and low volumes. This results in low profitability and inhibits further investment in growing the business.

Public markets contain pharmaceutical products funded and procured by governments. In these markets procurement systems and conditions shape the market. However, in many countries the more significant public market is funded by international donors and agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. In these institutional markets, drugs are purchased through a competitive bidding process. While branding does not play a role in these markets, WHO prequalification is essential.

Least developed countries enjoy some special privileges under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allowing them to not recognise product patents in pharmaceuticals.^[10] For example, Zimbabwe issued a compulsory licence that culminated in the first Antiretroviral medicines (ARVs) being produced by Varichem in 2002, after the government declared a state of emergency based on the HIV/AIDS epidemic. Government issued a compulsory licence to all domestic manufacturers to produce ARVs for local consumption and guaranteed to buy locally produced ARVs prior to production. Before the TRIPS agreement came into effect in 1995, individual countries could decide on patent regimes.^[11]

.....
[10]. TRIPS is an international legal agreement between all the member nations of the World Trade Organization (WTO). It sets down minimum standards for the regulation by national governments of many forms of intellectual property as applied to nationals of other WTO member nations.

[11]. India was one of the developing countries which took advantage of this flexibility and abolished product patent protection in pharmaceuticals in 1972. This was one of the major factors behind India's success in pharmaceuticals.

3

KEY CHALLENGES

TO TRANSFORMING

THE PHARMACEUTICAL SECTOR

3. KEY CHALLENGES TO TRANSFORMING THE PHARMACEUTICAL SECTOR

There are several challenges affecting the development of a more sustainable, dynamic and competitive pharmaceutical industry in Africa that serves local and regional demands.

How to reform the policy framework to promote pharmaceutical manufacturing: The development of a domestic pharma sector necessitates the design and implementation of a supportive policy framework. This chapter describes the approach and processes for designing and implementing such a framework. This includes the use of demand and supply-side industrial policy instruments, including incentives and improvements to the regulatory regime.

How to improve the competitiveness in the pharmaceutical sector: Competition drives the development of pharmaceutical markets and increasing competitiveness of African companies can ignite and develop the sector. Thus, governments across Africa must support improvements in local competitiveness and increase private investment into the sector.

How to improve access to new and more profitable markets: Because access to markets drives growth, pharmaceutical producers in Africa require better access to private and public markets. These markets are local, regional and global. This requires action by national governments and African regional economic communities, as well as by global medicine purchasers.

How to improve quality and develop the product portfolio: Quality is the hallmark of success in pharmaceutical production. Poor quality products undermine consumer trust and erode the opportunities for industry expansion. Thus, sub-Saharan African producers need to invest in quality improvements which, in turn, should lead to new market opportunities that drive growth in the sector. In addition, the current range of pharmaceutical products produced in SSA is limited and varies from country to country. The production of new, more sophisticated products for local and regional consumption is a major challenge requiring efforts by governments, industry associations and producers.

How to stimulate access to finance for the pharmaceutical industry: Accessing finance and investment are major challenges for African pharmaceutical firms. However, investment is desperately needed for the industry to upgrade production in terms of quality and portfolio. Facilitating much needed investments is a key aspect in successfully developing the industry. A concerted effort with other measures that improve competitiveness of the sector is necessary for companies to present viable business proposals to investors.

Many of the challenges discussed in the chapters are interlinked. Therefore development of the pharmaceutical sector requires simultaneous improvements to the investment

climate and business environment, the use of industrial policy tools and incentives to increase competitiveness, better access to markets, technology and finance, better dialogue between governments, industry and international programs, and stronger, more effective government coordination and monitoring. Each of these challenges is discussed in more detail in Part 2.

PART 2

POLICY AND STRATEGIC ADVICE FOR PHARMACEUTICAL PRODUCTION -IN AFRICA-

Part 2 focuses on a series of practical challenges faced by governments and businesses in the development of the pharmaceutical industry in Africa.

4

HOW TO IMPROVE
THE POLICY FRAMEWORK
FOR PHARMACEUTICAL MANUFACTURING

POLICY FRAMEWORK

Traditionally, industrial policy is seen as a top-down action by government to influence private sector behaviour that is implemented, monitored and withdrawn in a timely manner. However, this approach should be complemented by a more bottom-up approach that is based on a thorough understanding of the industry and consults with the private sector to identify effective policy measures by addressing key bottlenecks. In addition, flexibility and readiness to adapt policies to increase their effect is an ability that needs to be trained and requires close monitoring. Ideally, this process involves both private and public sector actors. The process of learning is generated internally and by external scientific, training and infrastructure institutions. The success of local firms depends on their current capabilities, where cumulative learning is driven by competition and cooperation. Markets are created and restructured as industrial development proceeds (Srinivas 2012). Moreover, industrial development encourages successful firms to gain market dominance and generate profits to reinvest. Public policy should recognise how differences in firm capabilities affect their ability to respond. As policymakers develop an in-depth knowledge of the local industrial sector and its dynamics and variations, they apply a problem-solving approach to development planning that builds government capability in addressing specific problems in a pragmatic and collaborative manner, rather than focusing on detailed policy frameworks (Srinivas 2016).

4.1 CHALLENGES

Pharmaceutical production in Africa faces several policy and institutional challenges (Kardas-Nelson 2015) as described earlier. These challenges are exacerbated by the paucity of detailed information available on pharmaceutical markets in SSA. Public policies and strategies have rarely been based on objective evidence or developed in close consultation with pharmaceutical manufacturers. They often lack coherence and are poorly coordinated across industrial development and health portfolios. Moreover, there are often significant gaps found between different government portfolios whose action or inaction inhibits the industry's development.

Government can encourage manufacturers to invest and grow in different ways. Public policy can enhance market access, remove infrastructural bottlenecks, reduce costs and improve profitability, enhance access to finance, and enhance technical capability and capacity as discussed in this document. Industrial policy can set a direction and drive development in the pharmaceutical sector towards a vision shared by public and private actors. For example, the national pharmaceutical strategy of Zimbabwe aspires to ensure Zimbabwe becomes a major player in the southern African market by providing quality, affordable essential medicines that contribute to positive public health outcomes (UNIDO 2017).

Industrial policy instruments contribute to the achievement of industrial policy objectives by influencing the behaviour of economic actors. It can be useful to classify the different types of instruments governments can use in this regard, as shown in the table on the next page.

While industrial policy is used to address the long-term transformation challenges of local firms and clusters, it can also help firms deal with the immediate, more pragmatic problems they face. This requires a combination of instruments described in the table on the next page.

Demand-side interventions are generally used to increase the market opportunities for the local pharmaceutical industry. They include the use of instruments to stimulate markets, lower the barriers to access public procurement and improve access to new, more profitable markets. This is discussed further in Chapter 6.

Supply-side interventions develop the capacity of the local pharmaceutical industry to become more competitive in national, regional and global markets. They include fiscal incentives (e.g., tax holidays and exemptions, export subsidies, and duties), infrastructural measures to reduce the costs of land, utilities, training and research and development (R&D), and regulatory measures to improve compliance, while reducing the costs and risks to private investors. Supply-side incentives are discussed further in Chapter 5.

TYPES OF INDUSTRIAL POLICY INSTRUMENTS AND SELECTED EXAMPLES	SUPPLY- SIDE	DEMAND- SIDE	
REGULATIONS: Formulated rules and directives that mandate economic participants to act in accordance with what is ordered in those rules and directives	Business start-up regulations	•	
	Environmental regulation	•	•
	Import/Export bans		•
	Anti-trust laws	•	•
	Labour regulation	•	
	Food and drug regulations	•	•
	Quality regulations	•	•
	Intellectual property laws	•	•
INCENTIVES AND DISINCENTIVES: The provision or removal of material resources or inducement to encourage certain behaviours by economic participants	Cash grants	•	
	Preferential lending	•	
	Tax exemptions, asset depreciation	•	
	Tariffs on imported medicines		•
	Tariffs on inputs	•	
	Sales taxes	•	•
	Preferential prices for land, water and power	•	
INFORMATION: The collection, dissemination and publication of information to promote economic activities	Trade fairs	•	•
	Economic and business information	•	•
	Data banks	•	
	Technology and management services	•	•
PUBLIC GOODS AND SERVICES: Government's establishment of enterprises and direct supply or demand of good and services	State-owned enterprises	•	
	Public procurement		•
	Infrastructure development	•	
	Industrial zones and parks	•	
	Public works employment	•	
	Public universities and training institutions	•	

Source: Adapted from UNIDO and GIZ (2017)

The context in which local producers operate needs to be carefully understood. The successful use of incentives can be complex and multifaceted. For example, the use of price preferences for local procurement may be an important response where overseas exporters benefit from subsidies. In addition local producers often incur additional expenses for supplying to the warehouses, while foreign suppliers typically only deliver to ports (i.e., ‘landed costs’). Still, local producers can bear additional costs from delayed payments while not benefitting from letters of credit or immediate payments as importers often do. Additional costs are incurred for holding a larger inventory of finished products, which is often required to avoid a penalty if products are not supplied on time. Thus, the nature and level of incentives must be carefully designed to address the practical challenges faced by local firms.

It is important to ensure the benefits provided by government are not misused or lead to unfavourable consequences. Incentives compensate for current market failures and should not create artificial advantages for local firms. While all incentives involve costs, the anticipated benefits should outweigh these. This can be clearly illustrated with respect to import protections which may increase domestic prices. While this is a cost of protection, without protection local firms would not be able to survive or grow. As local firms become more established in these markets, they gain experience and costs reduce and protections can be removed. It is essential to develop productive capacities, reduce cost differentials and manage prices and quality. If the dynamic scale economies do not work, if the beneficiaries of tariff protection do not take the steps necessary to learn and upgrade, if the expected cost reduction does not take place, then the country may not gain from the infant industry protection.

Horizontal policies ‘level the playing field’ by ensuring the same conditions for all companies, which promotes competition and often allows the strongest firms to survive. To complement a level playing field, vertical policies can be added to deal specifically with the sector-based challenges faced by African pharmaceutical manufacturers. Industrial policy is selective, and it can make sense to work with the strongest firms. Governments learn and build capacity to formulate effective policies in the process. Putting monitoring mechanisms in place is essential and policymakers should become sensitive to the dangers of capture by rent-seeking interest groups.

In most sub-Saharan African countries government intervention is necessary to develop a competitive pharmaceutical sector that improves access to medicines and sustainability of supply. The factors described in the following section can increase chances of success in the development of policies to promote the sector.

4.2 GUIDANCE

4.2.1 ASSESS LOCAL CONDITIONS AND INDUSTRY CHALLENGES

The formulation of industry strategy must be accompanied by an analysis of what the present situation is and a clear description of the objectives and desired outcomes. Policymakers must be in close touch with local firms, financial institutions and research organizations, and understand the constraints in concrete terms and what support the industry really needs.

4.2.2 BUILD STRONG POLITICAL LEADERSHIP FOR A COMMON VISION

The development of the pharmaceutical industry in Africa requires strong political leadership. Active support from the top is vital when designing and implementing strategies. African countries must have the confidence and political will to transform the industry guided by a clear vision. All stakeholders should share this vision. While it is not unusual to see differences cropping up between, say, the ministries of health and industry, intervention by senior political and bureaucratic leaders can reconcile such differences in pursuit of a common goal. The vision for change will be determined by the level of development of the pharmaceutical sector and the opportunities to integrate health sector strengthening with industrial development.

4.2.3 INTEGRATE VERTICAL AND HORIZONTAL POLICY APPROACHES

Building a more competitive local pharmaceutical industry requires sectoral policies that respond to the practical challenges and opportunities facing local producers. This includes policy, programs and initiatives to build the capabilities and capacities of local producers. However, these sector policies should be accompanied by broader, horizontal reforms that improve trade and competitiveness across all markets and stimulate productivity enhancements across the economy. Such approaches avoid a patchwork of sector policies, boost trade and create a more dynamic and competitive investment climate.

4.2.4 FORMULATE A COORDINATED PLAN OF ACTION

The lack of coordination between different ministries can be a major stumbling block. Governments require good coordination and leadership to effectively integrate industrial policy and incentives with health system strengthening. It is important to integrate all interventions, including access to markets, finance and addressing supply-side constraints. Strong leadership and political will is required spanning a wide range of ministries, departments and agencies. Effective coordination also requires a lead agency with the



authority to drive change. Lead agencies will vary in different countries. Past efforts to develop the pharmaceutical sector in African countries have been hampered by hesitant, piecemeal, uncoordinated, and poorly aligned actions. Different ministries often pursue different objectives, creating conflict with local manufacturers. For example, when medical products can be imported tax free, the ministry of finance may be reluctant to abolish import duties or VAT on raw materials. This can undermine the efforts of industrial policy and health systems strengthening.

4.2.5 LEAD THROUGH CONSULTATION AND PARTNERSHIP

While government must lead the formulation of policies to support industry development, this should be done in partnership with industry actors and other relevant institutions such as the national medicines regulatory authority (NMRA) and the Ministry of Finance. Care should be taken that measures do not crowd-out private initiative or investment. A consultative mechanism with the private sector should be found involving private sector sectoral associations and/or individual firms depending on the country context at regular intervals to understand the issues faced by local manufacturers. Private sector representatives should be invited to participate in working groups and steering mechanisms that guide and monitor the sectoral policy formulation process.

4.2.6 ADOPT A FLEXIBLE APPROACH

Success depends on the dynamic relationships between incentives, business responses, and the changing industry environment. Some incentives may work, others may not work. It is not always possible to decide a priori what will work and what will not. It is important to be flexible and learn from mistakes and find ways to institutionalize problem-solving (Srinivas 2016). The capacity of the government is not static - it learns by doing and through constant engagement with the private sector. Therefore, it is important to put monitoring mechanisms in place to detect unsuccessful approaches and stop them to limit waste of resources.



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HOW TO IMPROVE
COMPETITIVENESS
IN THE PHARMACEUTICAL SECTOR

COMPETITIVENESS

While industrial policy contributes to the achievement of industrial policy objectives by influencing the behaviour of economic actors, competition drives the development of pharmaceutical markets and industries. The current structures in Africa favour imports and in these established systems importers and often the wholesalers and distributors, have a disproportionate influence. It is in their interest to promote imported products over locally produced products and maintain the system. Creating a fair, competitive playing field for local and foreign firms recognizing system inherent disadvantages for local producers combined with measures to improve the competitiveness of local producers is a prerequisite for stimulating industry development and promoting health security.

5.1 CHALLENGES

Improving competitiveness requires good industrial policy, grounded in the realities faced by African pharmaceutical producers and their experiences in local and regional markets. Industrial policy describes how government interventions promote local production, transform markets and achieve specific targets. It responds to market failures that are rampant in underdeveloped economies and prevent or hinder private entrepreneurs from discovering new investment opportunities (Wade 2009). Governments provide leadership and coordination to encourage manufacturers to invest and grow. Government may also undertake R&D and provide funds when the private sector is not ready or confident to invest. The purpose of this support is not to negate the market or compete with the private sector, but to ignite local private sector growth. Unless these conditions are altered so that entrepreneurs are willing and able to invest, new industries will not develop.

Government support for industry development is most relevant where there are infant industries and technological and informational externalities that undermine local industry performance. This is particularly relevant to the pharmaceutical industry in sub-Saharan Africa.

- » **Infant industry** considerations and technological externalities: When a late industrialising country tries to start a new industry, the production costs will invariably be higher compared to those of more established foreign competitors. Costs are lower in experienced countries because they have higher skills based on the depth of their previous experience. Thus, developing economies and their nascent industries are at a disadvantage. This provides a justification for the use of time-bound protection of new industries through tariff and non-tariff measures. Because it takes time for investments to develop technology and skills, more experience lowers the average costs over time. However, protective measures on their own are not enough. They need to be combined with efforts to improve the capability, capacity and competitiveness of local firms.
- » **Information externalities:** When a country is exploring the possibility of starting a new industry it requires up-to-date market data to assess the risks and chances of success. Typically, the expected profitability is low for new ventures and this dissuades prospective entrepreneurs from experimenting and initiating new industries. Government can address these information externalities through various cost reducing and profit enhancing measures.
- » **Externalities present in R&D efforts and other knowledge-generating investments:** New industries require new technologies that can be developed in the country or acquired from abroad. This can be achieved through investments into R&D, which may include the use of foreign direct investment (FDI) as a source of technology. However, because the private sector may find these investments too risky in a developing

market, government initiative is required to facilitate increased private investment and knowledge disbursement.

- » **Coordination externalities:** The development of a new industry requires simultaneous investments in various sectors and activities. Insufficient and irregular supply of electricity, often accompanied by high costs, is a major problem facing manufacturers. Other infrastructural constraints relate to water, roads and transportation. Government can play a very important role by coordinating such investments and directly intervening through the creation of industrial parks and special economic zones such as Kilinto Industrial Park in Addis Ababa, Ethiopia.
- » **Capital market failure for funding growth:** Entrepreneurs need access to funds to successfully develop a new industry. Even when an entrepreneur is willing to invest, appropriate funding may not be available. The chances of success of new industries not being known, commercial sources influenced by short-term profit considerations perceive lending to be risky and therefore the risk-adjusted rate of interest charged is often too high for viable growth. When accessing loan finance becomes difficult, equity investments by venture capital and private equity funds can play an important role in providing risk capital. Specific interventions are necessary to correct these capital market failures (see Chapter 8).

The above points affect the development of the pharmaceutical industry in Africa and describe the pragmatic problems faced by governments and industrialists. Addressing these require a range of responses by governments, through public policy and industry incentives, as well as by industrialists and the broader private sector, through improved business practices and productivity improvements.

5.2 GUIDANCE

5.2.1 IMPROVE THE INVESTMENT CLIMATE AND BUSINESS ENVIRONMENT FOR INCREASED INVESTMENT IN PHARMACEUTICAL PRODUCTION

REQUIRED ARE LEGAL, REGULATORY AND ADMINISTRATIVE REFORMS DESIGNED TO IMPROVE COMPLIANCE, WHILE REDUCING COSTS AND RISKS TO PRIVATE INVESTORS.

THIS INCLUDES:



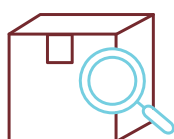
STREAMLINING

AND ACCELERATING THE APPROVAL PROCESSES FOR LOCAL FIRMS AND NEW INVESTORS



CREATING

A ONE-STOP SHOP FOR PRIVATE INVESTORS TO FACILITATE LEGAL AND REGULATORY COMPLIANCE BY PHARMACEUTICAL MANUFACTURERS



EXCLUDING

LOW QUALITY GOODS FROM THE MARKET THROUGH MORE STRINGENT IMPORT TESTING AND MARKET SURVEILLANCE



PROVIDING

REGULATORY GUIDANCE FOR LOCAL FIRMS WISHING TO UPGRADE TO GMP, WITH GUIDELINES FOR TECHNOLOGY TRANSFER TO SUPPORT THE PURCHASE OF DOSSIERS



INTRODUCING

REGIONAL REGULATORY HARMONIZATION TO INCREASE COMPETITION ACROSS THE REGION

5.2.2 APPLY FISCAL INCENTIVES TO STIMULATE LOCAL COMPETITIVENESS

This includes the use of tax holidays (including those in special economic zones), depreciation allowances, export subsidies, low interest loans, low cost utilities, and VAT exemptions. Fiscal incentives can also include grant funding for new technology or technology transfer, and better access to foreign exchange.

ETHIOPIA: INCENTIVES FOR LOCAL PHARMACEUTICAL PRODUCTION

The National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025) describes the current range of government incentives for local pharmaceutical production. These include tax-free loans of up to 70% for new investments (so the investor needs to invest only 30% of the project capital at inception) and up to 60% for upgrading projects during the first five years. These loans are granted by the Development Bank of Ethiopia.

There is also a 100% custom duty exemption on the import of all granted capital goods, such as manufacturing machinery, equipment and construction materials. Spare parts at up to 15% of the total value of imported investment capital goods are exempted from customs duty. Companies exporting 50% of their products or services or supplying 75% of their products or services as production or services input to an exporter, are exempted from income tax for five years. Companies exporting less than 50% of their products or services or supplying only to the domestic market are exempted from income tax for two years.

Investors that invest in high-priority areas to produce export products are given land necessary for their investment at reduced lease rates. Pharmaceuticals Fund and Supplies Agency grants local manufacturers a 25% price preference and pre-pays 30% of the tender value on awarding the contract; the 70% balance can be accessed interest-free through the Development Bank of Ethiopia if the local company requires additional capital and is willing to cede the tender to the bank. Product registration for local manufacturers is reduced to an average of one month.

Source: Federal Democratic Republic of Ethiopia (2015)

5.2.3 IMPROVE THE ACCESS LOCAL FIRMS HAVE TO AFFORDABLE LAND AND RELIABLE UTILITIES

The capacity and competitiveness of local producers can be improved through policy mechanisms that improve the access local firms have to affordable land and reliable

utilities. This may include the creation of special economic zones or specialised facilities, such as technology incubators. The governments of Algeria, Nigeria and South Africa, mindful of the effect of drug imports on the balance of trade, provide supply side incentives, such as tax exemptions and reduced land prices to encourage pharmaceutical companies to build manufacturing plants in their countries (McKinsey & Company 2015).

5.2.4 REDUCE TAXES AND TARIFFS FOR MANUFACTURING INPUTS

In many countries the importation of finished pharmaceuticals is exempt from tariffs and enjoys tax exemptions or reductions. By removing tariffs and taxes on imported inputs for local manufacture, governments can reduce the costs on items that directly affect the feasibility of local production. Tariff and tax exemptions and concessions for the import of APIs, excipients, packaging materials, and pharmaceutical production machinery can therefore promote local production. Similarly, reducing or removing any tariff exemptions/ tax benefits provided to the importation of medicines that are made locally can also put local producers at equal footing with importers, however such measures might raise prices and would need to be monitored closely.

5.2.5 SUPPORT SUPPLY CHAIN AND CLUSTER DEVELOPMENT

Support supply chain interventions and cluster development programs and services. The supply chain can be strengthened by working with packaging and excipient suppliers to better meet the requirements of the pharmaceutical industry. Cluster approaches bring public and private actors together within a defined local area, to enhance knowledge and skill sharing. Local networks of firms enable the sharing of activities linked to logistics, research and production, which are important ingredients in the upgrading and transformation of pharmaceutical firms (Capo, Brunetta and Boccardelli 2014).

5.2.6 PROVIDE CROSS-SECTORAL FUNDING TO SUPPORT INFRASTRUCTURE DEVELOPMENT

Governments can provide cross-sectoral funding to support infrastructure development. Multiple funding and policy interventions are important for generating a favourable investment climate that promotes industry growth. Cross sectoral funding that targets national investment in infrastructure, institutions and incentives boosts broad national technological capabilities (Lall 1992). Firms waste a lot of financial resources investing in alternative infrastructure such as generators because of unreliable energy supply.





6

HOW TO IMPROVE

ACCESS

TO NEW AND MORE PROFITABLE MARKETS

ACCESS

Because access to markets drives growth, pharmaceutical producers in Africa require better access to private retail and public markets. Potential markets are local, regional and global. Improving access to markets requires action by national governments and African regional economic communities, as well as by global medicine purchasers.

6.1 CHALLENGES

The share of local production in sub-Saharan Africa is low and declining in some countries. Local manufacturers find it difficult to compete against the more resource-rich companies from countries with a more developed industry that use economies of scale and can supply medicines at lower prices and still make a reasonable return. At the same time many local companies operate well below their installed capacity yet increasing production costs per unit because economies of scale cannot be exploited. Improving capacity utilization by servicing additional markets can help reduce costs of local production. Costs play a crucial role in the highly competitive segments of the market. African manufacturers suffer not only from higher production costs but also because exporters to Africa from countries such as India benefit from government assistance including export incentives (Mackintosh, et al., 2017; 18) and a favourable tax and tariff regime towards imports in recipient countries (see Chapter 5). Overall the existing supply systems often favour imports and procurement processes and distribution practices are often designed to cater for smoothly handling this most common form of supply.

The fact that the markets of local producers are squeezed between branded products and cheap imports, that in some cases fail quality criteria, limit market access for local companies. More rigorous regulation of imports by better resourced regulators and active promotion of generic prescription could ameliorate the situation. Furthermore, national markets are often small and do not allow for economies of scale while access to regional markets is hampered by regulatory obstacles and the lack of reliable market data.

Donor markets make up a significant share of the market for pharmaceuticals. In Ethiopia for example it makes up 70% of the public market (Kassahun 2018).^[12] Procurement for this share of the market is performed through international competitive bidding normally restricted to manufacturers with WHO prequalification for the products concerned that make up the majority of supply. Because only a handful of Africa-made products are WHO prequalified, most producers are locked out of this significant market.

Many of the issues discussed here and in earlier chapters inhibit the ability of sub-Saharan African manufacturers to access markets let alone advance into growing, more profitable markets. A few recommendations to ameliorate market access are given below, however in order to enable local manufacturers to use these opportunities these initiatives need to be complemented by measures on access to finance to invest in product quality, access to technology to diversify the portfolio and supply-side incentives to improve the cost structure of local manufacturers.

[12]. The public market makes up roughly 75% of the total market for pharmaceuticals.

6.2 GUIDANCE

6.2.1 PROMOTE NATIONAL AND REGIONAL TRADE AND COMPETITIVENESS

Effective government trade and competitiveness strategies are critical for improving access to markets. A range of tariff and non-tariff measures can be used to promote pharmaceutical manufacturing and trade within WTO rules to both encourage exports and give local industry relief from the competitive pressure of imports. This includes the use of import and export licenses and standards to verify the quality and specifications of both imports and exports. Care must be taken to ensure protection does not artificially sustain a permanently uncompetitive industry. Trade and competitiveness measures can also be applied at the regional level to expand markets, making investments in new production capacity or upgrading more feasible. Before putting restrictive measures in place, governments should ensure there is enough competition between local and regional suppliers, while monitoring prices and the effects of incentives on industry. Care should also be taken to ensure import restrictions do not send the wrong signals to international investors.

6.2.2 BALANCE SHORT-TERM PROTECTION WITH LONG-TERM CAPACITY BUILDING

Many countries have developed their pharmaceutical industries through the protection of local markets. This is justified where the local industry is weak while exhibiting a potential for growth. Protective measures should be time-bound and regularly reviewed as their effect on competitiveness is realised.^[13] Moreover, any efforts to protect local industries should be accompanied by measures to make local firms more competitive. This requires attention on technology promotion, the introduction of more efficient production methods, improvements to product quality and certification, and better access to finance (see Chapters 7 and 8). At the same time, the market should be monitored to avoid shortages and price hikes. One way to do this is to only restrict imports in product categories where there is strong national competition among local suppliers.

6.2.3 PREVENT MEDICINE DUMPING AND SUB-STANDARD IMPORTS

In international trade, ‘dumping’ concerns the sale of goods to overseas markets at prices (i.e., export price) lower than the selling prices of ‘like’ products in the domestic market (i.e., normal value). African governments should impose anti-dumping duties to guard the domestic industry from the surge in below cost medicine imports including stronger enforcement of standards to protect local companies from sub-standard competition (also see Chapter 7- 7.2.1).

.....
[13]. Import restrictions can have a significant impact on the growth of the industry in Africa. For example, in Ghana and Nigeria, countries with import restrictions, the sector has grown from five to 30 companies and 25-120 companies, respectively, in the last 30 years (AU 2012). An outright import ban in some northern African countries led to substantial growth in the industry (e.g., in Algeria, some 180 new firms were established).

6.2.4 PUBLISH MEDICAL ITEMS FOR LOCAL SUPPLY

Through the publication of the list of medical items for local supply only, governments can send clear signals to local producers. Governments should create priority health product lists. To improve access, local production should be encouraged to meet the health challenges that are identified within those lists as local priorities. Linkage between the industrial incentives outlined above and the public health needs those products are expected to meet will serve both policy objectives.

6.2.5 USE PUBLIC PROCUREMENT TO DRIVE COMPETITION AND INVESTMENT

Government and international agency procurement can improve the access local producers have to national and African markets. However, there are many problems in this field that undermine the opportunities for local firms. For example, the long procurement cycles through which government purchasing is carried out and unplanned variations in payment schedules create uncertainty in the system (Yadav 2015). Government policies and incentives can be used to lower the barriers to domestic procurement and policymakers can work with the health sector to improve supply chains. This may involve:

- » Introduction of local price preferences;
- » Improvements to local tendering and procurement procedures, including the promotion of new procurement opportunities and the simplification of tender processes;
- » Better access to finance for the local producers that win tenders;
- » Advance purchase commitments;
- » Longer contract periods to support investment for health sector priorities;
- » Prompt payment or advance payments (see box on Ethiopia in Chapter 5 and Chapter 8- 8.2.9); and
- » Apply same specifications to importers and local producers (landed costs vs. delivery to warehouses).

As discussed above, public procurement opportunities are only effective when the local industry has the capacity to respond. In the absence of adequate capacity to develop products for regulatory approval or in cases of inordinate delay in getting such approvals, this incentive may not be effective. Regulatory capacity and innovation capacity at the firm level might have to be addressed in parallel (see Chapter 7).

6.2.6 ALIGN PUBLIC PROCUREMENT WITH QUALITY IMPROVEMENTS

Align improvements in production processes leading to better quality products with new market opportunities created through government and international agency procurement. As quality improves and milestones along a GMP Roadmap are reached (see Chapter 7 esp. 7.2.3) companies gain access to national tenders. This helps local producers and investors see how investment in improved manufacturing practices can lead to new market opportunities and could potentially improve access to finance.

6.2.7 IMPROVE ACCESS TO INTERNATIONAL MARKETS

Government supply-side policies and incentives can support upgrading to enable manufacturers to meet required quality standards. Some technical barriers related to the tendering process and portfolio could be addressed in a dialogue between public and private actors. Policymakers and manufacturers associations can work with donors to reform the terms of international tendering, to become more local supplier-friendly and/or offer support to companies in the upgrading process to meet quality requirements. For example, UNICEF procures essential HIV medicines through international tenders from WHO prequalified vendors. However, obtaining WHO prequalification involves significant investments. For domestic manufacturers to be willing to invest to meet the quality standards, they require a reasonable assurance that the medicines will be procured from them and they can recoup their investment. Similarly, investors also require confidence that the investment will lead to increased revenues (see Chapter 8).

GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA PROCUREMENT

The Global Fund is encouraging local manufacturing as an explicit objective as part of its market shaping strategy. Especially in its procurement strategies for bed nets and anti-malarial medicines. Their multi-year framework agreements are geared to provide certainty, a key requirement for financiers as it enables a longer-term vision on financing, volume and pricing (underwritten by allocations and commitments in the resulting framework agreements). The Global Fund is also adjusting the commercial landscape to level the playing field through a broad definition of value beyond price, responsiveness and customer proximity, and re-balancing of tenders by increasing the emphasis on total landed cost. The Global Fund has diversified its supply base through intensive supplier engagement, including engaging directly with Africa-based manufacturers. To date, the Global Fund has increasingly procured artemisinin-based combination therapy (ACTs) from CiplaQCIL in Uganda, reaching 23% of total volume in 2017 for artemether-lumefantrine out of eight suppliers. Similarly, the Global Fund is sourcing essential medicines from a limited number of Africa-based manufacturers including Universal Corporation Ltd. in Kenya.

Source: Jallow (2018)

6.2.8 BUILD ECONOMIES OF SCALE THROUGH REGIONAL MARKET HARMONIZATION

While many national markets in Africa are not large enough to benefit from economies of scale, regional markets often are. Collaboration between African countries is required to ‘defragment markets’ and increase the sustainability of manufacturing through economies of scale (Sidibé, et. al., 2014). Thus, the development of regional pharmaceutical markets through the regional harmonization of pharmaceutical laws and regulations (including the reduction of tariffs and non-tariff barriers) is critical.^[14] While the PMPA provides a broad roadmap for market harmonization across Africa, most harmonization efforts are focused on the regional economic communities. For example, the EAC Regional Pharmaceutical Manufacturing Plan of Action: 2017-2027, presents a framework for the harmonization of pharmaceutical production in the East African Community.^[15]

6.2.9 GENERATE MARKET INFORMATION AND FOSTER RESPONSIVENESS TO LOCAL DEMANDS

Market information on African markets is often difficult to obtain. This source of uncertainty deters investors. Governments can institutionalize the collection of market data by connecting existing sources of data on imports and local production usually available at national medicines regulatory authorities, the customs department of national revenue authorities and domestic manufacturers. International companies willing to invest can benefit from partnerships with local firms and their local sales teams and their market knowledge. Local organizations should also ensure that they are responsive to the needs of local markets.

6.2.10 FACILITATE ACCESS TO FOREIGN MARKETS

Governments can help to expand markets for local manufacturers through export facilitation. They can introduce export subsidies and improve export market information and support. Incentives for exports and trade agreements for market access with other countries are approaches through which local manufacturers can penetrate markets at sub-regional and regional levels and later progress to far-off markets.

[14]. Plans for the creation of a new African Medicines Agency have been adopted to support the varying regulatory capacities of African states and help set-up a comprehensive, regional system of regulatory supervision that serves to harmonize regulations across national boundaries, make efficient use of limited resources and deepen capacity building. The proposed agency will improve access to effective, quality therapies and vaccines across Africa. It is built upon and accelerates the current momentum of strengthening regulatory system in the continent, as outlined in the African Medicines Regulatory Harmonization (AMRH) initiative (International Federation of Pharmaceutical Manufacturers and Associations 2018).

[15]. The plan recommends strategic interventions applied at firm, institutional, national and regional levels to improve the business environment for pharmaceutical manufacturing, strengthen associated regulatory capacity and further develop human resource capacity through a programmatic approach. It sets out six primary strategic objectives (East African Community 2017), which include the promotion of competitive and efficient pharmaceutical production regionally, the facilitation of increased investment in the region, the strengthening of the region's pharmaceutical regulatory capacity, the development of appropriate skills and knowledge on pharmaceutical production in the region, the use of TRIPS flexibilities, and the mainstreaming of innovation, research and development within regional pharmaceutical industry.

THE 'ZAZIBONA PROCESS'

In Southern Africa, the 'ZAZIBONA process' started as a collaboration between national medicines regulatory authorities in Botswana, Namibia, Zambia, and Zimbabwe. The founding neighbouring countries have a combined population of around 34 million. It has recently been opened for other SADC countries. The ZAZIBONA process aims to create a region in which good quality medicines are available to all those who need them. It seeks to significantly reduce time taken to grant market authorization (i.e., registration) in the individual countries and promote the efficient use of resources within national regulatory authorities in the region through work-sharing. The process facilitates access to good quality medicines through work-sharing in the assessment of medicines and inspection of medicine manufacturing and testing facilities. Products that meet assessment criteria are granted registration in the participating countries, in which Common Technical Document (CTD) format applications for registration would have been submitted. Where countries agree that is necessary, variations to the products which have been registered under this collaboration may be handled through the same process. This collaboration does not remove the need to submit applications for registration in participating countries, but facilitates cooperation among ZAZIBONA authorities on assessments and inspections. As a result, medicine manufacturers benefit from an accelerated registration process, a single set of questions during the registration process and in principle harmonized registration decisions, which facilitate an easier review of any post-registration variations.

Source: Medicines Control Authority of Zimbabwe (2016)



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HOW TO IMPROVE

QUALITY

AND DEVELOP THE PRODUCT PORTFOLIO

QUALITY

Quality is the hallmark of success in pharmaceutical production. Poor quality products undermine consumer trust and erode opportunities for industry expansion.^[16] Non-compliance with international standards restrict the public procurement of medicines from local producers especially by international procurement entities. Achieving and enforcing local production at WHO GMP is an explicit goal for African governments laid out in the Business Plan for the accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA BP). Thus, African producers need to invest in quality improvements that can open new market opportunities with international procurers and drive growth in the sector. Similarly, investments in the production of new, more sophisticated products for local and regional consumption can improve revenue and profitability for the company and access to medicines locally. Both the quality and the portfolio challenge can be addressed through partnerships between companies, but also addressed in a concerted effort of public and private actors.

.....
[16]. WHO (2017) estimates that one in ten medical products circulating in low and middle-income countries are either substandard or falsified.

7.1 CHALLENGES

Many sub-Saharan African countries have relatively weak medicines regulatory authorities. This creates the conditions in which local manufacturers strive to produce quality products, while competing against sub-standard and counterfeit products.

A key challenge in all pharmaceutical production is adhering to Good Manufacturing Practice (GMP).^[17] GMP ensures products are consistently produced to the quality standards appropriate to their intended use and as required by the regulatory authority. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production and ensuring that manufacturers do not place patients at risk due to inadequate safety, quality or efficacy.

^[18] The AU's PMPA and its associated business plan set out the ultimate objective for all pharmaceutical production in Africa to adhere to WHO GMP standards. Many companies in sub-Saharan Africa have not yet attained WHO GMP standards. However, many companies are now in the process of upgrading their facilities to meet these standards.

GMP covers all aspects of pharmaceutical production: starting with materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that affects the quality of the finished product. There must be systems to provide documented proof that the correct procedures are consistently followed at each step in the manufacturing process, every time a product is made. A problem that most manufacturers in sub-Saharan African countries face is that the technical knowledge required to set up and run WHO GMP compliant manufacturing plants is deficient. Experience from countries such as Kenya, Nigeria and Zimbabwe show that improvement in GMP, with the goal of reaching full compliance with WHO GMP standards, is possible over time, but also challenging. Companies who have invested in GMP compliant processes and facilities find it hard to recoup the costs as their cost structure might change and make production more expensive. To counterbalance this effect companies can invest in increasing efficiency of production. Furthermore to encourage companies to upgrade despite the challenges is important and governments can play a decisive role here. Governments have direct control over the preconditions to participate in government tenders. These can be altered to incentivize companies to upgrade and

[17]. The WHO defines GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice', as the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. GMP defines quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. Specific GMP requirements relevant to classes of products such as sterile pharmaceuticals or biological medicinal products are provided in a series of annexes to the general GMP requirements (go to: https://www.who.int/biologicals/vaccines/good_manufacturing_practice/en/)

[18]. The main risks associated with pharmaceutical production are: (a) unexpected contamination of products, causing damage to health or even death; (b) incorrect labels on containers, which could mean that patients receive the wrong medicine; and (c) insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

gain stepwise access to tenders as quality of production improves.

UNIDO GMP ROADMAP CONCEPT

A GMP Roadmap is a plan devised and enforced by the national regulatory authority to bring the local pharmaceutical industry to full WHO GMP compliance within a defined timeframe. The stepped program has defined milestones that represent increasingly more stringent GMP enforcement over time. At a given time all companies have to comply with previously defined criteria or cease production. This ensures a level playing field for market players. No company should be allowed a market advantage through non-uniform enforcement of GMP standards in the industry. As part of this process all pharmaceutical manufacturers are assessed on 17 key quality elements associated with WHO GMP standards. Each firm is then categorised, based on two parameters for GMP compliance: compliance of the production site with WHO GMP standards and compliance of the quality management system (QMS) with WHO GMP standards.

Source: UNIDO (2015)

Ideally the GMP Roadmap is part of a broader pharmaceutical sector development strategy which addresses other key bottlenecks simultaneously. These could encompass access to finance, access to technology and human resources development. As an important stimulus the national procurement system can act as a 'pull' mechanism and restrict tenders to companies that have achieved certain quality criteria.

With few exceptions, African countries are generally involved in the manufacturing of generics i.e. the formulation of products for which the patent has expired. Local production accounts for a small share of the demand for medicines in sub-Saharan Africa and is concentrated in relatively basic products with relatively small margins. Thus, a key challenge for producers is how to expand the portfolio. The R&D challenge in this context is formulation development. In addition when introducing new products local firms often lack the marketing resources required to compete against products of multinational corporations and foreign generic companies that dominate the market.

There are two options for a company wanting to broaden its product portfolio. The first is to develop the formulation required to produce the generic version of a medicine in-house. However, often there is lack of technical capacity in companies to develop generic formulations for regulatory approval, particularly complex formulations or the development costs are higher than purchasing a dossier. The purchase of a dossier is the second option. This option is, however, hampered in many countries by unclear regulatory requirements when registering the product. This uncertainty deters companies from investing in new dossiers. In addition, regulatory approval processes can be lengthy yet increasing costs and risks for local producers. If the sub-Saharan African pharmaceutical industry is to reduce import dependence and to develop local production, then it is essential that

formulation skills are accessible to manufacturers and regulatory uncertainty is reduced. To strengthen formulation development capacity, linkages between research institutions and universities on the one hand and industry on the other hand must be enhanced. The curricula in pharmacy schools and in other academic programs must be reformed so that these are more aligned with industry requirements.

A common means for transferring new technology into pharmaceutical production in Africa is through joint ventures or investments by foreign firms, often multinational enterprises. This is one of the easiest and fastest ways for African firms to obtain new technology. For example, in a joint venture between Cipla, an Indian company, and Quality Chemicals in Uganda, Cipla provided the necessary know how relating to all aspects of the setting up and running of the plant, including plant design and installation, product and process development, quality control, maintenance, raw material sourcing. The absorption and assimilation of these technologies removed the technological bottleneck Quality Chemicals^[19] was facing (UNCTAD 2011). Despite the benefits of joint venture and foreign investment arrangements, there are only a few examples found in Africa.

Few foreign companies have the confidence to enter into a joint venture straight away. A first step in a nascent partnership could be limited to distribution. Such a distribution partnership, which gives the technology provider access to new markets, can then integrate backwards with packaging being an intermediate step before a manufacturing partnership is established, which should involve technology transfer. A model to start with is to produce one product locally and import other products for distribution by the local partner.

Technology transfer can also be done through various formal or informal channels including, technology licensing, capital goods imports, technical assistance, using the services of foreign consultants, and movement of skilled labour from abroad. Technical expertise to support capacity building in Africa is widely available internationally. For example, pharmaceutical technical knowledge in India is highly diffused and there are numerous experts with the requisite knowledge and skills who are willing to work in Africa. There are also consultants available around the world who are willing to provide technical services. Some firms in Africa already use the services of foreign technical experts. However, many African firms do not have the capacity and, in the absence of proper funding, the ability to use foreign technical resources.

.....
[19]. Now known as Cipla Quality Chemical Industries Ltd.

SUPPORTING AGENCIES

There are examples of a successful involvement of international agencies in facilitating technology transfer in pharmaceutical production. Technical expertise is available from a variety of organizations including:

- » Senior Expert Services connect experienced former industry staff with companies in developing countries in need of expertise. Most European countries have a Senior Expert Service e.g. German Senior Expert Service (SES) <http://www.ses-bonn.de/en/startseite.html>
- » Equipment and excipient suppliers are often offering technical assistance in the application of their products. An example is Excellence United, a consortium of pharmaceutical equipment manufacturers: <http://www.excellence-united.de>

To encourage technical upgrading and portfolio diversification governments can employ ‘pull’ and ‘push’ incentives. Pull mechanisms improve the functioning of the market to increase certainty, without which entrepreneurs are unlikely to invest in quality improvements or R&D for portfolio development (e.g., off-take guarantees). Push programs stimulate upgrading or R&D by providing funds and inputs to reduce costs. Push incentives include indirect support to the private sector to undertake R&D, here mainly formulation development, such as tax incentives, grants, loans, and subsidies. These measures work best when the local industry already has some capacity. In the case of many sub-Saharan African producers, existing R&D capacity is sometimes very low. Thus, other more direct support from government in building capacity in the form of grants or technical assistance may be more appropriate.

7.2 GUIDANCE

7.2.1 STRENGTHEN THE ENFORCEMENT OF REGULATIONS ON SUB-STANDARD PRODUCTS

A critical first step in improving quality in the national medicine market is to exclude low quality goods through more stringent regulation and market surveillance. The AU Strengthening Pharmaceutical Innovation in Africa program recommended the strengthening of policies and enforcement of regulations on substandard drugs, dumping of medicines, and donated drugs. Furthermore, the capacity of national regulatory authorities should be built to ensure safe, high quality medicines, especially for inspection, quality control and laboratory work (Berger, et al., 2010). While governments need to support the development of strong national regulatory authorities as an essential part of improving access to good-quality products, local production that meets the criteria of improving access should also be considered for fast-track authorization (WHO 2011).

7.2.2 IMPLEMENT GMP ROADMAP

In order to approach WHO GMP it is essential that policymakers adopt measures to encourage local manufacturers to improve their production processes. This can be done using supply-oriented incentives (discussed in Chapter 6). Government ministries, in collaboration with national regulators and industry, should formulate and implement a stepped program to full GMP compliance, with clearly identified milestones that represent increasingly more stringent GMP enforcement over time. Ideally such measures would be part of a comprehensive sector development strategy. As quality costs i.e. adhering to WHO GMP can make the production process more costly, measures to increase efficiency of production in order to safeguard the competitiveness of local producers should be applied simultaneously. As upgrading production to meet WHO GMP standards requires substantive investments, measures improving access to finance (see Chapter 8) should be considered as part of the GMP Roadmap.

7.2.3 LINK QUALITY IMPROVEMENTS WITH INCREASED ACCESS TO MARKETS

Local pharmaceutical producers need a clear path for development that connects improvements in product quality with new market opportunities to incentivize upgrading (see Chapter 6.2.6). This provides firms with a clear connection between upgrading production processes and growth opportunities. Links between quality improvements and access to public and international program procurement is critical. Once local producers have verifiably improved their production processes, new procurement opportunities should be offered and particularly government tenders opened for local production. If donor procurement procedures and policies are in the way of local sourcing, the government can discuss changes in these procedures and policies with the relevant donors, so that the local industry is enabled to participate in donor procurement.

7.2.4 SUPPORT DOSSIER PURCHASE AND PROVIDE CLEAR GUIDELINES TO FACILITATE APPROVALS

It is important to build local technical capabilities and capacities. Thus, firms should consider purchasing dossiers and hiring consultants who can help bridge the technology gap manufacturers face in developing products for regulatory approval. Just buying dossiers is not enough, though. It is important to obtain the relevant registrations. There is a lack of clarity in some countries about what the regulatory agency will or will not accept for registrations including whether they will be exempt from stability and bioequivalence studies, which constitute a major cost. Regulatory authorities should provide clear guidelines for product registration, including the possible exemption of bioequivalence studies and stability studies. They should ensure regulatory procedures are simple and clear^[20] and relatively fast in order to reduce costs incurred by delays and uncertainty. Some countries offer fast-track registration procedures for locally produced products. Government ministries and departments, in collaboration with national regulators, should also support technology transfer. This requires general incentives, such as tax incentives and public programs to attract potential technology partners.

7.2.5 IMPROVE ACCESS TO FOREIGN EXPERTISE

Often, access to foreign expertise is constrained by domestic policies that restrict the employment of foreigners. It is important to reform these regulations so that local firms can use the services of foreign experts over a significant time period. Moreover, the employment of foreigner experts may be made more attractive by providing tax incentives on expert income designed to subsidise the cost of employment. Most African countries have restrictions on employment of foreigners. It is important to reform visa rules so local firms can use the services of foreign experts over a significant period. However, care should be taken to ensure local manufacturers do not misuse these provisions. Foreigners may be employed only when such expertise is not readily available in the country.

7.2.6 CREATE A BUSINESS CASE FOR TECHNOLOGY-BASED PARTNERSHIPS

Initiating joint ventures or investments between local and foreign firms requires a clear understanding of how each party will benefit. While local firms clearly benefit from the injection of funds, skills and technology, the opportunities for foreign partners also need to be explicit. Partnerships involving technology transfer make sense for the technology provider if they involve savings or reduce risks over importations. These criteria are met if the partnership increases the security of supply, serves to avoid import duties or other hurdles or protects from currency fluctuations. For the technology provider it is important to be able to recoup earnings and profits and to be able to retrieve their funds.

.....
[20]. This is consistent with the AU's Strengthening Pharmaceutical Innovation in Africa program recommendation that African governments assist local manufacturers to overcome challenges of prequalification, especially the cost of bio-equivalence studies (Berger, et al., 2010).

7.2.7 FOSTER COLLABORATION BETWEEN INDUSTRY, ACADEMIA AND RESEARCH INSTITUTES

Government should consider the ecosystem in which new pharmaceutical products are developed. In the long term, this will require improving the domestic capacity for R&D within the context of an emerging pharmaceutical sector. Thus, government should facilitate and encourage industry-led approaches that enhance collaboration with academic and research institutes. This can be achieved using grants, training programs, internships and technical cooperation with international donor and development agencies, and multinational pharmaceutical corporations. Support for the establishment of technology incubators in the pharmaceutical sector could also be strategic. In addition, international agencies and domestic governments can provide the necessary support to facilitate the transfer of technology by promoting business linkages and organize business and investment forums for African manufacturers.

7.2.8 FACILITATE INTERNATIONAL COOPERATION FOR LOCAL PRODUCTION

Governments can invite international organizations (e.g., UNIDO, UNCTAD, WHO) and bilateral donors to support special projects for upgrading the local production capacity for medical products. However, care needs to be taken to ensure that donor initiatives are not working at cross-purposes with private local production initiatives in ensuring greater access to medicine and medical products (WHO 2011).



A large, bold, red number '8' is centered in the upper half of the page. The background is a light pink color with a complex, low-poly geometric pattern of various shades of red and pink, creating a modern, abstract aesthetic.

HOW TO STIMULATE

ACCESS TO FINANCE

FOR THE PHARMACEUTICAL INDUSTRY

ACCESS TO FINANCE

Accessing finance and investment are major challenges for African pharmaceutical firms. However, these cannot be isolated from the other challenges already identified in this guide. Thus, it is important to integrate the financial and investment challenges with those related to access to markets, quality improvements, government procurement, and competitiveness. Indeed, in their efforts to gain greater access to finance and investment, sub-Saharan African pharmaceutical producers are required to transform their business models and strategies to demonstrate their profitability and long-term competitiveness.

8.1 CHALLENGES

Access to finance for the African pharmaceutical sector falls within the broader challenges of financing small to medium enterprises (SMEs). It is, however, even more challenging for African pharmaceutical SMEs because it encompasses financing for innovation, technology transfer, technological capability upgrading, industrial development and economic development for a skills and technology intensive sector with relatively high investment volumes that may not be well understood by financial institutions on the ground (Banda 2013). On top of that, investors may see the sector as carrying reputational risk in the event that defective products are released which could cause illness or death.

To comply with WHO GMP pharmaceutical manufacturers in Africa must improve their standards in medicines production by upgrading their production and quality assurance facilities and processes. This is a key target in the Business Plan for the implementation of the Pharmaceutical Manufacturing Plan for Africa (AU 2012). In addition, to access new international donor markets, WHO GMP is required and increasingly national regulatory authorities demand WHO GMP. However, international investors are reluctant to invest in companies that operate below WHO GMP because of the perceived risk for the investor's reputation if they invest in a company, which produces medicines in a WHO GMP non-compliant production facility. Nevertheless, the upgrading of production facilities to WHO GMP requires sizable investments into site, facilities and processes as outlined in Chapter 7.

The cost of upgrading to WHO GMP is a major hurdle for many companies. The level of funding required depends on several factors including firm size, the current level of GMP, any associated facility expansion, and the choice of equipment. A typical medium-to-large firm with significant deficits in GMP may require around USD 5-10 million, while a new state-of-the-art manufacturing facility will cost around USD 10-20 million (UNIDO 2018). However, when considering all the associated costs and infrastructure challenges, upgrading is often more expensive and less attractive compared to building a new facility, which is WHO GMP compliant. Building a state-of-the-art facility optimizes production flows and maximises efficiency of production^[21] and avails the opportunity to leap-frog to the latest technology in terms of process optimization, lean production and flexible production units.

The Pecking Order Theory^[22] explains that companies when faced with an option to use internal or external finance, their first choice is internal finance and for external finance bank debt because it is less onerous in terms of reporting requirements and accountability

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[21]. An analysis of efficient production scale is offered by McKinsey (2019), recommending an annual output of around 500 million tablets.

[22]. Myers (1984); Myers and Majluf (1984).

(to investors/funders) compared to the third-choice hybrid bonds^[23]. Companies as a last resort choose equity, which managers view as being onerous on reporting requirements and accountability to investors and also dilutes their power and control of the company.

Venture capital (VC) is the choice for de-risked start-ups or emerging firms with no established management track record, which have not generated a high credit reputation and have unknown future prospects. Growing firms, which can demonstrate experienced management skills and have poor to good market performance prospects, medium to high credit risk and have built a decent credit reputation can access debt finance from banks. Such relatively new companies can benefit from bank monitoring activities^[24]; hence the preference for bank loans as a key source of external finance (Diamond 1991). On the other hand established companies with experienced management, low credit risk and well established credit records find it easy to access capital markets.

The most prevalent source of external finance in many African countries are commercial banks. The interest rates for loans can be very high often around 15-25% in local currency.^[25] To a lesser extent venture capitalists and equity providers, except for Kenya and South Africa where these actors are more prevalent than in other parts of sub-Saharan Africa, provide funding opportunities. However, there is a lack of early stage investors in Africa and a minority of investors provide smaller amounts below USD 500,000. Private Equity (PE), VC and the stock market are still underutilized in sub-Saharan Africa and in particular in the pharmaceutical industry where many companies are family owned and there is a reluctance to dilute ownership and control to an outside party. Such companies, however, might miss opportunities to professionalize their business and develop strategic capabilities. Private Equity investors usually work with a 5-7 year investment horizon and require a clear exit strategy, however, this is often too short a period to build a new facility or engage in comprehensive upgrades and generate the required returns in the pharmaceutical sector.

The figure on the next page provides an overview of the possible financing required by pharmaceutical producers at different stages of development.

.....
[23]. Hybrid bonds or hybrid securities are instruments that combine both debt and equity aspects.

[24]. When banks lend to companies, they give financial and management performance conditions to the borrowers, and as banks monitor these key performance ratios it helps the firms improve their operations.

[25]. For example, in Kenya the interest rate for loans in Kenyan Schillings is 14%, which is capped by the Government or 8-9% on loans in US dollars. In Uganda, the interest in Ugandan Schillings is 20-25% and 7-8% in US dollars. In Ghana interest rates can reach 25-30% (UNIDO stakeholder interviews 2017 and 2018).

INVESTOR'S RISK APPETITE				
TYPE OF FUNDING	DEBT	MEZZANINE/ HYBRID	EQUITY	GRANTS/ CHALLENGE FUNDS
STAGE OF COMPANY'S DEVELOPMENT	Mature	Growth stage	Early stage	Any stage but generally very early stage / proof of concept
TENURE	Short->Long	Medium->long term	Long term	Long term / most of the time no need to repay
NEED FOR CASH FLOWS	Existing cash flows (to pay interest and repay principals)	←	Limited existing cash flows (return to investor through dividends and eventual sale)	None
COST	Cheaper (capped cost through an interest rate)	→	Expensive (participation in the company's upside) ^[26]	Match funding
USE OF PROCEEDS	MEDIUM OR LONG TERM: capex, land, opex SHORT-TERM: working capital	Capex, opex	Capex and growth	Specific use of funds the grant is meant to finance (R&D, technical capacity, technical assistance, etc.)
NEED FOR COLLATERAL	High Long term: fixed assets Short term: receivables/	Varies (e.g., share pledges, guarantees)	Low	None
FINANCIAL INSTITUTIONS	Commercial banks	Development Banks	Development banks	Impact investment
			Enterprise development funds	Resesarch funders
			SME funding schemes	Innovation acceleration funders
	Leasing Financial Institutions	Venture Capital	Sovereign wealth funds	Crowdfunding
			Insurance firms	Charities
	Mortgage firms -industrial property	Venture Capital		

[26]. Upside means an anticipated or projected increase in the price of an investment - thus when a stock will in the future have a higher price than the current one on the stock market, it is said to have a higher upside.

It is important that companies match their financing need with the right type of finance with right tenure; short-term financial instruments should finance short-term finance needs and long-term finance needs should be funded using long-term financial instruments.

Financing packages need to align with the cash flow profile of the business. To get a project off the ground, substantial equity is required, including reserves for any cost overruns. For a Greenfield project, the debt to equity ratio would need to be anywhere from 30:70 to 60:40. The exact figure depends on the specific case, taking into account availability of corporate or personal guarantees, security, and time needed to get the project to cash flow generation. Any debt at this stage would need to have sufficient grace period in order to delay the debt service until the time when the business generates cash. Fundamentally, funders do not typically take construction risk, which is generally handled by the owners (through equity). Debt comes in to finance equipment, working capital, capital improvements, and initial operating losses.

A typical term loan for long-term capex needs would suit best with a short-term credit line for any working capital requirements, subject to adequate interest rates. Typical debt to earnings before interest tax debt and amortisation (EBITDA) levels would be debt 2-3x EBITDA.

Mismatching finance needs and funding instruments is detrimental because it can constrain cash flows imposing impossible loan servicing conditions. Therefore, companies need to develop financial capabilities that allow them to astutely negotiate for favourable interest rates, loan tenure (duration of the loan or debt), covenants (conditions imposed by financiers) and monitoring triggers (for credit risk management). Accepting too stringent borrowing conditions will set a company up to fail and ruin their credit reputation.

Mezzanine financing is often a way to bridge the gap between the company's need for substantial capital and its inability to withstand the cost associated with the risk profile of the financing. One example would be a loan with a fixed coupon^[27], bullet repayment^[28], and a penny warrant^[29]. This allows lowering the fixed interest rate in the short term to allow the company to grow in exchange for a share in the company, if it succeeds. The bullet payment also alleviates the key risk of an equity funder of not getting capital back while minimizing debt service for the company for the entire term of the loan. International development finance institutions (DFIs) have used this product in other sectors, such as pharmaceutical retail, and are finding it very relevant in the pharma manufacturing space as well.

Next to investment, pharmaceutical producers in Africa require working capital in local and foreign currencies because APIs and excipients are predominantly imported. As the cost of borrowing is very high it is advantageous to reduce working capital requirements. However, long payment cycles, late payment on government contracts, a challenging

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[27]. A fixed coupon arises when interest on a bond does not change over the life of the bond.

[28]. A bullet payment occurs when at the end of the tenure a loan is paid up as a lump sum.

[29]. A penny warrant allows the holder to purchase an amount of a firm's securities at a nominal exercise price – usually set at a very low value, one penny (£0.01) for example.

business environment, a longer stock conversion cycle and large upfront costs associated with purchase of APIs and larger inventories inflate working capital requirements.

Using trade finance and facilities such as on-shore bonded warehouses to reduce supply lead times as well as improved payment discipline by the government could ameliorate the situation.

There is a lack of in-depth appreciation of the complexity surrounding access to finance by local pharmaceutical firms in some African countries (Banda 2013). This is especially critical because of the close link between finance, technological capability upgrading, innovation and markets. Key to the access to finance challenge for pharmaceutical firms is to identify a convincing business model including matching current and future technological capabilities with market demand and building an attractive portfolio. It has been observed that African pharmaceutical firms find it difficult to pitch robust project proposals to potential financiers in terms of business model and formal criteria.

This is one of the reasons why finance institutions in Africa are reluctant to invest in the pharmaceutical sector. Some of the factors that often deter investors include the long investment horizons of upgrading or building new facilities and the relatively large amounts of capital often sought. Other issues include the highly technical nature of the industry, which causes bankers, who are mostly generalists and have no specific knowledge of the sector, to be hesitant about making positive investment decisions. Financial institutions prefer to lend to companies that already operate at WHO GMP standards, placing firms seeking finance to upgrade at a disadvantage. Investors fear the risk that a company they invest in produces sub-standard products that have negative effects on people's health or cause deaths. As such cases get a lot of media attention they can have a very negative knock-on effect on the investor. However, especially companies producing below WHO GMP are in need of investments in order to be able to improve quality and access additional (donor) markets.

Foreign Direct Investment (FDI) is often cited as a source of finance. Indeed, because pharmaceutical production is a part of a tightly integrated, global industry, foreign investment is critical. FDI can be used to increase product range and upgrade facilities, and can improve access to technical know-how and finance. Inviting and inducing FDI can be an effective way of developing an emerging industry in a developing country. FDI can inject much-needed capital into the local industry while also transferring the knowledge, skills and technology required by local firms to become more competitive. However, experiences in different countries show that FDI does not drive industrial growth without local capabilities. While opening the doors to FDI is critical, success in industry development requires complementary measures that build the capacity of local firms to participate in and benefit from joint ventures and partnerships with foreign investors. To date, FDI does not present a viable option for many local pharmaceutical producers, simply because most sub-Saharan African producers do not represent attractive investment opportunities for international manufacturers in the current market conditions. To increase

the attractiveness to investors challenges around competitiveness, market access and portfolio need to be addressed at the same time to increase the attractiveness of the sector to domestic and international investors. Therefore the below recommendations should not be considered in isolation, but be combined with those of former chapters to change the business case.

8.2 GUIDANCE

8.2.1 USE TIME-BOUND SUBSIDIES TO LOWER THE COST AND RISK OF COMMERCIAL FINANCE

Governments can reduce the cost and risk of financing pharmaceutical industry development. Direct government expenditure to reduce cost of financing can include: Governments to facilitate access to affordable investment capital by subsidizing interest payments and granting tax breaks. To reduce the risk governments can provide subsidized capital and guarantees. This includes the use of export credit guarantees^[30] to underwrite and guarantee credit access for export activities and subsidised export finance program.^[31] Such measures can level the playing field for local manufacturers against subsidised imports at point of manufacture thereby improving the financiers' risk appetite for more competitive local producers (Banda 2013).

8.2.2 SUPPORT THE DEVELOPMENT OF MORE DIVERSE FINANCIAL PRODUCTS

Government and the private sector can work together with financial service providers to improve the access pharmaceutical manufacturers have to finance. They can work with financial institutions to develop a diverse product portfolio that is fit for purpose. This includes expanding the range of debt and equity financing options. For example, instead of using expensive overdraft and short-term loans for working capital, banks and other finance providers can use trade products to finance the import of raw materials and the export of finished goods.^[32] For firms that export, arranging structured trade finance deals using export proceeds as security/collateral avoids the trap of credit rationing because of focusing on lending based on balance sheet strength only. Governments can also support better access to equity by removing existing restrictions on institutional investors to provide equity or by introducing prescription ratio rules for institutional investors like life insurance companies. If governments adopt the innovation principle^[33] and financing pharmaceutical innovation is framed as financing industry and economic development then there is scope for governments to use prescription ratio approaches backed by guarantee schemes from for example DFIs which have access to international financial markets.

[30]. Exports can be particularly targeted because they generate foreign currency which enables the firms to import APIs, excipients and spare parts.

[31]. In India, interest subsidies to pharmaceutical manufacturers supported rapid development of the sector. Using public resources to support debt servicing, rather than providing debt can be a more efficient use of state resources (Smith and Banda 2016).

[32]. Offering trade finance instruments is attractive because it is less demanding on risk weight adjusted capital.

[33]. The innovation principle argues that 'innovation is the single most important driver of societal prosperity and it is indispensable for sustainable development and economic growth' – European Risk Forum (2015).

8.2.3 CREATE SECTOR FUNDING MECHANISMS

There are several options national governments can draw on to address the financial constraints experienced by African pharmaceutical manufacturers. These include direct capital provision through sector specific support funds. For example, the Government of Ghana introduced a USD 20 million reserve for the pharmaceutical sector through the Export Development and Agriculture Investment Fund (Smith and Banda, 2016). The AU Strengthening Pharmaceutical Innovation in Africa program recommended that African governments establish a fund to provide low interest loans (Berger, et al., 2010). One such initiative is the Fund for African Pharmaceutical Development, known as 'FAP-D' promoted by the AUC and the New Partnership for Africa's Development (NEPAD).

8.2.4 IMPROVE THE FINANCIAL COMPETENCIES OF LOCAL MANUFACTURERS

Successful pharmaceutical manufacturers should invest in skilled, competent and experienced finance staff who are conversant with a diverse range of sources for finance and various financing instruments within country and offshore. It is essential that firms demonstrate to funders that their business is viable, efficient and competitive. This requires that a robust business model is developed that connects markets with current and future product portfolio and technical capabilities. Robust project finance documents need to demonstrate the firm's technological, managerial, organizational, and financial capabilities. Challenges with regard to business planning are the reliability and availability of market data (see 5.2.9) and barriers to accessing markets (see Chapter 5).

8.2.5 IMPROVE FINANCIAL BROKERAGE IN THE PHARMACEUTICAL SECTOR

Firms should match their financing need with the right type of finance. For example, short-term finance should finance short-term needs, while long-term financial instruments should fund long-term finance needs. Firms should negotiate for favourable interest rates, loan tenure, covenants (conditions imposed by financiers) and monitoring triggers (for credit risk management). Accepting too stringent conditions will set them up to fail and ruin their credit reputation.

8.2.6 IMPROVE CORPORATE GOVERNANCE TO ATTRACT INVESTMENT

Family owned businesses, including other types of closely owned SMEs tend to be reluctant to accept external equity and relinquish significant management control in spite of the fact that injection of new management styles by external capital injectors and improving corporate governance standards can be beneficial and facilitate growth of the company. Given the high risk associated with equity investment, businesses need to understand that the level of management team and business plans scrutiny is higher because equity is based on backing people/management and their ability to succeed, and therefore equity funders need to see a path to liquidity. Investors insist on a transparent shareholding structure and, wherever possible, a clear separation of ownership, management and oversight functions. This can be a challenge for family owned businesses, however if the business wants to grow using external funding, then these are issues that need to be



confronted. The company has to be willing to accept to enact strong corporate governance policies. This would also call for the protection of minority shareholder interests.

8.2.7 BUILD PARTNERSHIPS WITH THE FINANCIAL SECTOR

A lack of understanding regarding the pharmaceutical sector in Africa can limit the way the financial sector responds to proposals. Relationship managers and credit-risk managers need to develop an in-depth knowledge of the local and international pharmaceutical sector to be able to assess and manage risk profiles. Pharmaceutical industry associations could arrange workshops, conferences and training clinics to encourage knowledge exchange between the pharmaceutical and finance sectors. Financial institutions can help pharmaceutical firms appreciate what key attributes are important when analysing a project proposal, while pharmaceutical firms could explain the sector's business models, opportunities and scenarios. Transparency on the loan process (timings and responsibilities) and formal requirements of a bankable business plan can also improve the interaction between financial institutions and pharmaceutical manufacturers.

BANK-INDUSTRY LINKAGE

The greatest learning opportunities occur at disciplinary boundaries. An international bank's agro-banking division improved the quality of project proposals from new farmers by holding interactive workshops with the farmers where they discussed key determinants of a successful project proposal. After these interactive coaching clinics, which also improved bankers' knowledge on new farming operations, the bankers reported a significant improvement in project proposal quality.

Source: Banda (2018)

8.2.8 ENCOURAGE FOREIGN INVESTMENT IN THE SECTOR

There are a range of ways governments can encourage foreign investment in the local pharmaceutical sector. These include broad investment climate and business environment reforms that open the economy and make it more conducive to private investment, the establishment of an investment promotion agency and programs, and the formulation of sector strategies that specifically identify opportunities for foreign investment. In addition, governments can encourage FDI by providing mechanisms to cope with local currency depreciation, which acts as a major disincentive for foreigners to invest. One way to do this is through designated bank accounts that are used to retain export earnings that enable equipment purchases or the repatriation of profits.

8.2.9 ADAPT PROCUREMENT PRACTICES ESP. IMPROVE PAYMENT TERMS FOR LOCAL SUPPLIERS

The opportunities arising from public procurement to promote local companies and increase their market access are discussed in Chapter 6. Public procurement can create

markets for new and existing technologies by actively shaping demand. It can thereby stimulate sustainable consumption and production patterns. In public health system drug procurement payments can take at least three forms: (1) advance payment, (2) cash on delivery and (3) credit terms. Each of these affect production cash flows, the cost of finance and the cost of production.^[34] For example, advance payments of 30% of the tender value is provided to pharmaceutical firms in Ethiopia to help firms access the balance from financial institutions at concessionary lending rates (Gebre-Mariam, et al., 2016). Improving the payment terms for local producers can decrease working capital requirements, reduce finance costs and thus have a positive effect on the cost structure of the company. Depending on contexts, adapting procurement practices to improve market access for local companies can be an active industrial policy tool to reduce costs and enhance viability of local production and thus make companies more attractive to investors.

MEDICAL CREDIT FUND

The Medical Credit Fund (MCF) is a funding facility that offers debt financing to private health care facilities in Africa in the range of USD 1,000-2.5 million. Loans are accompanied by technical assistance on commercial and quality aspects. A quality improvement program called 'Safecare' was established to overcome the problem that investors were only willing to invest in high quality facilities recognizing that financing is needed to improve the standards at the facility. Run by the Dutch NGO PharmAccess with partner banks in developing countries, the MCF began with contributions from two Dutch philanthropists and institutional investors. The fund has distributed more than 1,700 loans amounting to USD 33 million. The pharmaceutical manufacturing sector faces similar challenges in terms of the size of investments (USD 500,000-5 million) and in terms of quality requirements investors must protect themselves from reputational risk. The MCF could be an interesting model to pursue for the African pharmaceutical manufacturing sector.

Source: Mulder (2018)

8.2.10 ENCOURAGE INVESTMENT IN UPGRADING TO WHO GMP

On the one hand investors are reluctant to invest in companies that operate below WHO GMP standards. Some international investors such as the IFC even make WHO GMP a precondition for any investment in the pharmaceutical sector. On the other hand companies need investment to upgrade to WHO GMP. To break this deadlock especially in countries where a GMP Roadmap is in place, financial institutions can consult with the national regulator to identify low-risk companies in terms of quality and portfolio so that the

[34]. Advance payment and, to some extent, cash on delivery are sources of finance for the firm. Long credit terms cause producers to seek alternative, but often expensive external finance. For example, onerous credit terms and conditions of delivery demanded by local health systems on local manufacturers compared to international suppliers force local firms to borrow expensive short-term bank finance, generating recurrent cash flow problems (Chataway, et al., 2016). The cost of bank finance for working capital is generally very high.

access to funding for upgrading is improved. Independent agencies such as UNIDO can also assess and guide investors to limit the perceived reputational risk of an investment in a company that needs to upgrade to reach WHO GMP.



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P.O. Box 300, 1400 Vienna, Austria
Email: tii@unido.org
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