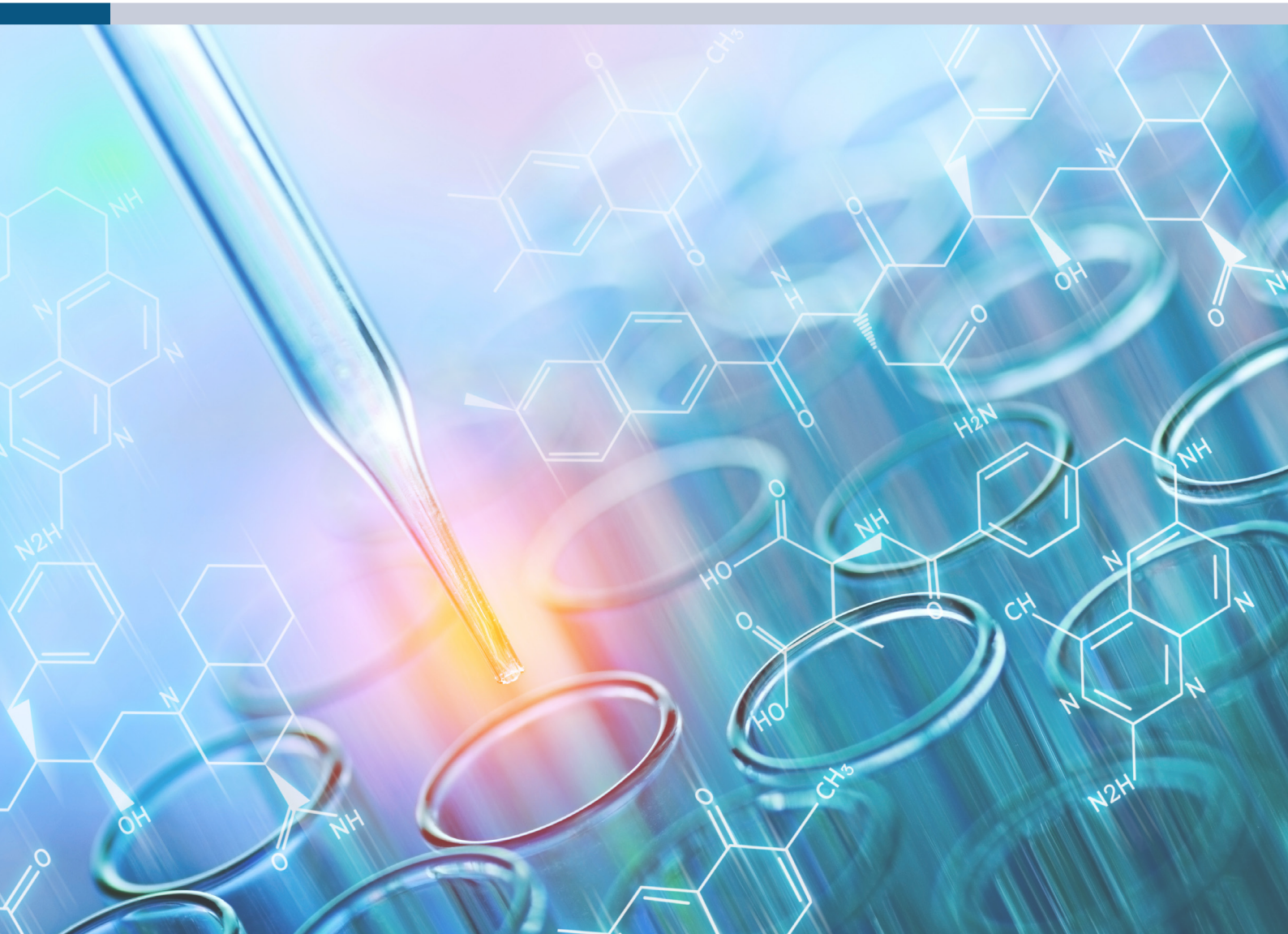


Review of Policies and Strategies for the Pharmaceutical Production Sector in Africa

Policy Coherence, Best Practices and
Future Prospective



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Abbreviations

AfCFTA	African Continental Free Trade Agreement
AIDA	Accelerated Industrial Development of Africa
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization Programme
API	active pharmaceutical ingredient
ARV	antiretroviral
CAMI	African Union Conference of Ministers of Industry
EAC	East African Community
ECA	Economic Commission for Africa
ECOWAS	Economic Community of West African States
FAP-D	Fund for African Pharmaceutical Development
FOB	free on board
GATT	General Agreement on Tariffs and Trade
GMP	good manufacturing practice
IFC	International Finance Corporation
MNC	multinational corporation
NEPAD	New Partnership for Africa's Development
NGO	non-governmental organization
NMRA	National Medicine Regulatory Authority
PMPA	Pharmaceutical Manufacturing Plan for Africa
R&D	research and development
REC	regional economic community
SADC	Southern African Development Community
TDB	Trade and Development Bank
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNIDO	United Nations Industrial Development Organization
USP	United States Pharmacopeia
WHO	World Health Organization
WTO	World Trade Organization

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Definition of terms

Active pharmaceutical ingredient	Any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when utilized in the production of a drug, becomes an active ingredient in the drug product.
Brand/innovator drug	A pharmaceutical product that has a trade name and is protected by a patent (it can be produced and sold only by the company holding the patent).
Counterfeit drugs	These are forged or altered pharmaceutical products. They may be contaminated, contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. These illegal drugs are a health risk to patients.
Finished pharmaceutical product	A pharmaceutical product that has been subjected to all the stages of production and testing, including packaging in its final container and labelling.
Free trade area	A region encompassing a trade bloc whose member countries have signed a free trade agreement. Such arrangements involve cooperation between at least two countries to reduce trade barriers – import quotas and tariffs – and to increase trade of goods and services with each other.
Generic drug	A generic drug is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance and intended use. In most cases, generic products become available after the patent protections afforded to a drug's original developer expire.
Good practices	The agreed description of the pharmaceutical organization, procedures and standards that enable the required quality of service to be delivered, including criteria for organizational structures, personnel, facilities, equipment, materials, all kind of operations, quality control, etc.
Harmonization	The name given to the effort by member States to replace the variety of national pharmaceutical policies, practices and standards currently adopted in favour of uniform regional policies, "good practices" and standards, which are at an internationally acceptable level.

Health products	Health products include other pharmaceutical and health-related products (such as bed nets, laboratory and radiology equipment, and supportive products), as well as single-use health products (such as condoms, rapid and non-rapid diagnostic tests, insecticides and injection syringes).
Intellectual property rights	Exclusive rights of a person or company to use their plans, ideas or other intangible assets without the worry of competition, at least for a given period. These rights can include copyrights, patents, trademarks and trade secrets. A court may enforce these rights via a lawsuit. The reasoning for intellectual property is to encourage innovation without the fear that a competitor will steal the idea and take the credit for it.
Orphan medicines	Medicines used for the diagnosis and/or treatment of rare diseases or conditions.
Pharmaceutical industry	A manufacturing industry that is engaged in the research, development, manufacture and marketing of drugs and biologicals for human and veterinary use. These companies may be involved in the production of brand or generic medicines as well as medical devices. They are governed by a variety of laws relating to the patenting, testing, safety, efficacy and marketing of pharmaceutical products.
Pharmaceutical market	An actual or theoretical place where forces of demand and supply operate, and where buyers and sellers interact (directly or through intermediaries) to trade pharmaceutical products, medical devices, services and contracts for money or barter.
Pharmaceutical procurement and supply management system	This system is composed of all steps in the procurement and supply system: selection, quantification, shopping, tendering, negotiation, ordering, storing, selling, distributing and dispensing of essential medicines and medical supplies.
Pharmaceutical products	These include an active pharmaceutical ingredient in their finished dosage form that is intended for human use.
Pre-qualification	An initial evaluation of the capabilities of suppliers (technical and financial) and the quality of their products to allow them to participate in the procurement process.
Protectionist policies	Policies that seek to shield a country's domestic industries from foreign competition by taxing imports

Public procurement	Free on board (FOB) prices contracted by national medicines procurement agencies in member States. It is recommended that the public procurement agency knows the FOB prices of the products procured. Only FOB prices allow for analysis of logistics costs (freight, insurance, clearing and others), as well as for international benchmarking and comparison within the region. Actual supply contract may still specify any other International Commercial Terms that include freight and other costs, as long as in the supplier's tender submission, and in the procurement agency's information management system, FOB prices are also documented.
Quality assurance	The quality assurance of pharmaceutical products is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use.
Quality control	The quality control of pharmaceutical products is a concept that covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that the raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Research and development	Investigative activities a business conducts to improve existing products and lead to the development of new products and procedures.
Standardization	The process of establishing a technical standard, which could be a standard specification, standard test method, standard definition, or standard procedure. Standardization means that there is a standard specification, unit, instruction or something that is understood globally.
Technology transfer	The transfer of new technology from the originator to a secondary user, especially from developed to developing countries, in an attempt to boost their economies.
Tracer medicines	Medicines selected by the surveyors in the 2010 Pharmaceutical Marketing Analysis study, of which the assembled data form the baseline for measuring implementation of the strategy.

Foreword

Over the past decade and a half, Africa has embarked on a trajectory to strengthen its pharmaceutical manufacturing capacity and contribute to the improvement of public health outcomes, access to medicines, and socioeconomic and industrial development. Significant progress at a continental, regional and national level has been made since the commitment by the Heads of State and Government Assembly Decision 55, made in Abuja in 2005, and other subsequent decisions to promote the development of a sustainable pharmaceutical manufacturing industry on the continent taking full advantage of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and bolstering of research and development. Since 2011, the African Union Conference of Ministers of Industry (CAMI) prioritized, among other sectors, the local pharmaceutical sector as a potential driver of industrial development, thereby incorporating the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the Accelerated Industrial Development of Africa (AIDA) Plan of Action.

African leaders continue to facilitate the creation of an enabling environment where every person has the opportunity to optimize his/her development potential. Efforts to create an enabling regulatory and legislative environment for medical products regulations – including the African Medicines Regulatory Harmonization (AMRH) Programme (2009), African Medicines Agency (2014) and an African Union Model Law on Medical Products Regulations (2015) – have been developed as continental frameworks for adoption and adaptation to support regional economic communities (RECs) and member States' initiatives. Platforms such as

the AMRC and AMRH governance structures to encourage dialogue among regulators have been established.

Despite the progress, the health status of most Africans remains suboptimal, and access to medicines for many infectious and non-communicable diseases remains low across the continent, in addition to weaknesses in the supply chain systems. Africa bears a significant burden of infectious diseases and non-communicable diseases. Outbreaks of emerging infectious diseases, such as the Ebola pandemic, has further underscored the need to respond rapidly. This consequently creates an opportunity for pharmaceutical companies in Africa to expand their markets and collaborate within the continent and internationally, as well as for national Governments to reduce their dependency on development partners and facilitate a more secure supply of these essential products. Africa's pharmaceutical industry is one of the world's fastest growing. In past 10 years, the market has exploded to \$21 billion, with a projected estimate of \$60 billion by the end of 2020. This growth can be optimized if challenges such as policy and regulation incoherence, shortage of specialists, weak quality regulatory agencies and fragmented markets are addressed.

Furthermore, there is growing consensus in Africa today that pursuing a local pharmaceutical manufacturing agenda, taking full advantage of the political commitment at the highest level of leadership of its decision-making and policymaking organs, is the most viable way for its sustainable development. It is also imperative to harness the existing opportunities that come with Africa's rapidly

growing population size and combined gross domestic product growth, increasing urbanization and disposable income of households, patent expiry of many leading medicines in the world, growth of pandemics and increasing numbers of people on treatment, a population experiencing longer life spans, increase in lifestyle diseases, improved health insurance and coverage environment, among others. In addition, there is a realization that local pharmaceutical manufacturing is important for national, regional and continental medicines' supply security, especially in the event of global or local pandemics.

This Review of Policies and Strategies for the Pharmaceutical Production Sector in Africa: Policy

Coherence, Best Practices and Future Prospective, therefore, provides an overview of the status of pharmaceutical production in Africa, and identifies levels and quality of production on the continent. Using country case studies and data, where available, the study assesses the extent of the challenge by subregion and country category, compares policy frameworks, and identifies good practices that can support the growth of the pharmaceutical industry in Africa. Lessons drawn from successful manufacturers and countries on the continent, and frameworks on how to design public policies that can foster an enabling environment for the pharmaceutical industry, are highlighted.

Vera Songwe

United Nations Under-Secretary-General and
Executive Secretary of the Economic Commission for Africa

Executive summary

Background

Africa faces significant challenges in accessing high-quality pharmaceuticals, exacerbating a continued high burden of disease. The availability of essential drugs in the public sector across the continent has been reported to be less than 60 per cent. One factor contributing to this shortfall is Africa's heavy reliance on imported medicines. There is growing consensus that strengthening the continent's ability to produce high-quality, affordable pharmaceuticals would have a positive impact on public health and economic development. In 2007, the African Union Commission developed PMPA. In 2012, a business plan was also developed that provides a road map for supporting the African pharmaceutical manufacturing sector and the production of high-quality essential medicines.

This ECA study, based on desk research and primary data collection, provides an overview of the status of pharmaceutical production in Africa, and identifies levels and quality of production on the continent. Using five country case studies (Cameroon, Morocco, Ghana, Kenya and South Africa) drawn from each of the five geographical regions of the continent (Central, North, West, East and South, respectively), the study compares policy frameworks and seeks to identify best practices that have supported the development of the pharmaceutical industry in Africa.

Findings

The African pharmaceutical market is currently small, representing an insignificant share of the global

market. Moreover, with the exception of Morocco, domestic manufacturers in the case study countries supply only a quarter of the current consumption, with the rest predominantly imported from Europe, India and China. However, the market is growing, and there is emerging potential for the development of African pharmaceutical manufacturing. This study explores various opportunities and challenges in the establishment of sustainable pharmaceutical industry on the continent.

Political factors

African countries generally do not support their domestic industries with trade or tax policies that level the competitive environment. Domestic manufacturers cannot compete with international firms producing at higher volumes and lower costs. While the African Union is clearly committed to increasing pharmaceutical production on the continent, national Governments have been slower to implement policies and regulatory frameworks that are necessary to complement this continental political will. Government expenditure on health also remains low, meaning most countries are heavily reliant on donor assistance in procuring pharmaceuticals, to the disadvantage of domestic manufactures. Moreover, many countries have not incorporated the internationally-negotiated flexibilities on intellectual property rights into their national legislation to allow production of generic medicines.

Production factors

African manufacturers depend on imports for the bulk of their production inputs. This reliance on imports has significant implications on production

timetables and costs. The pharmaceutical manufacturing industry also requires specialized skills that are either in short supply or concentrated in other industries in Africa. As a result, outside of Morocco and South Africa, few companies meet international standards for quality. Investment in research and development (R&D) is also needed to ensure that new products are available to meet Africa's unique disease patterns.

Market factors

The African Continental Free Trade Agreement (AfCFTA) is an intergovernmental instrument, negotiated between representatives of sovereign States, with its ultimate goal to create a more conducive regulatory framework within which the African private sector may conduct its business, free of the usual obstacles, whether in the form of tariffs or non-tariffs barriers. AfCFTA provides an opportunity through a sectoral approach for the enhancement of capacities in the area of pharmaceuticals, improving collaboration and reducing barriers to movement of goods, services and people. The involvement of the private sector to complement African Governments can boost intra-African trade on pharmaceuticals and health-care services, to achieve economies of scale in health infrastructure, expand employment opportunities and deepen regional integration.

Affordable investment capital is a key challenge that limits investment in the pharmaceutical industry, requiring new sources of financing, such as the Fund for African Pharmaceutical Development (FAP-D). Foreign direct investment and partnership in Africa's pharmaceutical industry will also be necessary to stimulate its growth, and it will require incentives from Governments to reduce risk and cost.

Recommendations

- African countries should systematically apply policy regulations that level the playing field for finished products versus APIs.

- Political will on its own is insufficient; policy development should always be accompanied by the necessary capacity development and resource mobilization for implementation.
- National and regional procurement laws should consider allocating percentage points informed by local content policies, if the quality of the products is deemed to be of the required standards.
- Governments should encourage foreign direct investment into local production through incentives that lower the cost or risk for the investor, or both.
- Governments should work with international funding entities – such as the Investment Fund for Health in Africa, the International Finance Corporation's (IFC's) Health for Africa Fund, Afreximbank and the African Development Bank – to mobilize investments in the pharmaceutical sector.
- The African Union should invest in the development of regional centres of excellence, focusing on the pharmaceutical industry, and encourage national Governments to do the same.
- The African Union should set up its own pre-qualification process, providing the funding platform or leading the process of resource mobilization.
- The African Union should also support international good manufacturing practice (GMP)-compliant local companies in leveraging global funding mechanisms.
- The African Union should develop a self-sufficient, pan-African R&D system that addresses evolving public health issues to

harness the untapped power of collaboration among African researchers by linking up with African universities.

- The African Union should speed up the operationalization of FAP-D to address the critical issue of access to capital, and ensure the speedy implementation of PMPA.

I. Introduction

A. Background

Africa continues to bear a disproportionate burden of diseases with, for example, 75 per cent of the world's HIV/AIDS cases and 92 per cent of the deaths due to malaria occurring in Africa (African Union Commission–UNIDO Partnership, 2012a; WHO, 2016a). People on this continent suffer more than most from tuberculosis, and there are many other infectious diseases that cause substantial morbidity and mortality. Non-communicable diseases are also becoming increasingly prevalent across the continent, and they are predicted to overtake infectious diseases as the leading causes of death in Africa by 2030 (Mathers and Loncar, 2006).

Because of the foregoing, among others, medicines consume between 45 and 60 per cent of each African nation's health-care budget (Cameron and others, 2011). Despite these high expenditures on medicines, the continent is still heavily reliant on imported medicines. This often leads to the non-availability of the lifesaving commodity. In the public sector, across Africa, the availability of essential medicines has been reported to be less than 60 per cent by the World Health Organization (WHO) (ibid.). There is, thus, limited access to safe, effective, quality and affordable medicines, vaccines and diagnostic tools.

Different factors account for the poor medicine availability within the continent, including long lead times for international orders, high transport and distribution costs, poor logistic and storage capacity, limited public finances, inadequate public health procurement systems, and gaps in global

production of medicines for diseases that affect the poor disproportionately. Regarding infrastructure, most countries in Africa do not have adequate transport networks for the efficient distribution and administration of medicines. This is a real impediment to improving access to medicines, particularly in remote areas.

Local tariffs (24 per cent in some cases) and taxes on health-care products also continue to be high. The persistence of these tariffs and taxes calls into question the political will in many African countries when it comes to improving access to medicines. High taxes and lack of regulatory frameworks constitute a real barrier to the access of innovative medicines in developing countries. Without reform in these areas, the health of the population in many African countries will remain an afterthought.

B. Initiatives to address the situation

Efforts have been made by the African Union and its partners to address the challenges of access to medicines. For example, in 2005, the Assembly of African Union Heads of State and Government committed to pursuing the development of local capacities and capabilities to produce essential medicines – taking full advantage of the flexibilities within TRIPs – and to R&D. Subsequently, and as mandated by the Assembly in 2007, the African Union Commission developed PMPA, in the framework of NEPAD.

PMPA was adopted by the Conference of African Ministers of Health in April 2007 and endorsed by

Heads of State and Government in Accra in July 2007. In 2012, the African Union Commission developed the PMPA Business Plan as a continental framework to complement the efforts of the member States and regional economic communities (RECs), on the basis of which stakeholders' support could be galvanized for the growth of the pharmaceutical sector on the continent. Health leaders and experts recognize that strengthening the continent's ability to produce high-quality, affordable pharmaceuticals across all essential medicines would have a positive impact on the public health and economic development of individual countries and the continent as a whole.

PMPA envisions African people having access to essential, quality, safe and effective medical products and technologies, by facilitating the development of a competitive pharmaceutical industry in Africa to ensure medicine self-reliance. Implementation of the PMPA Business Plan identifies key solution areas to address various challenges hampering the growth of the pharmaceutical sector and its ability to maintain a sustainable supply of the much-needed medical products of assured quality, safety and efficacy at affordable costs.

The United Nations Industrial Development Organization (UNIDO) assisted the African Union Commission in developing this plan. The business plan was designed to provide guidance towards the development of a sustainable supply of affordable, quality essential medicines; provide guidance towards the improvement of public health outcomes; and contribute towards economic and industrial growth. The business plan adopts a road map approach, with strong emphasis on the production of high-quality essential medicines

produced at an international standard. The plan also considers the need for the provision of support to the manufacturing industry.

C. Purpose of this study

As briefly described above, the pharmaceutical industry in Africa faces many challenges. Facilities and production practices need to be upgraded to meet international standards. Large capital investments, highly specific expertise and specially trained workers, increased regulatory oversight, as well as an overall positive business environment, are all necessary for the industry to develop. There is evidence emerging from case studies suggesting that – although India, China and Brazil continue to be major producers and suppliers of cheaper medicines serving the needs of African markets – the pharmaceutical sectors in many African countries are transforming. Strong strategic interests are beginning to catalyse direct government support of local production, with an emphasis on the promotion of access to medicines, followed closely by industrial policy concerns.

This study provides an overview of the state of pharmaceutical production in Africa and identifies challenges in the sector. Additionally, it assesses the coherence or/and inconsistencies of policy frameworks surrounding the pharmaceutical sector on the African continent, and recommends policies to increase the production and sustainability of the supply of medicines for improved health outcomes. Also, the study seeks to identify best practices that have supported the development of the pharmaceutical industry in Africa and other continents.

Table 1 Local pharmaceutical production capacity in Cameroon, Ghana, Kenya, Morocco, Nigeria and South Africa

Country	Number of active manufacturers	Number of registered importers	Percentage of country needs met by local production	Size of the pharmaceutical market (billions of United States dollars)
Cameroon	9	22	12.5	0.36
Ghana	33	300	25	0.6
Kenya	35	2 130	25	1.2
Morocco	40	50	65	2.0
Nigeria	157	554	40	3.0
South Africa	39	1 200	27	5.2

Source: Information collected from key informants during this study. Information on Nigeria was collected during the programme validation exercise.

Questions this study seeks to answer to promote the development of the pharmaceutical industry in Africa

- How does a country develop the human resources to support pharmaceutical manufacturing ?
- Which form of government support fostered the development of the sector?
- How can a country tap into local and foreign markets?
- How do local producers successfully compete with imports?
- How can a country develop supportive and safe regulation for the sector?

This compendium of country-based case studies on local production focuses on bringing to light newer, lesser-known and lesser-researched cases of successful local production and related technology transfer in the field. Chosen with a view to shed light on the ways and means in which countries and firms build capacity in the pharmaceutical sector, the case studies enhance our understanding of how complex firm-level, country-specific and international political economy-oriented factors interact towards building capacity in pharmaceutical enterprises in African countries. Newer firms in Africa are showing some potential to move up the technological ladder to

capture some of these production spaces and cater to greater access to medicines. However, capacities in these countries are diverse and do not lend themselves to generalizations.

To conduct the study, we applied several information-gathering techniques. A desktop review of relevant literature and reports on policies and strategies in the African pharmaceutical industry was carried out. This is presented in chapter II, along with the conceptual framework for our analysis.

This review is supported by case studies that include visits to Cameroon, Ghana, Kenya, Morocco and South Africa. However, following a stakeholders' validation exercise, where it was felt Nigeria was too important a country to exclude from such a study, Nigeria was included. A case study method substantiated by semi-structured questionnaires that were used to elicit firm-level data was chosen as the appropriate methodology for this exercise, given the need to improve our understanding of how local firms produce and innovate in this sector. When choosing the firms for the case studies, due regard was given to these countries' specific realities and geographical considerations, without prejudice to any one model of industrial development, health-care system or related policies.

II. Conceptual framework and the political economy of the pharmaceutical industry

In Africa, the pharmaceutical sector value is expected to reach \$65 billion by 2020 (Holt, Lahrichi and Santos da Silva, 2015), propelled by a convergence of changing economic profiles, rapid urbanization, increased health-care spending and investment, and increasing incidence of chronic lifestyle diseases. There are also a number of medical factors that would stimulate the development of the pharmaceutical industry on the continent, such as:

- (a) Patent expiries of many leading medicines;
- (b) Growth of the pandemics and an increasing number of people on treatment;
- (c) Improving health insurance coverage, leading to an increase in the number of people with access to health care;
- (d) A population that is living longer and a consequent increase in lifestyle diseases.

As discussed briefly in chapter I, the African population has the world's highest burden of infectious and neglected diseases, and faces a rapidly-rising burden of non-communicable diseases, yet the continent consumes less than 1 per cent of global health expenditure and manufactures locally less than 2 per cent of the medicines it consumes. A healthy nation means a productive economy. Africa cannot realize its long-awaited demographic dividend unless it is able to respond to the continent's need for a secure and reliable supply of quality, affordable, accessible, safe and efficacious medicines, by facilitating the development of a competitive African pharmaceutical industry to ensure self-reliance.

Strengthening Africa's ability to produce high-quality, affordable pharmaceuticals across all essential

medicines will contribute to improved health outcomes and the realization of direct and indirect economic benefits. This is the vision enshrined in PMPA and endorsed by the Heads of State and Government. Achieving this vision requires a clear understanding of the state of the pharmaceutical industry in Africa and modus operandi of the pharmaceutical business.

A. State of the pharmaceutical industry in Africa

The African pharmaceutical market accounts for only a small portion of the global pharmaceutical industry. In 2007, IFC estimated that Africa without North Africa accounted for just under 0.6 per cent of the global pharmaceutical market, which was estimated to be \$934.8 billion in 2017 and was expected to reach \$1.17 trillion in 2021, growing at 5.8 per cent (IFC, 2007). In 2014, QuintilesIMS Health, a health technology company, estimated that the African market was worth approximately \$24 billion and could be worth between \$40 billion and \$65 billion by 2020 (Holt, Lahrichi and Santos da Silva, 2015). To cite a few examples of individual market sizes, in 2016, the Cameroon market was estimated to be \$36 million, Ghana at \$600 million, Kenya at \$1.2 billion, Morocco at \$2 billion, Nigeria at \$3 billion and South Africa at \$5 billion. This is rapid growth compared with what the market was a decade ago. However, this growth in pharmaceutical markets has not been matched by a corresponding increase in local manufacturing capacity. Reasons for this are discussed later in this section.

Table 2 List of countries that supply medicines to Cameroon, Ghana, Kenya, Morocco, Nigeria and South Africa (2015/16)

Country	1 st supplier	2 nd supplier
Cameroon	India	China
Ghana	India	China
Kenya	India	United Kingdom
Morocco	Local	France
Nigeria	India	China
South Africa	India	Germany

Source: Data from key informant interviews. Information on Nigeria collected during the programme validation exercise.

Based on the information gathered during the country visits for this exercise, over 70 per cent of medicines are imported. Among Cameroon, Ghana, Kenya, Morocco, Nigeria and South Africa, only Morocco has a local pharmaceutical industry that supplies more than 50 per cent of national demand. Table 1 gives approximate figures for key pharmaceutical development indicators in the five countries visited.

Table 2 demonstrates that accessing pharmaceutical products in most African countries is skewed towards importation rather than manufacturing. There is strong evidence that manufacturing plays a key role in the economic growth of developing countries. Not necessarily specific to pharmaceuticals, manufacturing can greatly benefit a country by helping to grow the economy by generating productivity, stimulating R&D and investing in the future.

Most African manufacturers are small, privately owned companies that primarily serve their national markets. However, there is potential to develop the pharmaceutical manufacturing sector in Africa. For instance, there are publicly listed companies (for example, Ayrton and Starwin in Ghana), and companies that have invested in their facilities through accessing international equity financing (for example, Universal in Kenya). In Cameroon, a local company, Pharmaceutical Industrial Company (CINPHARM) – in

joint venture with Cipla, an Indian company – employs over 300 people, including 20 pharmacists.

There are other positive examples at country level. Some domestic manufacturers, such as Aspen in South Africa, are now comparable in size to leading international generic manufacturers. Also, in South Africa in 2010, a \$211 million joint venture between a leading Swiss manufacturer of APIs and the South African Government led to the creation of a pharmaceutical plant that produces APIs for antiretrovirals (ARVs), the first of its kind on the continent. Even though the Swiss manufacturer pulled out of this venture in 2013, the Government of South Africa took over the entire operation. Currently, the entity, Ketlaphela, is the first on the continent to produce APIs for ARVs. In addition to local manufacturers, the leading global innovator companies have manufacturing facilities in various African countries. They include, among others, GSK, Johnson and Johnson, Sanofi (with plants in six African countries), Sandoz and Ranbaxy. Ranbaxy has three manufacturing facilities situated in South Africa, Morocco and Nigeria.

B. Conceptual framework

With these basic facts as background, this report moves on to assess the political economy of the pharmaceutical industry, with particular focus on how local and global factors interact to impact the African market's competitiveness and intellectual property-related issues. To do this, we use a conceptual framework that characterizes these factors into three broad categories: political, production and market factors. Below we define the key themes of these categories, providing some initial examples to illustrate the opportunities and challenges these pose for African countries in developing domestic pharmaceutical industries.

1. Political factors

One of the reasons why access to affordable, safe, quality and efficacious medicines on the African

continent has been a major challenge for decades is weak or non-existent regulatory systems for medical products in many African countries. Strong and competent regulatory authorities are necessary if the quality of medicines is to be assured. The main goal of regulation is to ensure the quality, safety and efficacy of medical products, as well as to assure the relevance and accuracy of product information (WHO, 2013). Most of the efforts to improve regulation of medicines in Africa are hampered by the lack of clear policies or legal and regulatory frameworks for regulating medicines at national as well as regional levels. Moreover, countries that have policies in place do not have implementation plans, creating gaps in execution. The African Union Model Law on Medical Products Regulation and Harmonization¹ was adopted in 2016. It aims at addressing legislative gaps that hamper effective regulation of medicines and regional harmonization by ensuring a systematic approach for the development of harmonized legislation on regulation of medicines in African countries. This initiative is part of the African Union's effort to promote local production of pharmaceuticals, with a view to the protection of public health and contribution to economic growth (NEPAD, 2014).

In many African countries, lack of harmonized technical requirements for registration of medicines and insufficient regulatory capacity are further compounded by chronic shortages of human, technical, financial and other resources. For instance, many of the National Medicines Regulatory Authorities (NMRAs) within Africa lack the capacity to fully perform their core regulatory functions, while poor industrial infrastructure and services lead to high operating costs. In order for Africa's

pharmaceutical industry to develop, countries must create an enabling environment through easing access to capital for investment, while simultaneously enabling African businesses to access expertise and technology.

In 2011, the African Union Conference of Ministers of Industry (CAMI-19)², held in Algiers, identified the pharmaceutical sector as a significant contributor to the overall industrial development of the continent, thereby integrating PMPA into the Action Plan for AIDA.³ Many African Governments are increasingly considering supply of medicines as a national security issue, recognizing that integrating health and industrial policies to foster local pharmaceutical production is critical for the development of African countries. Investment in the growth of Africa's domestic pharmaceutical manufacturing sector also has an important role in achieving economic transformation goals enshrined in the African Union's Agenda 2063,⁴ and the access to medicines goals set out in the United Nations' Sustainable Development Goals.⁵

2. Production factors

Pharmaceutical manufacturing in Africa can be broadly classified as consisting of: relatively small, privately-owned companies that serve their national markets; a few large manufacturers (such as Aspen in South Africa, which is in the top 10 largest generic manufacturers in the world); as well as public sector manufacturers. As discussed previously, the level of development of the manufacturing system varies dramatically among African countries, ranging from over 200 registered in Nigeria to none in a number of other countries. In total, it is estimated

1 African Union Model Law on Medical Products Regulation – NEPAD. Avail <https://www.nepad.org/publication/au-model-law-medical-products-regulation> . Accessed on 25 March 2020.

2 African Union Conference of Ministers of Industry (CAMI-19). Available at https://au.int/sites/default/files/newsevents/workingdocuments/14614-wd-ti12654_e_original.pdf. Accessed on 9 December 2019.

3 African Union. AIDA – Accelerated Industrial Development for Africa. Available at <https://au.int/en/ti/aida/about>. Accessed on 9 December 2019.

4 Available at www.un.org/en/africa/osaa/pdf/au/agenda2063.pdf. Accessed on 25 March 2020.

5 Available at www.undp.org/content/undp/en/home/sustainable-development-goals.html. Accessed on 9 December 2019.

that some form of manufacturing takes place in 38 countries, but only South Africa has limited primary production of APIs and intermediates. Local production in Africa, therefore, relies on imported active ingredients (African Union Commission–UNIDO Partnership, 2012a). As a result, the supply of African pharmaceuticals remains highly dependent on foreign imports.

There are generally two types of pharmaceutical companies: large multinational corporations (MNCs) that do research and development for new drugs and aim at getting these patented, and smaller generics companies that manufacture products that are not patented or products whose patents have expired. There are few pharmaceutical MNCs, and they are exceptionally large, with most of their head offices located in developed countries – mainly in the United States, the United Kingdom, Switzerland, France and Germany – but operate all over the world.⁶

A distinctive characteristic of the “Big Pharma” companies, as they are commonly known, is a very high level of investment in R&D. On average, it takes about 10 to 15 years and millions of dollars to develop a new medicine. According to industry statistics, only about one in 10,000 chemical compounds discovered by pharmaceutical industry researchers proves to be both medically effective and safe enough to become an approved medicine, and about half of all new medicines fail in the late stages of clinical trials. Not surprisingly, according to the National Science Foundation’s report “Research and Development in Industry: 2001”,⁷ in 2001 the pharmaceutical industry had one of the highest R&D expenditures as a percentage of net sales. Only strong market development could allow such investments.

3. Market factors

The patent system and the marketing power of the MNCs are at the root of their worldwide dominance. Naturally, for the products patented by the MNCs, they enjoy a monopoly status. They rely on growing sales of their patented drugs, and they also use an elaborate marketing infrastructure to maintain dominant market shares after patents expire. Even when the product is protected through patents, the MNCs promote their drugs under brand names – that is, through trademarks – rather than under generic names, which are commonly used in scientific literature. The Big Pharma companies continue using these brand names to take advantage of brand loyalty, even when generic companies enter the market after the expiry of patents. Intellectual property is, therefore, the pharmaceutical industry’s most valuable resource, and its protection is a key to companies’ future success. Recent challenges over patents for HIV drugs have reminded the industry that progress is still needed in balancing the opposing forces of innovation through protection of intellectual property rights versus the provision of affordable drugs for all. Pharmaceutical companies must face the daily challenge of creating value through the exploitation of intellectual property rights, while also avoiding reputational harm.

Notwithstanding the rise of generic companies from emerging countries, such as China and India, leading to more robust competition, there is still very little significant change in the ranking of the leading pharmaceutical companies in the world. To safeguard their market dominance, MNCs have also started introducing new brands to compete in the generic markets. The dual-brand strategy enables them to compete in the price-insensitive segment of the market, while dominating the top end, too. If African pharmaceutical producers are to compete with foreign manufacturers, they need to be able to operate in a fair

6 Wikipedia, List of largest biomedical companies by revenue. Available at https://en.wikipedia.org/wiki/List_of_largest_pharmaceutical_companies_by_revenue. Accessed on 9 December 2019.

7 Available at www.nsf.gov/statistics/iris/excel-files/nsf_05-305/tn.doc. Accessed on 9 December 2019.

business environment that enables them to sell at a lower price and remain profitable and viable.

Another form of structural change emerging in the industry is the establishment of new strategic alliances and joint ventures. Since the 1990s, the global pharmaceutical industry has experienced a shift in industry dynamics, stemming from both a thinning drug pipeline and rising drug development and production costs. As a result, most companies have been consolidating their production and manufacturing activities through mergers and acquisitions; new joint ventures creating “centres of excellence/expertise” in a few countries characterized by large, low-cost units in logistically well-placed areas; or creating spin-offs from their core business.

Recently, there have been multiple examples of such initiatives. For example, in 2016 alone, two mergers occurred: American pharmaceutical giant Abbot agreed to buy Alere Inc. for \$5.8 billion (or \$56 a share) to become the lead holder in the market for medical tests and diagnostics; and Mylan agreed to a takeover of Swedish drug maker Meda for \$7.2 billion. In 2015, eight such strategic alliances/joint ventures occurred. Although the size of the company on its own does not guarantee its success, it provides a significant advantage, especially in the pharmaceutical industry. As well as economies of scale in manufacturing, clinical trials and marketing, bigger companies can also allow investments in more R&D projects to diversify their future drugs portfolios and promote stability in the long term.

The interrelationship among the conceptual framework explained above is characterized into three broad categories: political, production and market factors. It is at best described as within a “fact of life” – the unlimited demand for health care, confronted with limited resources for its funding, all intertwined together, influence the changes in the pharmaceutical sector.

The legal and political environment makes a direct impact on all production and marketing mix instruments. Through its provisions and prohibitions, legislation and political decisions determine a large number of production and marketing decisions – designing, manufacturing standards, labelling, packaging, distribution, advertising, and promotion of goods and services. All of this concludes into the complexity of the supply chain and demand side of pharmaceuticals.

C. Report structure

The rest of the report provides a detailed assessment of these three factors, focusing on key themes within each. Chapter III reviews political factors, including policies and strategies that support the pharmaceutical sector, as well as the regulatory and institutional framework for the manufacturing of the pharmaceutical products in Africa.

The following two chapters focus on production factors. Thus, chapter IV examines the scarcity of API and other pharmaceutical excipients and its impact on the production of the pharmaceutical sector. Chapter V discusses issues related to R&D and African countries’ limited capacities to develop new molecules.

The following two chapters provide in-depth analysis of market factors. Chapter VI explores the role of finance and how African pharmaceutical firms can be sustainably funded to produce safe, efficacious and affordable medicines. Chapter VII examines the huge human resources gap and analyses the education needs.

The report concludes with chapter VIII offering policy recommendations of actions that would need immediate attention to scale up the pharmaceutical manufacturing in Africa. Political will, policy and regulatory and institutional framework

III. Political will and organizational commitment

This chapter examines the political will and regulatory and institutional framework that support and regulate the manufacturing of pharmaceutical products in Africa. It further discusses institutions, policies and standards in place to support the sector. Moreover, this chapter examines how regional integration and trade policies, including AfCFTA, should serve as enablers to scaling up pharmaceutical production.

A. Political will and organizational commitment

From the interviews that were conducted, it is evident that the African Union is highly committed to increasing pharmaceutical production within the continent. This is demonstrated by the existence of PMPA at the continental level and a number of similar documents/instruments at the regional level to support this intent, including; the Southern African Development Community (SADC) Pharmaceutical Plan (SADC, 2007), the East African Community (EAC)'s Regional Pharmaceutical Manufacturing Plan of Action (EAC, 2012), and the Economic Community of West African States (ECOWAS) Regional Pharmaceutical Plan (West African Health Organization, 2014).

Among the six countries visited for the purpose of this exercise, all have national manufacturing plans for improving pharmaceutical production in their countries. Aside from these six, Ethiopia, the United Republic of Tanzania and Zimbabwe also have national pharmaceutical manufacturing strategies, and Nigeria is currently developing a plan, which is being led by the Pharmaceutical Manufacturers

Group of Manufacturers Association of Nigeria and the Federal Ministry of Industry, Trade and Investment (Nigeria). However, the existence of policy documents and the manifestation of political will do not always translate into implementation. Policy development should always be accompanied by the necessary capacity development and resource mobilization to match political aspirations. Continental and regional policies rely on member States and other stakeholders for implementation. Political will should, therefore, be accompanied by the development of the necessary capacities to implement these policies.

B. Enabling policies

Across Africa, there are many policies in place – such as the National Drug Policies, Medicines Regulation Policies, and Pharmaceutical Procurement Policies – that impact on the pharmaceutical manufacturing sector. Among these, the National Drug Policy is the most important with regard to pharmaceutical issues. The purpose of a National Drug Policy is to promote access to safe, effective, quality medicines at an affordable price, as well as to promote the rational use of medicines. All the six countries visited for this study have pharmaceutical policy documents. Outside these six countries, most countries in Africa have national drug policies (Hoebert and others, 2013; WHO, 2003), though most need updating.

Another key objective of drug policies is to promote the local production of essential medicines, which is critical in the development of the pharmaceutical manufacturing industry. However, there are many other policies and legislative tools that impact

pharmaceutical manufacturing. During this study, consultations were held in the countries of interest with the Ministries of Health, Trade and Industry, and Finance. These are all relevant stakeholders in the manufacturing of medicines and related commodities. Traditionally, the production of medicines and their access have been the responsibility of the Ministry of Health. Of late, however, stakeholders have realized that the Ministry of Health alone does not control the full range of instruments that impact on the local pharmaceutical industry. The involvement of other Ministries – such as Trade and Industry, and Finance – calls for interministerial coordination, with a view of promoting policy coherence.

C. Incentives and protectionist policies

Countries with thriving pharmaceutical industries, such as India and China, provide support to their producers in the form of incentives and protectionist policies. Policy instruments that have been used to protect pharmaceutical sectors in developing countries include high tariffs on imported finished products, such as the application of differential and more favourable treatment (Wolf, 1987). Differential and more favourable treatment of developing countries is a fundamental principle of the General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO). Because developing countries are disadvantaged in international trade, the international community has agreed that these countries should be subject to somewhat different rules and disciplines in international trade than those that apply to developed countries, and that the latter will implement their obligations under GATT and WTO in ways that would be favourable to development. Brazil, for example, charges 15 per cent tariffs on finished products,⁸ while India has been reported to charge as high as 56 per cent. Among African countries, tariffs are not necessarily higher for finished products. For

example, in South Africa, Kenya and Ghana, the tariffs for APIs are in the same bracket with those for finished products, while in Cameroon, there is no tariffs at all except the (Société générale de surveillance – SGS) of 1 per cent. The result is that final formulation imports to Africa have benefited from substantial government support in their countries of origin, and then often do not attract duty at their destination. Furthermore, inputs for local production often attract duty. This is being resolved in some countries, though in general not in a particularly systematic way.

There is, thus, a need for African countries to systematically apply policy regulations that level the playing field between finished pharmaceutical products and the APIs. Other typical incentives could be applied while Governments build competitiveness in their economies in general. With competitive economies, it is not necessary to provide incentives such as tax holidays, that end up reducing Governments' abilities to provide services. In the meantime though, the lack of a level playing field poses a genuine threat to the sustainability of high-quality pharmaceutical production in Africa, and limits the ability of companies to make the investments required to upgrade their plants. It is imperative that this imbalance is addressed in order to achieve the environment needed for sustainable high-quality production of finished products in Africa.

Preferential policies – such as those in India, Brazil and the Russian Federation – can also be used to support the African pharmaceutical industry. Preferential policies could target an outcome of reduction in the importation of certain products that can be manufactured locally. Ghana and Nigeria have reportedly used these to some favourable effect (Tijani, 2017; African Union Commission–UNIDO Partnership, 2012b, pp. 25–66). In addition to the Ghanaian and Nigerian examples, Uganda, in

8 Brazil – Import Tariffs. Available at www.export.gov/article?id=Brazil-Import-Tariffs. Accessed on 9 December 2019.

Countries using procurement preference to encourage local manufacturing

Brazil has a 25 per cent price preference, and the **Russian Federation** is reported to have introduced measures to ensure that 70 per cent of products procured by the State are locally manufactured. **Botswana** has laws that prefer local suppliers for the procurement of pharmaceutical commodities. **South Africa** has local production preference points in tenders, but is also reportedly in the process of replacing these with a new system where a percentage of designated products will be procured only from domestic producers. **Kenya** has a 15 per cent price preference for locally manufactured products in its tenders.

2010, resisted the Affordable Medicines Facility for Malaria operating in the country, on the pretext that it would ruin the local antimalarial manufacturing company, Quality Chemicals. In Algeria and Tunisia, once a locally manufactured generic is registered, the innovator is given two years in which to commence local production. Failure to do this can result in a ban on importation of the finished product, and the market can then only be served through locally produced products. Lessons can be learned from these examples, as Africa seeks to develop and sustain the pharmaceutical manufacturing industry.

D. Regulatory framework

Oversight of the pharmaceutical market is a function of NMRAs. As of 2016, 22 countries in Africa had NMRAs.⁹ These agencies are responsible for regulation and control of various aspects of the pharmaceutical value chain, from medicine registration to the access of medicines by clients. NMRAs are also responsible for ensuring that the manufacture, import and export, distribution and wholesaling of all medicines are properly regulated. In addition, NMRAs ensure that pharmaceutical facilities are properly licensed, conform to good manufacturing practice (GMP), and

observe good distribution practice in all activities and on all premises.

Appropriate regulation of a country's pharmaceutical sector is necessary for ensuring that only safe and high-quality products are available on the market. In general, poor regulation limits access to safe and affordable pharmaceuticals in Africa.

Among the six countries visited in the study, there are robust and functional NMRAs. Regulatory systems exist, although these are not classified as stringent, according to international standards. Even though some progress has been recorded in the performance of regulatory functions, most African NMRAs face immense challenges, such as a severe shortage of funding, inadequate human resources, and a lack of capacity to perform core regulatory functions.¹⁰

Given the inherent capacity challenges faced by all regulators, and the particular resource constraints in many African countries, there is a need for the continent to work together to build strong regulatory frameworks. Thanks to AfCFTA, Africa is now in a position to come together and ensure that a strong regulatory framework is put in place to guarantee that medical products of a foreign or local origin are safe, of good quality, sustainable and rationally used. With regard to funding, most of the regulatory authorities in Africa receive funding from their Governments; however, a majority supplement these funds by charging fees for services.

Most African countries still do not meet the regulatory standards required.¹¹ The legal frameworks for some of the NMRAs are complex, with unclear definitions of the responsibilities, regulatory gaps and overlaps. Some NMRAs are not

9 Regulatory intelligence sources for pharma professionals. Available at www.reg-info.com/other/africa/. Accessed on 9 December 2019.

10 State of medicines regulatory authorities in Africa. Available at www.who.int/medicines/publications/druginformation/DI_28-1_Africa.pdf?ua=1. Accessed on 25 March 2020.

11 Ibid.

Kenya's paucity of human resources capacity

The Kenyan Pharmacy and Poisons Board has only six full-time GMP inspectors, and it is impossible for them to meet the desirable level of inspection. In addition to inadequate human resources, a lack of harmonized technical requirements for medicines registration, as well as insufficient regulatory capacity, limits the efficiency of medicine regulatory authorities across Africa. Technical, financial and other constraints limit many NMRAs in Africa from performing the regulatory functions stated above.

fully established and, thus, not performing their full range of regulatory functions. Moreover, most of the NMRAs are underfunded and understaffed. Other challenges that plague NMRAs in Africa include inadequate operational resources, no quality management systems, and no staff development programmes. There is also poor coordination between the stakeholders involved in regulating the industry. To ameliorate some of the challenges that the continent faces in medicines regulation, harmonization of regulatory functions across the continent is necessary.

E. Regulatory harmonization

In February 2009, NEPAD, in collaboration with its partners, held a workshop on the harmonization of medicines registration in Africa (Berger and others, 2010). The objective of the workshop was to improve standards and requirements related to the regulation of and access to safe, high-quality medicines for the African population. As a result of this meeting, the African Medicines Regulatory Harmonization Programme (AMRH) was established. The overall aim of AMRH is to create — in partnership with the African Union Commission, WHO, the Bill and Melinda Gates Foundation and the World Bank — an African Medicines Agency (AMA), which will operate under the authority of AMRH.

To augment the medicines regulatory process across the continent, the African Union Executive Council endorsed a road map for the establishment of AMA.¹² This was a recommendation from the first African Ministers of Health meeting, jointly convened by the African Union Commission and WHO.¹³ In line with the ministerial commitment, the African Union Commission and WHO established a task team to facilitate the establishment of AMA. The first task team meeting was held in November 2014 in Addis Ababa, and adopted its terms of reference and a four-year action plan (2015–2018) for the operationalization of AMA. The African Union Commission, WHO and the NEPAD Planning and Coordinating Agency serve as a joint secretariat for the task team.

Development of the AMA business plan for the African Union Commission is one of AMA's four-year action plans to operationalize the continental agency. The AMA business plan provides the rationale for the continental agency; background to the genesis of AMA; policy issues at regional, continental and global level; an environmental scan; the approach that was adopted in the development of the business plan, including the consensus-building process; its business model, including a financial plan; and a monitoring and evaluation framework.

AMA is intended to be an organ of the African Union, legally mandated by member States to coordinate national and subregional regulatory systems for medical products, provide regulatory oversight of selected medical products to start with, as well as promote cooperation, harmonization and mutual recognition of regulatory decisions. As a continental agency, AMA will serve the purpose of pooling expertise and capacities, and strengthening networking for optimal use of the limited resources available for regulatory authorities, and complement

12 African Union Executive Council, Twenty-Sixth Ordinary Session, 23–27 January 2015. Addis Ababa EX.CL/Dec.851-872 (XXVI)

13 First meeting of African Ministers of Health jointly convened by the African Union Commission and WHO. Luanda, 16–17 April 2014.

and enhance the efforts of ongoing harmonization initiatives. Furthermore, AMA is to augment the functions of NMRAs and subregional Medicines Regulatory Authorities, which will be established by the regional economic communities (RECs), but not replace them.

African Health Ministers have taken the lead on the project, since a meeting held in Luanda in April 2014. Among other recommendations, AMRH proposes that all drug registration efforts should be situated within the RECs, which are:

- (a) Community of Sahel–Saharan States;
- (b) Common Market for Eastern and Southern Africa;
- (c) Economic Community of West African States (ECOWAS);
- (d) East African Community (EAC);
- (e) Economic Community of Central African States;
- (f) Southern African Development Community (SADC);
- (g) Intergovernmental Authority of Development;
- (h) Arab Maghreb Union.

NEPAD and its partners proposed that there should be strong collaboration among member States within a REC and among different RECs through the establishment of inter- and intra-REC collaborative forums. With an end goal of minimizing the duplication of efforts and ensuring that there is proper allocation of resources, NEPAD and its partners proposed the sharing of expertise and the use of risk-based approaches. RECs were encouraged to implement WHO's "Regulatory Documentation Package" and to maintain project activities after the withdrawal of initial support.

Given the challenges that the African continent faces in this area, the AMRH programme provides the right direction for the harmonization of medicine registration. However, the evident lack of capacity at national and regional levels requires much more groundwork to build NMRA capacity before harmonization can be completed. Moreover, for proper harmonization to occur, a minimum set of standards is required from member States. AMRH should have solid capacity-building frameworks to support NMRAs and RECs, to allow the programme to operate effectively from the outset.

Progress among the RECs in regard to harmonization

EAC, a REC with six member countries — Kenya, Uganda, the United Republic of Tanzania, Rwanda, Burundi and South Sudan — launched its Medicines Registration Harmonization Project in March 2012. It was the first of the RECs participating in the AMRH programme in Africa to do so. The launch of the project marked the beginning of the implementation phase of the AMRH programme across the continent.

In Southern Africa, as a way of advancing regulatory harmonization, four NMRAs – Zambia, Zimbabwe, Botswana and Namibia – started collaborating on the fast-tracking of registration and mutual recognition of medicines in mid-2013. South Africa has now joined this initiative. The SADC Ministers of Health officially endorsed this initiative in January 2015. Within this work-sharing framework, the NMRAs share their work plans, assessment reports and inspections for common products. They utilize the SADC and WHO standards to remove duplication, accelerate registration of selected products and develop mutual confidence. They also provide a platform for training, harmonization of requirements and practices, and collaboration among NMRAs in other regulatory fields. Other regions, such as ECOWAS, have begun work on developing proposals for the harmonization of the regulatory functions under the AMRH programme. The Central African Economic and Monetary Community launched the regional programme for harmonization of national pharmaceutical policies in Central Africa, which is run by the Coordination Organization for the Fight Against Endemic Diseases in Central Africa. The harmonization of pharmaceutical policies consists of agreeing on the various regulatory texts and practices that govern the pharmaceutical sector, with a view to opting for an identical and common course of action in the countries of the subregion.

F. Quality of production/ products

Key informants in Morocco and South Africa indicated that the range of quality standards to which manufacturers adhere are close to international standards. Companies, such as Aspen in South Africa, export products to North America, Europe and Australia, among other places. Because of the stringent regulatory environment in these markets, it demonstrates that these companies do indeed adhere to international standards. Other manufacturers who have, at one point, received WHO pre-qualification for anti-infections medicines are Universal in Kenya and Varichem Pharmaceutical in Zimbabwe. Some other manufacturers – such as Quality Chemicals in Uganda, which is a wholly owned subsidiary of Cipla of India – has a licence to produce Cipla pre-qualified products.

These, however, are the exception to the rule. In fact, the whole of the West Africa region did not have a single manufacturer that was pre-qualified as of 2013.¹⁴ Nigeria, for instance, with over 200 companies in the industry, does not have a single manufacturer that is WHO pre-qualified. However, the Nigerian National Agency for Food and Drug Control has been working with WHO and some companies to achieve international quality standards.

The fact that Africa has only a few entities that are pre-qualified, despite there being various companies

WHO pre-qualification process

The WHO pre-qualification process is the stringent assessment of product dossiers, inspection of manufacturing sites and of contract research organizations, pre-qualification of national pharmaceutical quality control laboratories (NPQCLs), and advocacy for medicines of assured quality. By doing this, procurement and distribution of quality medicines are accelerated.

manufacturing pharmaceutical products, implies that ensuring quality is still an issue. There are genuine challenges confronting companies that aspire to improve quality and to realize their ambition of achieving international GMP status.

One reason why manufacturers do not want to invest in the pre-qualification process or in enhancing GMP might be related to the cost involved in the exercise. The fees and expenses involved in the qualification process can be prohibitive (WHO, n.d.). In addition to this, key informants noted that international funding organizations – such as the Global Fund to Fight AIDS, Tuberculosis and Malaria – only contract suppliers based on prices, and the African market is currently not competitive enough to beat these prices. However, the global procurement agencies have recognized this issue and the Global Fund has, for example, developed a market shaping strategy that includes looking to source products from African companies.

If manufacturers were to further invest in the pre-qualification processes, such investments would have to be recouped via increases in prices. To ensure guaranteed markets, national and regional procurement laws would need to consider allocating percentage points for local producers, if the quality of the products is deemed to be of the required standards by the regulators.

Apart from allocating percentage points for locally produced products, the African Union Commission, through AMA and other relevant institutions, should be encouraged to set up its own pre-qualification process. Such a process would still have technical support from WHO and other agencies, but could be financed via different mechanisms. This would make the pre-qualification process affordable and more attractive to African-based manufacturers. However,

14 Abigail A. Ekeigwe. Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation. AAPS Open volume 5, Article number: 3 (2019). Available at: <https://link.springer.com/article/10.1186/s41120-019-0032-x>.

Quality of imports

Africa's dependence on imported medicines makes it vulnerable to substandard medicines. Over the years, the continent has experienced various incidences of counterfeit imported medicines. In Nigeria, a 2011 WHO survey found that, due to the weak nature of regulation and widespread non-compliance with international GMP, as well as other critical components of the quality system for both local and imported drugs, 64 per cent of antimalarial drugs were counterfeit. In Cameroon, counterfeiting is well developed, and the illicit drug sector represents about 30 per cent of the pharmaceutical market (WHO, 2011).

an African-led pre-qualification process should not be seen as an avenue to lower the quality standards of medicines and related commodities. It should be seen as a sustainable way to improve the production capacity of local pharmaceutical industry on the continent.

G. Trade policies including market integration/ continental free trade area

Trade can impact population health in both direct and indirect ways. The free flow of goods and services can potentially improve population health directly, if free trade agreements support equitable access to better quality medicines and health technologies, through expanded cross-border sharing of services; and enable cooperation and economies of scale across the continent in research and development, regulatory oversight and quality control of medicines, technologies and health services.

Through its impact on economic growth, free trade can also: (a) improve population health indirectly if free trade agreements enable African Governments to invest more domestic resources in the health system, including the delivery of health services, reducing dependence on foreign donors for development assistance for health; (b) enable Governments to invest domestic resources in the broader determinants of health – such as education, water and sanitation – and transportation infrastructure; and (c) increase household revenue

across socioeconomic groups to improve health outcomes through better nutrition, housing, access to water and sanitation, and reduced stress.

Enhanced integration on the continent provides a huge opportunity for Africa's pharmaceutical industry. The adoption of the Boosting Intra-African Trade Initiative in 2012 and the launch and ongoing ratification of AfCFTA by African countries have brought about a shift in focus towards bringing down the costs of intra-African trade regarding tariffs, and lowering of non-tariff barriers to trade. Negotiations for AfCFTA that began in 2015 culminated with the signing of AfCFTA on 21 March 2018. The AfCFTA processes provide an opportunity for the enhancement of capacities in the area of pharmaceuticals. It provides a unique opportunity to safeguard public health as long as the AfCFTA final agreement integrates an awareness of the multiple ways in which trade impacts health and health systems to ensure that the agreement, on balance, benefits health outcomes on the African continent.

In addition, AfCFTA could have several other significant positive impacts on health and health systems within the continent. First, under the right conditions, free trade in the African context could potentially be a catalyst for better health outcomes. If AfCFTA contributes to inclusive economic growth, this will have its own independent and positive effect on health through reduced poverty.

Second, AfCFTA could conceivably work to improve the quality of medicines and other health commodities by clarifying the rightful place of generic medicines in the African market and supporting policies to facilitate access to generics, promoting an integrated market for emerging African pharmaceutical manufacturers, as well as strengthening the fight against counterfeits.

Third, AfCFTA could enable the African continent to negotiate as a coherent bloc, strengthening its ability to ensure that TRIPS flexibilities are fully utilized

in efforts to ensure access to essential medicines. AfCFTA needs to be TRIPS-compatible (with careful attention to ensure it preserves TRIPS flexibilities), and member States should be encouraged and supported to pass domestic TRIPS-compatible patent legislation.

Finally, if AfCFTA reduces barriers to trade in services – particularly, if it complements the realization of the Protocol on Movement of People, in addition to reducing barriers to innovation across Africa's borders – it would address some key impediments to African States collaborating in the cross-border delivery of health services and sharing of research and technology.

However, free trade also has the potential to negatively impact health, if trade agreements:

- (a) Reduce access to affordable medicines through restrictions placed on the importation of generic medicines;
- (b) Increase population consumption of unhealthy products, such as processed and sugary foods;
- (c) Enable the unregulated movement of pathogens and hazardous goods; and
- (d) Reduce numbers of health professionals/workers in certain countries by enabling out-migration of health professionals.

For trade agreements to positively impact population health and health systems, these multiple and diverse effects must be analysed and integrated into trade agreements. Moreover, in the context of least developed and lower/middle-income countries, official development assistance must also be leveraged to support a progressive trade agenda, including for health.

H. Supporting the development of pharmaceutical clusters

The clustering approach has been instrumental in the development of the pharmaceutical industry in many parts of the world.

In India, Andhra Pradesh's pharmaceutical cluster has grown from a single company owned by the central Government into one of the world's largest producers of bulk drugs. There are many other pharmaceutical clusters throughout India, and their emergence is largely due to the changing policy environment in the country. India being a predominantly poor country, it has a large need for lifesaving drugs, but lacks the means to pay market prices for them. In 1970, the Indian Government passed the Patents Act, which allowed manufacturing processes in pharmaceutical products to be patented, but not the underlying products. This law allowed Indian pharmaceutical companies to reverse-engineer existing drugs and provide them to Indian consumers at a lower overall cost (as these companies did not have to recoup the large R&D investment made by foreign competitors). This led to a rapid expansion in the number and profitability of domestic pharmaceutical companies in India. The companies focused on manufacturing and were able to exploit the low cost of labour in India.

In 2005, in order for India to gain admission into WTO, it was forced to meet the TRIPS requirements. TRIPS required that countries honour and enforce the 20-year international product patents. This provided the intellectual property protection that multinational firms demanded, and encouraged investment in the Indian pharmaceutical industry. The sector in Andhra Pradesh was also aided by high-

Clustering in Switzerland

The Basel region is the pharma hub of Switzerland. About two thirds of all employees of the Swiss pharmaceutical industry work in this cluster, and the majority of value added in the pharmaceutical industry is generated in the Basel region. Established in the second half of the nineteenth century, the pharmaceutical industry quickly assumed a prominent place in the Swiss economy, and remains one of the strongest growth industries to date. Switzerland's capacity for innovation is an essential precondition for a prosperous pharmaceutical industry. Other factors – such as tax, accessibility and a large pool of highly trained employees – are attracting leading companies in the fields of pharmaceuticals, biotechnology and other related industries to Switzerland. Thanks to its innovation capacity, the pharmaceutical industry typically achieves an above-average level of productivity, and the productivity growth rate in the country also usually outstrips that of the industry as a whole.

quality human capital, above-average infrastructure, and helpful government incentives. Institutes for collaboration also assisted in the development of the cluster. However, coordination among firms, as well as with related and supported industries, needs to be strengthened to avoid a weak cluster.

The year 2015 was a challenging one for the Morocco pharmaceutical sector, characterized by slow growth rates in terms of both value and volume. The sector's

turnover stood at DH 13.7 billion (€1.3 billion), but the lower prices policy is likely to help stoke a rise in consumption, which should help the industry to recover in the coming years. Agreements signed between the Government and pharmaceutical associations in March 2016 to set up the first two of five new “ecosystems”, or pharmaceutical clusters, should help boost supply. With DH 440 million (€40.3 million) in public funding, the five clusters are planned under the Industrial Acceleration Plan and are set to add 5,000 jobs and generate DH 4.2 billion (€385.1 million) in value added by 2020. The first two will focus on producing drugs and medical devices while stimulating competition and helping bridge the industry's trade deficit, which stood at DH 6.4 billion (€586.8 million) in 2014.

Legislative changes should help bolster local manufacturing. Still, in Morocco, drug marketing authorizations, long deemed cumbersome and lengthy, have constituted an impediment to the growth of the industry. A February 2016 decree shortens approval times from two years to around 10 months. The reform will also benefit generics producers, which should see such processes completed within nine months for those having obtained prior consent from the brand-listed manufacturer.

IV. Inputs

Chapter IV examines the importance of active pharmaceutical ingredients (APIs) in the pharmaceutical manufacturing sector. The chapter goes on to explore the scarcity of APIs and its impact on the production of the sector. Furthermore, it also considers the availability of other pharmaceutical excipients.

A. Active pharmaceutical ingredients

Pharmaceutical manufacturing occurs in two general steps. During the first step, firms convert raw materials into APIs, which is a highly sophisticated, technically demanding chemical and biochemical fermentation and/or synthesis process. APIs constitute a significant portion of the total cost for a drug. For example, on average, 40–50 per cent of the cost of goods sold for oral solids comes from APIs (Contract Pharma, 2002). Commodity API manufacturing tends to be a high-volume, low-margin business, where economies of scale play an important role.

The second step in pharmaceutical manufacturing is the final formulation of the drugs. Unlike API production, final formulations belong to the manufacturing sector. During this process, firms first mix APIs and excipients (other non-active ingredients), then either press the mixture into pills

and tablets or prepare powders for solutions or filling of capsules, and finally, package the product for the public or private market. Final formulations require skills and equipment different from API manufacturing. Economies of scale matter, but less so than for API manufacturing, as manufacturers can produce 50 or more final formulations in a single plant with adaptable equipment.¹⁵

With regard to pharmaceutical manufacturing in Africa, most African countries' final formulation manufacturers, outside of South Africa and North Africa, manufacture non-complex, high-volume, essential products, such as basic analgesics, simple antibiotics, antimalarial drugs and vitamins. While many African manufacturers could make higher-end products, consumers may not purchase them. In these markets, many consumers are extremely price-conscious. Also, cheaper drugs have lower working capital requirements. The price of an API may deter small final formulators. Often, these firms are relatively new and have small capital bases. The six-month lag between purchasing an API and then selling the subsequent final formulation requires a working capital investment. Therefore, firms may be attracted more to drugs where the API cost is relatively minor, compared with more complex drugs, where the APIs can cost thousands of dollars per kilogram.

¹⁵ International Society for Pharmaceutical Engineering website, available at https://ispe.org/?ci_id=12970. Accessed on 10 December 2019.

API manufacturing in India and China

API manufacturing has slowly been shifting from the historical leaders in Western countries to newer firms in India and China. This trend will continue as the Indian and Chinese API industries are growing at, respectively, nearly 19.3 per cent and 17.6 per cent annually.* While Italy still remains the world market leader in APIs destined to sectors such as cardiovascular or the central nervous system, China leads in anti-infective APIs, with approximately 43 per cent of world market share (Mangia, 2007).

Lower production costs in India and China drive much of this growth. For example, to develop, test, manufacture and market a generic medicine in India costs 20–40 per cent less than what it costs in the West (VanEck, 2016). Lower production costs in India and China mainly derive from the following:

(a) Lower labour, infrastructure, transportation and equipment costs: If a typical Western API company has an average wage index of 100, this index is as low as 10 for the typical Indian API firm and 8 for a Chinese one, respectively. Not even the higher productivity of a Western company (due to the higher average automation level of the manufacturing processes) can annul the labour cost difference (Mangia, 2007). Additionally, India and China have lower electricity, coal and water costs. Indian and Chinese firms are also embedded in a network of raw materials and intermediary suppliers, and so have lower shipping and transaction costs for raw materials. Also, firms in these two countries often use less expensive equipment, leading to a lower depreciation cost.

(b) Fewer environmental regulations: Currently, Indian and Chinese firms have fewer environmental regulations regarding the buying, handling and disposing of toxic chemicals, which lead to lower direct costs for these businesses.

(c) Larger-scale manufacturing: IFC estimates that a factory making tablets in blister packaging needs to manufacture around 1.0 billion–1.5 billion tablets per year to be said to be operating at scale (Bates, 2012). Indian and Chinese firms have often reached scale when firms in other countries have not. For example, IFC estimates that a third of the 30–40 per cent cost disadvantage that a leading Ghanaian final formulations manufacturer suffers versus high-scale Indian manufacturers is attributable to scale (IFC, 2007). The AfCFTA could provide scale.

* Chemical Pharmaceutical Generic Association (2006), as referenced in Van Arnum (2007).

B. Challenges for APIs in developing countries

In general, the global API market is an efficient market based on commodities. However, two potential challenges may impede equality of access to quality APIs for small final formulators in developing countries.

1. Transparency

Small local final formulating firms procuring APIs on the global merchant market, usually from API-manufacturing firms located in either India or China, can find that navigating the market is challenging, especially when procuring non-WHO GMP or Stringent Regulatory Authority-approved APIs. Furthermore, historically, Chinese API manufacturers could not directly export but had to go through a State-owned trading company, and many Chinese API manufacturers still use such trading companies.

As a result, some firms may use a trader or merchant intermediary to source APIs.

2. Ensuring API manufacturers stay in the market

API manufacturers are finding their margins squeezed and are under tremendous pressure to produce more for less. If market prices move too low, API manufacturers may decide to leave the market. As a result, final formulators may not be able to find the low-cost, high-quality API they currently procure. Final formulators continuously push for lower API prices as they face incredible price competition themselves, to the point of sometimes focusing more on market share than on profitability (Kuhrt, 2006). At the same time, raw material prices and environmental costs are rising.

C. Other pharmaceutical excipients

A report published by Allied Market Research, “Pharmaceutical Excipients Market”, projects that the world pharmaceuticals excipients market would reach \$6.4 billion by 2020. Despite having small shares in the global market, the Middle East and Africa account for shares of roughly 5 per cent and South-East Asia for 4 per cent in the global pharmaceutical excipients market. A growing population, increasing government health-care expenditure, developing health insurance industry and the increase in the

prevalence of chronic disease, among others, are vital contributors to the pharmaceutical industry’s growth in these regions (Kline Team, 2015).

However, these markets are heavily dependent on imports for pharmaceutical raw materials with minimum-to-no domestic manufacturing. Even basic excipients, such as starch or colorants, are imported by manufacturers in Africa. There is thus a need for companies in Africa to be self-reliant on the basic excipients, which would also help save on costs.

V. Innovation, research and development

This chapter discusses issues related to R&D and examines the huge financial and human resources required for R&D.

A. Research and development

Because of the unique disease patterns on the African continent, cutting edge R&D should be an important focus area for the continent. Competencies in this field need to be built up significantly. Less than 1 per cent of all the thousands of new chemical entities developed in the last 30 years are for treating the neglected diseases that predominantly affect Africa (De Vré, Rial Verde and Santos da Silva, 2010). With regards to resourcing R&D, in 2002, the continent spent just 0.3 per cent of gross domestic product on R&D, versus the global average of 1.7 per cent, and had only 1.2 per cent of the world's researchers (UNESCO, 2004). The lack of R&D activity is also evidenced by the fact that the African countries responsible for the largest number of biomedical research publications – such as Egypt, Nigeria and South Africa – generate 15 to 150 times fewer research articles than leading developed countries (De Vré, Rial Verde and Santos da Silva, 2010).

In order to increase the productivity of R&D efforts, it is important to harness the synergies generated by networks of scientists with complementary skills and capabilities. These collaborative networks also benefit when expertise is transferred from one network member to another, which builds capabilities and increases a network's capacity. In academic environments, the availability of funds drives the creation and work of collaborative networks, so African scientists strongly tend to

collaborate not with one another, but with scientists in Europe and the United States, where research funding and technology are more readily accessible. Available evidence shows that only 10 per cent or less of the funding of R&D at many public health research centres in Africa is local; the rest comes mostly from the United States and Europe (Kalua and others, 2009).

What makes the situation above dire is that, as long as the bulk of R&D investment comes primarily from foreign sources, alignment between local R&D efforts and local priorities will remain difficult to achieve. This situation demands attention from African Governments, the African Union Commission and regional initiatives.

The solutions to these issues lie within Africa. The paramount objective should be to develop a self-sufficient, pan-African R&D system that can address not only today's problems, but also evolving public health issues. The key is to harness the untapped power of collaboration among African researchers by forming and supporting networks of research groups in Africa. This model would turn laboratories that complement each other technically and functionally into cohesive networks engaging in projects specifically aimed at developing new tools to address African diseases. Financial support for these networks would also develop the capabilities of local scientists and improve Africa's health R&D infrastructure. The success story of the Drug Discovery and Development Centre at the University of Cape Town – whose founder Professor Kelly Chibale, overseeing a team of over 60 staff members working on cutting edge pharmaceutical

research, announced in 2012 the discovery of MMV390048, a compound that can be used as a single-dose treatment for malaria, in collaboration with international researchers and the Medicines for Malaria Venture – serves as a good example.

Due to high logistics costs, foreign companies are discouraged from investing in the pharmaceutical manufacturing sector in Africa. A weak patent protection system and the lack of an affluent consumer market further discourage investment. Diseases that disproportionately affect Africa, therefore, remain under-researched. WHO estimates show that these diseases are accountable for 50 per cent of Africa's disease burden (IFC, 2007). These diseases reduce the continent's gross domestic product by as much as 20 per cent or US\$ 200 billion per year. Africa cannot rely on foreign interest to address these diseases; it needs drugs and R&D efforts owned by Africans.

The sustainability of the African pharmaceutical supply chain remains highly dependent on foreign funding and manufacturing. Current estimates are that imports account for over 70 per cent of the pharmaceutical market in Africa – 60.4 per cent from Europe, 11.7 per cent from India, and 9.54 per cent from China.¹⁶ Only 3.3 per cent of the pharmaceutical imports originated from within Africa.

B. Intellectual property rights and full use of TRIPS flexibilities

In the TRIPS agreement, efforts were made to introduce safeguards to ensure a balance between intellectual property rights and the right to the highest attainable standard of health. Least developed countries are exempt from implementing the TRIPS agreement for pharmaceutical products until 2033 (WTO, 2015). Flexibilities include the

ability of national Governments to determine when patents should be issued (including data exclusivity); the ability of governments to issue compulsory licenses; and the use of competition laws to address potential abuse of intellectual property rights.

These flexibilities were reinforced by the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which affirmed that “the Agreement can and should be interpreted in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all”. Yet many Governments in Africa do not fully utilize these flexibilities. In some cases, Governments may not see the need to use them because national treatment programmes are presently being sustained by health financing mechanisms, such as the Global Fund and the United States President's Emergency Plan for AIDS Relief. In other countries, where multilateral health financing is not available, political will or capacity constraints may impede their effective use. Intellectual property laws are complex; technical assistance tailored to specific country contexts and needs, while drawing on international experiences and good practices around improved coordination between different ministries, could strengthen the negotiating ability of countries to ensure national and public health objectives are achieved.

In the context of this study, all the six countries visited belong to the World Intellectual Property Organization and the World Trade Organization (WTO) and, consequently, observe international norms and standards with respect to TRIPS. The same can be said of most other countries in Africa. Protection of such rights is enshrined in national legislation and, in cases of infringement, legal action can ensue. Most African countries enjoy the early working provision that allows companies to research and develop a product before patent expiry. Thus, market entry in non-least developed country Africa

¹⁶ United Nations Conference on Trade and Development. Accessed Feb 2018. <http://unctadstat.unctad.org/wds/TableViewer/tableView.asp>

Reasons why African countries, at least those with production capacity, have not taken advantage of the TRIPS flexibilities

- (a) A lack of political will to enact the necessary amendments to intellectual property rights law;
- (b) A general lack of knowledge among the technocrats tasked with dealing with intellectual property rights and access to medicine issues; and
- (c) Capacity constraints – such as weak legal and regulatory frameworks, and weak supporting technical know-how and administrative capacity – which remove any incentive.

Recommendations for government action on TRIPS

- (a) Revise national intellectual property legislation in order to ensure that TRIPS flexibilities specifically geared to promote access to medicines are incorporated into national laws and regulations.
- (b) Take the necessary legislative action, where appropriate, to use the transitional period and not to grant pharmaceutical patents, as provided for in the Doha Declaration.
- (c) Encourage regional cooperation to develop intellectual property and trade policies that promote innovation, consistent with TRIPS.

can occur immediately upon patent expiry. However, despite these provisions and largely because of small markets and delays in medicine registrations, many international companies rarely register patents in African jurisdictions or launch generic equivalents already developed ahead of patent expirations.

In addition to the above, article 31 of the TRIPS agreements grants Governments the right to license third parties to use patents without the consent of the rights holder, if it is in the public interest; in cases of national emergency; if there is failure by the rights holder to exploit the patent or there is insufficient working; and, lastly, as a remedy to anti-competitive practices. This provision is mainly for the supply of the local market, but it does not preclude use for exports to least developed countries without any manufacturing capacity. African manufactures in countries such as South Africa could thus manufacture products under article 31 and export

to Malawi, Zambia, Cameroon or the Democratic Republic of the Congo. Similarly, Kenya could manufacture products under article 31 and export to Uganda, the United Republic of Tanzania, or the Democratic Republic of the Congo.

Many least developed countries have not incorporated these flexibilities into their national legislation and, therefore, have not exploited them.

Since the extension of TRIPS flexibility from 2016 to 2033, Africa has some leeway to fully utilize these. As global priorities change and profitability in the production of infectious disease medicines, such as for HIV/AIDS, continue to drop, Africa might well depend on its ability to fully utilize the flexibilities to produce its own medicines. This would become a commodity security issue, which may require intervention at the African Union level.

VI. Finance

This chapter analyses issues relating to access to credit/resource mobilization for the private sector involvement in manufacturing and distribution of pharmaceutical products. Issues of subsidies and how they may impede/support the sector are considered as well.

According to PMPA, a stronger and more reliable local pharmaceutical industry will contribute to economic development, job creation and development of human resources and of related industries. Medicines treat diseases, save lives, promote health, and they are a core component of the universal right to health. The pharmaceutical sector has a special role to play, especially when its products are safe and efficacious, in providing effective health care for all. Many African countries, therefore, see the need to enhance the capabilities of this industry locally; hence, the pharmaceutical industry is identified as a priority sector in AIDA for Africa.¹⁷

Local production has many benefits; it could be a source of quality assured medicines and supplant substandard and counterfeit medicines that presently enter the African supply chains and are hard to control for many resource-strapped regulators. Local production can help prevent discontinuities of medicines supplies (stockouts) that can be regularly observed in many African countries, especially in cases of outbreaks. It also promotes local value addition, creates jobs and generates income. Moreover, given that it is a knowledge-intensive industry, it will lead to technology spillovers. The

production of medicines locally or regionally can service the expanding markets that are brought about by growing populations and the advancement of non-communicable diseases in many African countries. Finally, local production can be a step towards the sustainability of treatment programmes and prepare the grounds for maintaining access to medicines beyond the current era of drug donations.

A sustainable and expanding pharmaceutical industry in Africa must reach essential quality standards and constantly upgrade, moving up the technology ladder while improving cost efficiency. This requires a cocktail of incentives in which finance is key (Chataway and others, 2015). These incentives, in turn, rely on the building up of appropriate financial capabilities within firms and financial institutions, as well as within Governments. This chapter considers the factors that determine financial sustainability, sources of health-care funding and strategies to achieve financial sustainability of the pharmaceutical industry.

A. Essential building blocks for pharmaceutical financing

It is well established that finance influences industry genesis, modernization and development, and that there is a close link between a country's financial system and economic growth (King and Levine, 1993). Research has indicated that it is not just access to finance that is problematic, but a financial capability deficit in the African pharmaceutical

¹⁷ African Union. AIDA – Accelerated Industrial Development for Africa. Available at <https://au.int/en/ti/aida/about>. Accessed on 9 December 2019.

industries and mainstream financial institutions that exacerbates the challenge. There are also complexities and technological capabilities as well as expertise and knowledge surrounding financing of African local pharmaceutical manufacturing.

Pharmaceutical companies require finance capability to access financial resources for capital investment and working capital needs. Financial institutions/funders, on the other hand, require sector-specific expertise and knowledge to analyse and manage risk, as well as approve disbursements, monitor, and control loans disbursed to pharmaceutical firms. Additional challenges emanate from incoherent direct and indirect financing mechanisms and policies by Governments, financial institutions, and local and international procurement agents. At industry level, pharmaceutical firms may lack essential capabilities in raising and managing finance effectively, as well as leveraging the short-term funding capabilities of trade credit to reduce the cost of working capital finance (Banda, 2013).

Essentially, pharmaceutical financing must be viewed in the overall context of health financing, where funding for health services comes from public sources (national and local governments and national social health insurance), private sources and external development aid. The cost of investment capital for African pharmaceutical investors remains a barrier for many companies in countries where interest rates on bank loans may exceed 25 per cent (West and Banda, 2016). Manufacturers need access to capital to invest in making production facilities GMP-compliant and improving drug quality standards. Most new medicines continue to be made in developed countries, such as the United States, Switzerland, France, the United Kingdom, Japan and Germany. Medical R&D as well as intellectual property frameworks in those countries enable the private sector to control both downstream drug development and marketing.

While success stories of local industry players exist in Morocco, South Africa, Cameroon, Ghana and Zimbabwe, most African countries have struggled to compete for two reasons. Firstly, the high costs of APIs in Africa have left most of the companies unable to compete on price with Asian generic manufacturers, and unable to access the most in-demand therapy areas. Secondly, domestic manufacturers have struggled to implement good manufacturing practices and ensure quality production. As a result, few companies have WHO pre-qualified products. For this reason, NGOs, which have historically been prime procurers of medicines on the continent, have refused to buy essential medicines (such as anti-infectives) from domestic manufacturers.

However, a solid and stable political system is the number one requirement for attracting investment to a country for any industry. In addition, pharmaceutical financiers look for key elements within an industry that will qualify the business for funding. Consequently, factors including the sector's capacity to compete with cheap imports from India and China, the regulator's success in enforcing uniform quality standards across all supply sources, regulatory efficiency in areas such as product registration, and government measures to support local manufacturers are all important considerations, when evaluating an investment opportunity in the pharmaceutical sector.

1. The role of government in financing the pharmaceutical sector

Most pharmaceutical companies in Africa are limited in their ability to upgrade their facilities because of lack of access to financing. Capital needed by pharmaceutical manufacturers in Africa runs into millions of dollars, and mostly requires long-term financing. Local manufacturing companies may be deterred by the cost required to reach and operate at an international quality standard, such as the standard required for WHO pre-qualification. A tailored package of incentives by African Governments will encourage local pharmaceutical

Examples of government initiatives to support the pharmaceutical industry

In 2014, Ghana announced that, from the Export Development and Agriculture Investment Fund, 50 million cedis would be set aside for soft loans to the pharmaceutical sector (approximately \$20 million given currency depreciation at time of disbursement). The Government of Nigeria also proposed a 200 billion naira (roughly \$100 million) fund to support the sector, but this has not yet materialized. Given how few such examples there are, it implies that direct capital provision for many nations may not be viable or of a sufficient magnitude and impact to enable the transformation of the industry. Creating a fund of sufficient magnitude to tackle the capital funding gap for a number of firms in different geographic contexts will vary, depending on different Governments' financial endowments. Public funding for the pharmaceutical sector demands development of financial capabilities in the public sector, unless the funds disbursements are managed by financial institutions.

companies to survive fierce competition from the globalized pharmaceutical sector. Examples of such incentives include preferred local public procurement, grants, soft loans, subsidies and non-fiscal facilitations, in order to improve the financing of health services. Development of cohesive policy frameworks, strengthening national regulatory authorities, support for capacity-building, creation of an investment-friendly environment and infrastructure development facilitate joint ventures and encourage international cooperation (Anyakora and others, 2017). The level and duration of incentives have to be decided according to the situation in different countries.

2. Direct government expenditure to reduce the cost of financing

Governments can also facilitate access to affordable investment capital through subsidizing interest payments. Interest subsidies were made available to Indian pharmaceutical manufacturers to support their development. Using public resources to support the servicing of debt rather than providing the capital itself can be a more efficient use of public resources. However, limitations on the political acceptability of direct transfer of public

funds to the private sector, given other pressing demands on public expenditure, may make such a model untenable for many African countries. At the least, mechanisms are essential to control waste of resources and limit government financial liabilities. Creating institutions/mechanisms that underwrite and guarantee credit access by pharmaceutical firms, such as export credit guarantee agencies, is another way that can reduce cost of funding.

3. Local and international procurement agencies: Innovative procurement

In the economic development literature, and in the debates on public policies, such as defence procurement, there is a long-standing recognition that public procurement can operate as industrial policy. "Buy local" campaigns and local preferences often form part of industrialization policies. Public procurement creates and enhances markets for new and existing technologies by shaping the demand environment. It can promote sustainable consumption and production patterns. Public drug procurement can be done in at least three ways – advance payment, cash on delivery or credit terms – and each affects a manufacturers' cash flow, cost of finance and cost of production. The payment model can be a source of finance for the firm or can cause a producer to seek external expensive finance. Onerous credit terms and conditions of delivery demanded of local manufacturers can constrain firms to resort to expensive short-term bank financing, generating recurrent cash flow problems.

4. National technological capabilities: Infrastructure, institutions and incentives

Creating a conducive setting for pharmaceutical manufacturing involves the combination of multiple interventions which tackle dimensions that impact the overall business environment. Indirect funding, which benefits all industrial sectors, falls into three categories using Lall's national level technological capabilities: infrastructure, institutions and incentives (Lall, 1992). Thus, investment in electricity, transport and energy infrastructure not

only benefits the pharmaceutical industry, but the whole economy, making the ease of doing business more attractive. Investing in building and sustaining strong institutions, especially medical regulatory agencies and contract research organizations for bioequivalence testing that feed into and support local medicines production, is critical. Under incentives, levelling the playing field between imports and local manufactures can be achieved through value added tax and duty structures, in addition to industrial and financial policies that leverage corporate tax rates and special economic zones. For example, the PMPA Business Plan, and regional plans and national strategies, call for time-limited incentives.

B. The role of local and international financial institutions

Da Rin and Hellman (2002) presented a theory of financial institutions (banks) as catalysts for industrialization arguing that banks promoted the creation of new industries. The caveat was based on the notion that the banks needed to be of a sufficiently large size and enjoy enough market power to mobilize resources and make profits from coordination processes. Evidence has shown that the current financial system architecture on the continent, through historical linkages, is geared to finance commerce and trade, and not industrial development. Financing local pharmaceutical manufacturing requires affordable, foreign currency, long-term loans to import capital equipment, and long-term mortgage facilities for putting up greenfield and brownfield structures.

For working capital requirements, the domain of commercial banks in the pharmaceutical sectors is challenged by high interest rates and general credit rationing. Unless there is purposive coordination of funding mechanisms, industrial development of the sector will take a long time to gather momentum.

1. The need for offshore or foreign currency loans

Using structured export finance for import of capital equipment has been successfully used in mobile telephony when the technology was adopted in Africa in the 1990s. Firms tended to bootstrap, and use retained earnings over several annual operating cycles to buy equipment. This is inefficient and delays accumulation of critical mass for scaling up of production. The challenge is in demonstrating the business case and sustainable demand for production by the local health sector. From publicly available data, the most active financial institutions in availing medium-term finance, specifically to the pharmaceutical sector, is the Trade and Development Bank (TDB) – formerly PTA Bank – in Kenya, as illustrated by the examples in table 3.

International banks with subsidiaries in African countries are at an advantage in structuring export finance deals. Local financial institutions need to build correspondent bank relationships and put in place foreign lines of credit that can be advanced to local firms. The greatest challenge, though, lies in foreign currency risk – if borrowing is in foreign currency, when sales are in local currency. This is where African trade banks, such as Afreximbank, have played a major role in covering foreign currency and country risk. Greenfield and brownfield projects are the initiatives that fall in this category (see table 4).

2. Accessing affordable working capital finance

The cost of bank funding for working capital requirement is very high. For example, in Zimbabwe, in 2011, interest rate charges ranged from 16 to 30 per cent per annum. In addition, banks short-dated lending facilities to increase non-funded revenue streams. In the countries visited, access to affordable investment capital was reported by all those interviewed as a key challenge that limits investment in the pharmaceutical industry. Loans were accessible in all cases, but at very high interest rates. For traditional financing, interest rates were

Table 3 Example of some foreign currency loans made available to pharmaceutical firms by the Trade and Development Bank

Term loans to African pharmaceutical enterprises from Trade and Development Bank (TDB)			
Year	Recipient	Loan amount: Millions of United States dollars	Loan purpose
2005	Kisakye Industries Limited: Uganda	1.67	Procurement and installation of new machinery and equipment, furniture and fittings to manufacture pharmaceutical products in capsule, tablet and liquid form.
2005	Palm Healthcare International Limited: Kenya	1.8	Finance procurement of machinery and equipment for the establishment of a condoms manufacturing plant in Nairobi.
2006	Maria Assumpta Pharmaceuticals Limited: Uganda	2.385	Part finance procurement of machinery, equipment, furniture and fittings for clinical absorbent cotton wool manufacturing plant in Kampala.
2006	Abacaus Parenteral Drugs Limited: Uganda	8.53	Part finance establishment of an ultra-modern blow-fill seal plant to manufacture intravenous fluids and vials for water injections.
2008	SADM Pharmaceuticals Limited: Malawi	2.2125	Importation and installation of new equipment and machinery to complete the rehabilitation and expansion of a pharmaceutical manufacturing factory in Lilongwe.
2012	Varichem Pharmaceuticals Zimbabwe	10	Expansion of existing plant and improvement in production processes.

Sources: Banda, 2016; African Union Finance Minister's Conference on Unlocking the Potential of the Pharmaceutical Manufacturing Sector in Africa's Socioeconomic Transformation: Facilitating Access to Affordable Investment Capital; Innogen Institute, Science Technology and Innovation Studies, University of Edinburgh, United Kingdom, available at www.innogen.ac.uk/briefings/1150, accessed on 10 December 2019.

reported at 23 per cent for Ghana, 15 per cent for Kenya, 10–22 per cent for Cameroon, 4.2 per cent for Morocco, and 13 per cent for South Africa, while for Nigeria the rates averaged between 23 and 31 per cent. For most countries in Africa, with the exception of North Africa, interest rates have averaged between 15 and 30 per cent over the last two decades. Ethiopia has innovatively solved this challenge by

advance payment of 30 per cent of tender value to the pharmaceutical firms and access of the balance from financial institutions at concessionary lending rates (Gebre-Mariam, Tahir and Gebre-Amanuel, 2015). Depending on contexts, these innovations can be pursued to reduce production costs and enhance price competitiveness of locally produced medicines

Table 4 What is funded, types of funding and possible funders

Project type	Activity	Type of funding	Financial players/funders
1. Greenfield projects	Plant, equipment and machinery acquisition	Long-term funding ("Patient Capital" – bonds, equity, debt, hybrid instruments)	Development banks (e.g. AfDB, DBSA, IFC, TDB Bank), enterprise development funds (especially small and medium-sized enterprise funding schemes), Governments, sovereign wealth funds, insurance firms, venture capital
2. Expansion projects)	(a) Product range development (including R&D and translational activities)	Medium-term funding (bonds, equity, debt, hybrid instruments)	Development banks (e.g. AfDB, DBSA, IFC, TDB Bank), enterprise development funds (especially small and medium-sized enterprise funding schemes), Governments, sovereign wealth funds, insurance firms, venture capital
	(b) Production facility upgrading		
	(c) Local, regional or WHO GMP qualifications		
	(d) Upgrading standards		
	(e) New market entry		
3. Day-to-day operations	Short-term working capital	Short- to medium-term funding (overdrafts, short-term loans), trade finance products (including but not limited to: letters of credit, guarantees, bid-performance and maintenance bonds)	Commercial banks, continental and regional trade banks (e.g. Afreximbank and TDB Bank), innovative procurement by public health systems (supporting industrial development), trade credit
		Trade credit	Suppliers
		Advance payments	Innovative procurement by health systems
		Core working capital	Long-term funding

Sources: Banda, 2016; African Union Finance Minister's Conference on Unlocking the Potential of the Pharmaceutical Manufacturing Sector in Africa's Socioeconomic Transformation: Facilitating Access to Affordable Investment Capital; Innogen Institute, Science Technology and Innovation Studies, University of Edinburgh, United Kingdom, available at www.innogen.ac.uk/briefings/1150, accesson 10 December 2019.

3. Trade finance

In a supply chain structured-credit approach, firms can use the strength of the procurement agency's high credit rating to access finance. Use of confirmed orders leveraging the buyers' creditworthiness to access debt from financial institutions has not been extensively exploited, and neither has invoice discounting or factoring. As illustrated in table 4, trade finance products can be used to reduce dependence on expensive overdrafts and also encourage cost-effective importing of APIs and excipients, in addition to the exporting of finished products.

C. Establishment of a dedicated fund for local and regional financing

To ensure that resources are available for the implementation of PMPA, a proposal was made for the establishment of the Fund for African

Pharmaceutical Development (FAP-D) (African Union, 2017). This was with the objective of addressing the critical issue of access to capital. It was envisaged that FAP-D would provide affordable financing for activities geared toward attainment of GMP, capacity-building and enabling the growth of the African pharmaceutical sector. The fund would also provide for technical advisory services; oversee the efficient use of financing; and support partnerships and collaborations to enable private sector engagement in the development of herbal and traditional medicines, thereby seeking solutions through African innovation.

D. Role of pharmaceutical manufacturing firms

1. Building finance capability

Where firms secure financing, how they get finance and structure financial instruments and/or products drives the cost of finance and requires adequate

attention. Finance capability is defined as the capacity and capability of the firm to use knowledge, learning by doing and linkages to garner financial resources – internally or externally – by acquiring appropriately structured and priced debt or equity finance, and using their investment capabilities to apply the funds. This is followed by competent management of a series of asset conversion cycles, and repayment of the acquired debt. Consequently, at a pharmaceutical firm, finance capability is driven by the depth and breadth of skills of its finance department, especially treasury management, coupled with banking product knowledge.

For financial institutions, financial capability is the use of knowledge to build sector-specific skills and capabilities through learning by doing and leveraging internal and external linkages to competently analyse risks, structure appropriately priced financial products, disburse funds, and monitor and control the business activities of the borrower to ensure timely repayment of debt (their investment in the borrower). These skills and capabilities are critical for adequately understanding and assessing risks associated with local pharmaceutical manufacturing. Failure in applying these skills and capabilities will inevitably negatively influence risk analysis, risk management and the cost of finance.

2. Trade credit: Reduce cost of working capital finance

Firms can use input suppliers as sources of cheap, in-kind financing (trade credit) to reduce their call on their own funds or expensive short-term bank finance. Firms' private sector procurement mechanisms can manage working capital financing requirements and cash flows. By negotiating for generous trade credit terms, firms can fund varying proportions of raw material procurement, production and logistics processes using their suppliers. If they can also collect in advance or induce early payment by debtors, they can be a source of funds. Astute use of trade credit makes the procurement process a generator of in-kind finance. Failure to use innovative procurement

through trade credit or early debtor collection results in cash haemorrhages and higher production costs (Chataway and others, 2015).

E. How government can support access to capital

Government support is important for efforts to attract foreign direct investment and technology transfer into the domestic pharmaceutical sector. However, institutional responsibility for supporting the local production of pharmaceuticals is likely to be spread over several different agencies and ministries in a given country. Where economic issues are concerned, the ministries and agencies responsible for trade, industry and investment all have roles to play to the extent that the local pharmaceutical sector has been identified by the country as an important sector for the country's development. The investment promotion agency may be responsible for setting and administering incentives for the pharmaceutical industry; it may act as a processing window for necessary permits for investors. Customs and trade ministries set and administer policies with respect to export and import tariffs. Tax concessions are likely to be administered by the national revenue authority. Because the institutional framework is likely to be fragmented, any effort to attract foreign direct investment and technology transfer into building a local pharmaceutical sector will require close communication between these ministries and agencies, as well as internal coherence within each of these ministries and agencies.

Governments have various options for creating a policy environment that encourages foreign direct investment into local production. For instance, they can induce investment through incentives that lower the cost or risk for the investor, or both. The most important incentives are discussed in the following sections.

1. Duty-free or reduced tariffs on imported raw materials and capital goods

Most African countries must import active pharmaceutical ingredients. Firms in Africa often obtain their final or intermediate active pharmaceutical ingredients from China and/or India. The ability to import active pharmaceutical ingredients duty-free helps to keep costs down, thereby helping firms operate profitably. The same could potentially be said about imports of capital goods, such as the precision machinery used in formulation.

2. Free or inexpensive land

The physical requirements for a pharmaceutical factory include immovable assets such as land and a building complex, complete with appropriate storage facilities. As a strategic industry, countries have often been prepared to offer free land or reduced rent for pharmaceutical sector investments. These also help to reduce costs. Factories are a complicated issue, as pharmaceutical factory facilities must meet very stringent specifications, including those for storage and hygiene. An offer to provide an existing, unused factory may not be an attractive incentive for investors in the pharmaceutical industry.

3. Tax holidays

A typical incentive offered, for sectors where investment is being targeted, is a tax holiday. Tax holidays exempt or reduce a firm from paying corporate income tax for a specified period of time. For most developing countries, including in Africa, tax holidays are relatively simple to administer compared with other tax incentives.

4. Joint shareholding

Investment in a pharmaceutical production facility in a developing country is often seen as a high-risk investment. In some cases, the Government is prepared to share the risk of the investment by becoming a joint shareholder in a proposed investment to establish a local pharmaceutical factory. Such an action is designed to provide

Government incentives for pharmaceuticals – Ethiopia

In Ethiopia, the Government has now included the pharmaceutical manufacturing sector as a priority sector for industrial development and investment.* This categorization will make it easier for local firms in the sector to receive priority treatment for access to credit, tax holidays, upgrades of infrastructure and availability of technical support and technology transfer.

* In 2007, the United Nations Conference on Trade and Development provided advisory services to Ethiopia on the use of TRIPS flexibilities for local pharmaceutical production; and in 2008, it assisted the authorities of the Oromiya region in better exploiting efforts to attract investment into pharmaceutical firms in the region.

assurances that the Government is fully committed to the project and will not be allowed to fail easily after the investment has been made. In other cases, international organizations, such as the International Finance Corporation of the World Bank Group, have often co-financed investments in pharmaceutical firms in developing countries, sending a similar message to possible private sector investors.

5. Purchasing commitments

In many African countries, Governments have sometimes given preference to local firms by allowing greater price tolerance in procurement, or, in other cases, have even committed to purchase the output of an invested local firm.

Sometimes there are off-take agreements as part of a public–private partnership policy framework to support a loan payment plan by the Ministry of Finance; this must be initiated from the Ministry of Health, since they are the direct beneficiaries. However, this has never been used by the Ministry of Health because it is either unaware of it or unhappy with it.

6. Special economic or industrial zones

Making high-quality medicines requires the appropriate infrastructure. While reducing the cost of that infrastructure is one issue, providing

an appropriate location with guaranteed access to uninterrupted power and clean water is a business risk. Some countries have offered prime areas in their special economic zones or industrial zones

to pharmaceutical investors, as these zones often have their own infrastructure facilities that better guarantee consistent power and water quality.

VII. Skills development

This chapter will examine education needs for the pharmaceutical sector in Africa, in particular, curriculum development and training.

A. Skills and capacity of staff working in the pharmaceutical sector

The world is currently facing a global shortage of health-care workers (Campbell and others, 2014), especially pharmacists. Shortages of pharmacists have been reported in all sectors on a global scale (Gall, Bates and Bruno, 2012), and Africa is the continent most severely affected by these shortages (Bates and others, 2016). Africa has the smallest proportion of pharmacists working in the pharmaceutical industry, a majority of whom work in the community pharmacy setting. South Africa has 13,000 pharmacists, with the greatest number of these (43 per cent) in communities, 35 per cent in hospital settings, and only 6 per cent in the pharmaceutical industry (Gray, 2016). An assessment of pharmaceutical human resources in Ghana in 2009 highlighted significant shortages in pharmaceutical

human resources, as well as inequitable distribution, skill mix imbalance and limited capacity training.¹⁸

Even though the shortage of pharmacy personnel does not affect the manufacturing industry, the pharmaceutical manufacturing system requires specialized skills in a number of other disciplines, including chemistry (analytical, organic, synthetic, medicinal), the biological sciences (biochemistry, microbiology, molecular biology), engineering (mechanical, electrical, chemical, industrial, process), the life sciences (medicine, pharmacology, toxicology), management (strategy, financial and management accounting, operations, logistics, commercial law, etc.), and information and communications technology. In Ghana, Kenya, Morocco and South Africa, most employees in the pharmaceutical manufacturing industry are university graduates with science, engineering or pharmacy degrees. It can be assumed that the same is true for the rest of Africa. In Cameroon – as identified at the end of the General Census of Health Workforce in 2011¹⁹ and presented in the Human Resources Development Plan in 2011 – the

Table 5 Pharmacists in a selection of countries

Country	Population in thousands	Number of pharmacists per country	Number of pharmacists per 10 000
Study countries			
Cameroon	23 636	1 050	0.44
Kenya	41 610	2 206	0.53
Ghana	24 966	2 971	1.19
Morocco	31 951	9 266	2.90
South Africa	49 321	13 427	2.40

18 Assessment of Ghana Pharmaceutical Human Resources 2009 (unpublished).

19 This is the latest census of health workforce to date in Cameroon.

Table 6 Pharmacists in a selection of countries

Country	Population in thousands	Number of pharmacists per country	Number of pharmacists per 10 000
Other selected African countries			
Algeria	34 262	7 417	2.16
Angola	24 024	510	0.07
Egypt	82 637	149 987	18.15
Ethiopia	87 118	1 917	0.22
Mozambique	20 531	111	0.05
Mali	15 394	1062	0.69
Nigeria	162 265	15 416	0.95
Côte d'Ivoire	19 261	413	0.21
Senegal	12 230	107	0.09
Sudan, the	39 445	5 878	1.49
Uganda	34 543	553	0.16
United Republic of Tanzania	46 218	1 264	0.20
Zimbabwe	12 084	550	0.56
Selected European countries and the United States of America			
Greece	11 020	9 837	8.93
Spain	46 742	64 225	13.74
United Kingdom	62 736	50 691	8.08
United States of America	311 695	274 915	8.82

Sources: FIP, 2015; SADC, 2015; Global Health Observatory, available at <https://knoema.com/WHOGHO2016/global-health-observatory>, accessed 11 December 2019.

number of personnel was estimated at 38,207, with 25,183 in the public subsector (66 per cent) and 13,024 (34 per cent) in the private subsector. Based on data obtained from the third general census of population,²⁰ the staff/population ratio was 1.07 (medical doctor, midwife, nurse) per 1,000 habitants. This ratio is below the WHO standard, which stands at 2.3 per 1,000 inhabitants.

Although these degrees provide a sound scientific background to most of the key tasks performed day-to-day by employees, further on-the-job training is required. Stakeholders reported that it takes up to three years to convert an employee into a highly skilled pharmaceutical operator (African Union Commission–UNIDO, 2012b). In this regard, the African pharmaceutical industry faces challenges, with a lack of adequately skilled employees, due to limited opportunities to turn college graduates

into a skilled workforce. The resources and expertise needed to enhance these skills are insufficient, and there is limited know-how required to implement good manufacturing practices. Global institutions that offer bridging courses to address these gaps exist, but are expensive.

Initiatives to address the paucity of skills in this industry

WHO has an essential medicines group, which is responsible for organizing ongoing training activities aimed at supporting the pharmaceutical industry (WHO, 2016b). This group also provides technical assistance in capacity-building activities undertaken by national regulators. There has also been some involvement by the United States Pharmacopeia (USP) Convention in setting up training modules that can be used for production on the continent. In addition to the initiatives above, with financial

²⁰ This is the latest data available, as the fourth general census of the population is still awaited.

support of the Government of Germany, UNIDO has been running a project that aims at strengthening the local production of essential medicines in developing countries.²¹ Even though the project is not Africa-specific, Africa is a focus area. The project facilitates public–private dialogue and provides evidence-based inputs towards the joint formulation and implementation of national pharmaceutical sector development strategies. The project engages across various institutions to assist pharmaceutical manufacturers. Services range from specialized training programmes in industrial pharmacy to business membership organizations conducting advocacy activities on behalf of member companies. The project also provides support to medicines regulatory authorities and quality control laboratories. At the enterprise level, the project offers support to companies in assessing feasibility and economic viability of the production of quality medicines. In addition, a number of actionable tools and solutions have been designed that can be adjusted to various settings and scales of deployment, in order to support manufacturers in their upgrading and expansion efforts.

In addition to the above, collaborative approaches have been piloted as a means of enhancing human resource capacity on the African continent. A notable example of this is the Saint Luke Foundation in the United Republic of Tanzania, which has collaborated with Howard University and Purdue University in the United States of America, to establish a model for the training of pharmaceutical industry workers and regulators. Training is done at the foundation’s training centre in Moshi, the United Republic of Tanzania. Apart from this, various African universities and research institutes offer training to science undergraduates and NGOs, but these are usually shorter in duration. Industry-specific training programmes that target specific skills required to run the pharmaceutical industry are necessary. The

African Union and other regulators could identify and encourage universities to provide such training. In South Africa, technical universities, such as Tshwane University of Technology, provide some courses focusing on the pharmaceutical industry, but most of these are generic.

B. Transfer of technology and partner support

The development of a viable pharmaceutical industry requires investments and availability of the appropriate technology. Accessing such technology may require companies on the continent to partner with renowned companies in the developed world. Already, a few international companies are involved in joint ventures with local manufacturers on the continent, and some of these have involved the transfer of technology and the licensing of products to African manufacturers. One example is Cipla, a leading global generics company, which has an arrangement with Quality Chemicals of Uganda designed to create the leading pharmaceutical company in that country. Other examples include Ranbaxy of India, which is working with Community Investment Holdings of South Africa to manufacture and sell a number of ARVs. In Ethiopia, Zydus Cadila is working in collaboration with Almeta Impex, a local entity, to produce a number of formulations for the local market.

In Cameroon, Cipla had an arrangement with the Cameroonian Company Cady-Invest to establish a leading pharmaceutical company in Cameroon called CINPHARM. Today, CINPHARM employs 300 people, including 20 pharmacists. The African Union and national Governments need to encourage such partnerships and, where possible, offer incentives to ensure that such investments are a win–win situation for both the investors and the recipient countries. Another example is Africure Pharmaceuticals,

21 www.unido.org/sites/default/files/2016-01/Local_Pharmaceutical_Production_web_0.pdf. Accessed 25 March 2020 2018. www.unido.org/pharmaceuticals.html.

another Indian pharmaceutical company which signed an agreement with Cameroonian investors and pharmacists designated to create a local factory to produce generic drugs. Africure Pharmaceuticals Cameroon contributes in the transfer of technology, as 100 Cameroonians have been trained so far.

Even though support has been registered in the production of pharmaceuticals directly, international partners have been playing a significant role in supporting adjunct activities. This includes technical assistance in the areas of regulatory capacity strengthening, regulatory harmonization, skills development and technology transfer. However, if Africa is to make rapid progress

towards industrialization, partner support in key areas of technological transfer, financing and capacity development need to be accelerated; but more importantly, the model used needs to lead to sustainable transfer. More often, we have seen technical assistance models where continuous training and secondment of technical assistance agents become permanently embedded. Such models create a reliance on the technical assistance and have rarely produced results. There is need for the African Union and national Government to sit with technical assistance providers and design the best strategies to make capacity-building services effective and sustainable.

VIII. Conclusion and policy recommendations

The local manufacturing industry on the African continent is plagued with many challenges. Some of these include lack of policy coherence, inaccessible markets, lack of incentives, inadequate human resource capacity, and lack of access to finance. Addressing these challenges requires systemic approaches. Such approaches require the involvement of Governments, regional economic communities, and continental and international organizations.

Regarding policies, there is a need for African countries to systematically apply policy regulations that level the playing field. For example, strategic fiscal and trade policies could be employed so that finished pharmaceutical products and APIs have a level playing field, or tilt the balance in favour of the latter. This would enable local manufacturers to compete with their international counterparts. In addition to the enactment of policies, policy development should always be accompanied by the necessary capacity developing and resource mobilization to realize the benefits of political will. Continental and regional policies rely on member States and other stakeholders for implementation. Political will should, therefore, be accompanied by the development of the necessary capacity to implement policies and ensure that they are aligned to regional and national level policies.

To ensure guaranteed markets, national and regional procurement laws should consider allocating percentage points for local producers, if the quality of the products is deemed to be of the required standards. Apart from allocating percentage points for locally produced products, the African Union,

through AMA and other relevant institutions, should be encouraged to set up its own pre-qualification process. Such a process would still rely on technical support from WHO and other agencies, but the African Union would lead the process.

On the issue of R&D, the African Union should consider the development of a self-sufficient, pan-African R&D system that addresses evolving public health issues. The key to this is to harness the untapped power of collaboration among African researchers by forming and supporting networks of research groups in Africa. Financial support for these networks is necessary to develop the capabilities of local scientists and improve Africa's health R&D infrastructure. In addition to this, the African Union and RECs should invest more in supporting the development of regional centres of excellence, focusing on the pharmaceutical industry. To make the recognition of these institutions as centres of excellence meaningful, African Governments need to be encouraged to invest in these institutions so that they become world class facilities advancing health innovation.

To stimulate better research, one possible option is to create a competitive research fund with grants awarded to successful bidders across the continent. A forum to encourage interactions between researchers and industry should also be supported. By having a clear focus on issues of interest to the industry, the private sector is more likely to contribute to sustaining the platform.

Regarding incentives, Governments should induce investment through incentives that lower the cost or

risk for the investor, or both. Use of trade policies in a strategic way is another approach that Governments could support the importation of raw materials and capital goods. For instance, the ability to import active pharmaceutical ingredients duty-free, in an economy where the business and investment climate is right, helps keep costs down and thereby helps firms operate profitably.

Application of state-of-the-art fiscal instruments is another form of incentive from which investors could benefit. Well-designed tax holidays exempt or reduce a firm from paying corporate income tax for a specified period of time. Tax holidays are relatively simple to administer compared with other tax incentives. Apart from tax holidays, joint sharing is another incentive that could be encouraged. This is a system where Governments should be encouraged to share the risk of the investment by becoming a joint shareholder in a proposed investment to establish a local pharmaceutical factory. Such an action is designed to provide assurances that the

Government is fully committed to the project and that it will not be allowed to fail easily after the investment has been made.

For long-term finance development, financial institutions, in conjunction with commercial banks, can play a role in providing short- and long-term funding. Pharmaceutical firms need to develop finance capabilities to be able to choose the right type of finance for investment purposes. To enhance the implementation of PMPA, a proposal was made for the establishment of the Fund for African Pharmaceutical Development (FAP-D). The African Union should speed up the operationalization of FAP-D to ensure availability of resources, at least as a start-up fund. Also, Governments should be encouraged to work with international funding entities – such as the Investment Fund for Health in Africa, the IFC's Health for Africa Fund, Afreximbank and the African Development Bank – to mobilize enthusiasm for the sector and to encourage investments in the pharmaceutical sector.

Annex: Questionnaire

Information about the respondent

Name: _____

Functional title: _____

Organization: _____

Telephone: _____

Email: _____

Country where your organization is based: _____

Overview of the pharmaceutical industry

1. How many companies in your country are registered to **manufacture** pharmaceuticals and related commodities? _____
_ If a list of the companies is available, please provide a copy.
2. How many companies in your country are registered to **import** pharmaceuticals and related commodities? _____
_ If a list of the companies is available, please provide a copy.
3. What is the value, annually, of public sector procurement of pharmaceuticals and related products? _____ US\$
4. What percentage of these procurements was sourced locally (in-country)? _____ %
5. What percentage of the procurements was sourced within Africa? _____ %
6. What percentage of the procurements was sourced outside Africa? _____ %

7. List the **five** main countries of origin for pharmaceuticals and related commodities.*

Rank	Country	Value
1		US\$
2		US\$
3		US\$
4		US\$
5		US\$

*The information above should be available from the Central Medical Stores or from the Ministry of Trade and Commerce.

8. What percentage of gross domestic product is contributed by the pharmaceutical industry in your country? _____

9. Does a National Medicines Policy document exist? Yes
 No
 _ If yes, what is the latest year of update? _____
 _ If yes, please provide an electronic copy. _____

10. Does your country have a pharmaceutical strategy? Yes
 No
 _ If yes, please provide a copy. _____
 _ If yes, what is the publication date of your country's last pharmaceutical strategy? _____
 _ If no, has the Government approached technical assistance / multinationals to assist with developing a strategy? _____

Enabling environment

- | | | | |
|-----|---|-----------|--|
| 11. | Does the Government have a policy paper with the objective to support the pharmaceutical sector through the procurement process? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| | _ If yes, please request a copy. | | |
| 12. | Is your country familiar with the opportunities for industrialization, trade and investment offered by the pharmaceutical industry? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| 13. | Is there an existing domestic preference scheme? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| | _ If yes, how high is it? How much more expensive can it be to procure locally (in percentage)? | | |
| 14. | Does the country have start-up manufacturing protection? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| 15. | Are there tax incentives for manufacturers? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| 16. | Are duty-free importation taxes different between API or Fixed Dose Formulation? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| 17. | Are there other incentives for the pharmaceutical industry? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |
| | _ If yes, list the incentives: | | |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 18. | Does the Government use TRIPS flexibilities to promote access to medicines manufacturing? | Yes
No | <input type="checkbox"/>
<input type="checkbox"/> |

19. Does your country have a national essential medicines list (EML)? Yes
No
 _ If yes, from which year is the latest EML? _____

Human resource skills

20. Are there enough relevant skilled resources available to run at least one GMP-compliant manufacturing plant for medicines and/or commodities production in your country? Yes
No
 _ If yes, where are these people trained? _____

21. Are there enough relevant skilled resources available to run a regulatory authority in your country? Yes
No
 _ If yes, where are these people trained? _____

22. Is there a pharmacy educational institution that runs postgraduate courses in pharmaceuticals in your country? Yes
No
 _ If not, from where do the manufacturers obtain their required professional staff? _____

Special provisions of the pharmaceutical sector

23. Do legal provisions exist for licensing domestic manufacturers? Yes
No
24. Does your country have capacity for R&D to discover new active substances? Yes
No
25. Does your country have capacity for formulation from pharmaceutical starting material? Yes
No
26. Does your country have capacity for repackaging of finished dosage forms? Yes
No

27. What is the total number of manufacturers? Yes
 No

28. Does your country export pharmaceuticals to other countries? Yes
 No

_ If yes, please list the primary export destinations.

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____
- 7 _____
- 8 _____
- 9 _____
- 10 _____

29. Do legal provisions exist for licensing multinational manufacturers that produce medicines locally? Yes
 No

30. What is the total number of multinational pharmaceutical companies with a local subsidiary? _____

31. Do legal provisions exist for licensing importers? Yes
 No

32. Do legal provisions exist to inspect premises and collect samples? Yes
 No

33. Do legal provisions exist to ensure quality control of imported medicines? Yes
 No

34. Does your country have provisions for prioritizing women-owned companies? Yes
 No

35. Are there any barriers for importing generic essential medicines and/or commodities that are manufactured in other African countries? Yes
No

– If yes, please list the main challenges.

1 _____

2 _____

3 _____

4 _____

5 _____

Manufacturers

36. Does your company source raw or intermediate inputs from other African countries? Yes
No

– If yes, please specify the materials, companies and countries.

1 _____

2 _____

3 _____

4 _____

5 _____

37. Does your company export Fixed dose formulations to other African countries? Yes
No

– If yes, please specify the commodities and the main destination countries.

1 _____

2 _____

3 _____

4 _____

5 _____

38. Have you (the manufacturer) received or applied for financing? Yes
No

– If yes, please specify from where. _____

– Please describe the **direct** governmental support to reduce the cost of manufacture: Grants, 1854 subsidies, soft loans, provision of land, tax and duty exemptions for imported inputs for local 1855 production of essential medical products.

39. Have you received or applied for technical assistance? Yes
No
 _ If yes, please specify from where. _____

40. Among the products that you export, are there any which are pre-qualified by WHO? Yes
No
 _ If yes, please specify which ones.
 1 _____
 2 _____
 3 _____
 4 _____
 5 _____

41. If you are not already WHO pre-qualified, do you have plans to attain pre-qualification? Yes
No
 _ If yes, please critically assess the technical and human resource capacities you would need for expansion, upgrading and/or modernization of your plant in order to become WHO pre-qualified.

42. Are there any products which you produced in the last 10 years and for which you stopped production? Yes
No
 _ If yes, please list the products and explain why you stopped manufacturing.
 1 _____
 2 _____
 3 _____
 4 _____
 5 _____

National Medicines Regulatory Authority (NMRA) Questionnaire

- 43. Does a formal National Medicines Regulatory Authority (NMRA) exist? Yes No

- 44. If an NMRA authority exists, is it an independent agency? Yes No

- 45. Do legal provisions exist for market authorization? Yes No

- 46. Is the Regulatory Authority actively involved in regional harmonization initiatives? Yes No

- 47. Is the list of registered medicines publicly available? Yes No

- 48. What is the amount per application for medicines registration (originator products)? _____

- 49. What is the amount per application for medicines registration (generic products)? _____

- 50. What is the average length of time from submission of a product application to decision? (months) _____

- 51. How many of the existing manufacturers have been GMP approved? _____

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