

The background of the top half of the cover is a photograph of laboratory equipment. In the foreground, two clear plastic test tubes with white caps are visible, each containing a small amount of blue liquid. The test tubes have measurement markings from 10 to 15 ml. In the background, more laboratory equipment, including a large orange-topped container, is blurred. A solid green horizontal band is positioned below the photograph, serving as a backdrop for the title text.

21 COUNTRY PROFILES

An Introduction to Local Pharmaceutical Production
Opportunities in Africa



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FOREWORD FROM UNAIDS

A healthy population is essential for prosperity. This is a now accepted principle of development, reflected in the UN Sustainable Development Goals agreed in 2015, and in particular SDG3 for good health and wellbeing. The principle is also reflected in the African continent's vision for itself – Agenda 2063, also published in 2015 by the African Union, and in collective actions since 2015 by African countries to strengthen their systems – for instance by their unanimous adoption of a treaty in May 2018 to set up an African Medicine Agency (AMA). Indeed, health is a priority for most African country development plans for good reason. The African continent has approximately 15 percent of the global population and a disproportionately high disease burden. It is the continent where over 70 percent of the world's HIV cases and 90 percent of deaths due to malaria occur.

At the same time, many African countries are highly dependent on imported pharmaceutical and medical products. It is estimated that more than 80 percent of Anti-Retroviral drugs (ARVs) used on the continent are imported from outside, with 70 percent of all pharmaceutical and medical products market being served by foreign imports. Where there is local manufacturing, it mainly involves the production of non-complex, high volume essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs and vitamins. This is an unsustainable situation for two reasons. Imported products can be subject to mark-ups, while jobs are urgently needed on the continent, which local manufacturing could provide for.

This is why UNAIDS is so focused on encouraging global pharmaceutical manufacturers – including from China - to set up in African countries. This is based on the strong conviction (also articulated in the African Union Roadmap on Shared Responsibility and Global Solidarity, endorsed by Heads of States in 2012) that access to affordable, quality medication is integral to ending AIDS (and other major diseases) and achieving Universal Health Coverage. We

also strongly believe that local production of medicines and other health products in Africa is an attractive proposition - it is estimated that the African pharmaceutical sector holds a US \$45 billion market opportunity by 2020. Local pharmaceutical manufacturing in African countries presents an opportunity to save lives while creating jobs and improving the local economy.

However, our work with international partners has revealed that there remains a huge lack of information and misunderstanding about African countries, their needs, their status and opportunities. This is particularly acute in China where language barriers and very recent economic development hinders understanding of global markets.

I appreciate that our partners here in China – the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), and the whole of UNAIDS has supported this effort to provide a simple, consistent set of information for Chinese and other companies considering local production in African countries. With this effort, we hope they will all begin to realise the openness and willingness of African governments to bring in foreign investors into this sector, create joint partnerships, and inspire as many companies as possible to set a vision for how they can contribute to saving lives on the continent, in a sustainable yet profitable manner.



Ms Amakobe Sande
*UNAIDS Country Director and
Representative to the People's Republic
of China*

FOREWORD FROM CCCMHPIE

It is estimated that China has more than 5,000 domestic medicine manufacturers and 16,000 medical device manufacturers, making it the world's largest pharmaceutical manufacturing country. So far, 45 APIs, 24 preparations, 4 vaccines, 3 IVDs and 2 vector control products have passed the World Health Organization Pre-Qualification to enter global pharmaceutical markets. Hundreds of products have been registered successfully in USFDA, Japan's PMDA, the European Union and other regulatory agencies.

In December 2015, President Xi Jinping announced Ten Major China-Africa Cooperation Plans at the Johannesburg Summit of Forum on China-Africa Cooperation (FOCAC), encouraging Chinese enterprises to support local production of pharmaceuticals in Africa to promote access to medicines. In September 2018, at the next FOCAC, he then announced Eight Major Initiatives, including encouraging enterprises to expand their investment in Africa and establish or upgrade a number of economic and trade cooperation zones in Africa.

Africa is an important medical cooperation partner for China. Thanks to the steady implementation of FOCAC commitments, China-Africa pharmaceutical cooperation has accelerated, with more diversified cooperation, transforming from traditional trade-oriented to trade and investment. At the same time, the ability and willingness of Chinese companies to participate in China-Africa medicine cooperation has increased. Chinese companies such as Humanwell Healthcare, Guilin Pharmaceutical, Shanghai Pharmaceutical, Sansheng, and Yorkool have opened localized factories for health products or established distribution networks in African countries.

As the most internationally-advanced pharmaceutical industry organization in China, the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) has been actively promoting the

implementation of relevant measures in the pharmaceutical industry, providing services for enterprises to invest in Africa, encouraging localization and specific joint venture projects. We look forward to and commit to continuing to do so.

We appreciate UNAIDS's support for China-Africa medical cooperation. We hope that this market profiles of 21 African countries can provide Chinese companies (as well as those from other countries) with information on country policies and market trends, so that they can know more about Africa and invest in supporting access to better quality and affordable medicines in Africa. We will continue to work together to create a community of people in China and Africa to achieve win-win results and happiness with a shared future!



Zhou Hui

*President, China Chamber of Commerce
for Import and Export of Chinese
Medicines and Health Products*

ACKNOWLEDGEMENTS

UNAIDS China Office and CCCMPHIE would like to take this opportunity to acknowledge all parties who contributed to the development and finalization of these 21 Country Profiles.

We would like to acknowledge and thank a number African Embassies to China, who collaborated with us to verify the data presented in the Country Profiles, in particular the Embassies of Angola, Egypt, Ethiopia, Madagascar, Malawi, Rwanda, Senegal, South Africa, Tanzania, Uganda and Zambia.

At country level, we wish to sincerely acknowledge the support and input of the UNAIDS Offices in Algeria, Cote D'Ivoire, Kenya, Madagascar, Mali, Mauritius, Mozambique, Nigeria and Zimbabwe who worked with respective governments to also validate the contents of the report. The Regional Teams in Johannesburg, Dakar and Cairo and well as colleagues in UNAIDS Headquarters also provided valuable technical input.

We are also indebted and grateful to the following decision-makers, experts and resource persons who also contributed to the content and verification of data in this report:

Ethiopia: Private sector representative (importer)

Gabon: Export Promotion Agency Gabon

Ghana: Senior Member of the Pharmaceuticals Manufacturers Association

Madagascar: Senior Official from the Ministry of Public Health

Mauritius: Private sector representative and Senior Official pharmaceutical sector, Ministry of Health

Malawi: Chinese manufacturer

Nigeria: Representative, private pharmaceutical manufacturer

Zambia: Zambian Medicine Regulatory Authority and Zambia Development Agency

COMESA Secretariat

Last but not least, we would like to extend our sincere thanks to Development Reimagined, an independent consulting firm based in China, for the huge undertaking of putting together, completing, designing and translating this report and supporting the partnership between UNAIDS China office and CCCMPHIE is addressing knowledge gaps in this sector.

The contents of the profiles do not necessarily reflect the views of UNAIDS or CCCMPHIE.

INTRODUCTION TO COUNTRY PROFILES

This report provides Health Market Profiles of 21 selected African countries. The Profiles provide an overview of current developments and opportunities in the health market and pharmaceutical production capacity of the selected countries.

The 21 countries were selected on the basis of a range of criteria – including:

- Geographical representation to include the 5 sub-regions of Africa;
- Fairly good relations with China, and/or some existing economic cooperation with Chinese private sector actors;
- Have expressed interest in pharmaceutical production or have some production already taking place;
- There is a presence of UNAIDS and other stakeholders to support and provide a development lens on the pharmaceutical industry growth; and
- Political stability.

Together, in 2017, the 21 countries accounted for 73% of all exports to and 79% of all imports from China from the entire continent, so they also have significant economic weight. In addition, the continental sub-regions in which the countries are (East African Community, Economic Community of West African States, and Southern African Development Community) have initiatives to consolidate markets through regulatory harmonization.

Information has been collected and confirmed through desk research and, where there were gaps, discussion and verification with decision-makers in the African countries. The information is correct as of November 2018, although of course, subject to change thereafter.

The information contained in this document should be regarded as the first step in introducing African pharmaceutical markets to decision-makers in other country health sectors, including in China. In particular, it brings together information from the 21 countries in 7 areas:

- 1) Basic levels of development;
- 2) Country overview/relations with China;
- 3) Pharmaceutical market size;
- 4) Incentives for local production of pharmaceuticals;
- 5) Current Chinese markets in country;
- 6) Pharmaceutical companies currently manufacturing in country; and
- 7) Other interests in health investments.

Before presenting the detailed information by country, we briefly summarise the cross-country information in relation to the first 5 of these 7 areas below, which lend themselves most easily to comparative analysis.

1. BASIC LEVELS OF DEVELOPMENT

Access to basic infrastructure is crucial for a viable pharmaceutical manufacturing sector as well as ease of distribution of medical products to those that need them, including via timely logistics and hospitals. The 21 countries demonstrate varied levels of access to basic infrastructure, such as access to energy. For instance, on average, the electricity consumption per capita among surveyed countries is 692kWh. However, this figure varies dramatically across the continent. For instance, in Ethiopia, the electricity consumption per capita is a mere 70kWh, while in Mauritius this figure is over 31 times higher at 2183 kWh.

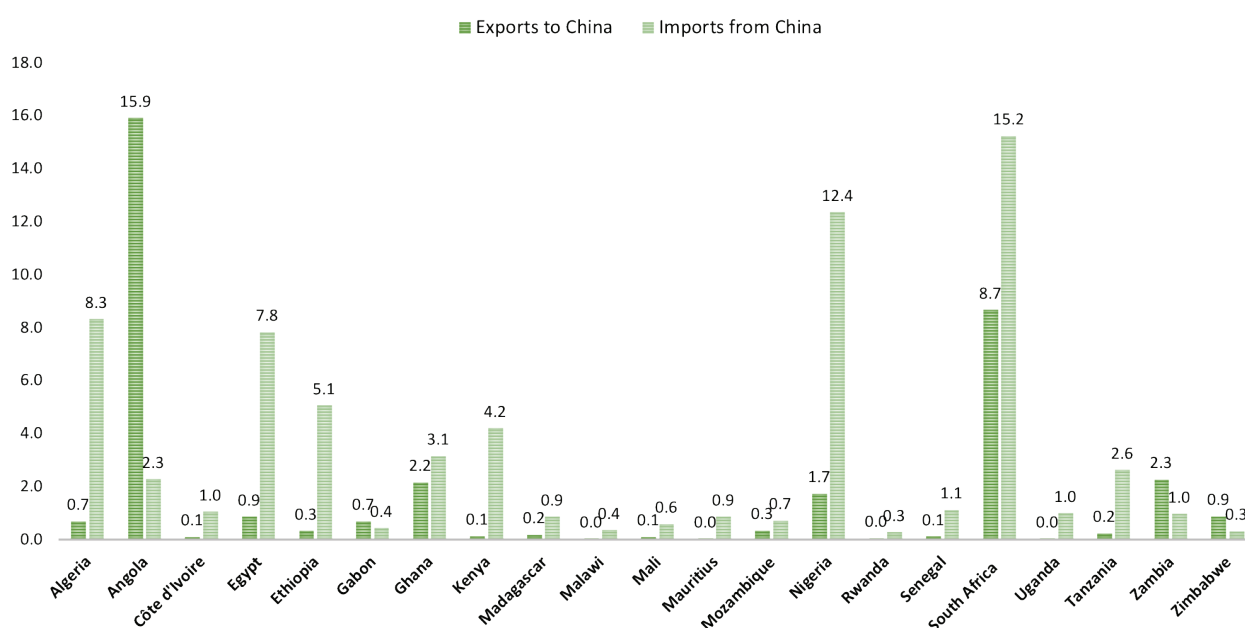
The varied access to basic infrastructure is also evident via figures on access to water. Across the surveyed countries, an average of 75% of their populations have access to water. Among these countries, only in Malawi, Gabon, Egypt and Mauritius do 90% or more of the populations have access to water. On the other end of the spectrum, less than 60% of the populations in Angola, Madagascar, Tanzania and Ethiopia have access to water.

2. RELATIONSHIP WITH CHINA

The 21 countries all have diplomatic relations with the People's Republic of China, however, some established these relationships earlier than others, also depending on their own political trajectory (e.g. date of independence). The political relationships are complex and vary greatly. For instance, many of the 21 countries have "Strategic Partnership Agreements with China" and some, but not all, are members of China's Belt and Road Initiative (BRI). According to the latest list and other media reports, Ethiopia, Egypt, Kenya, Madagascar, Senegal, South Africa, have all officially signed Memorandum's of Understanding with the Chinese government on BRI.

Nevertheless, economic engagement with China for most of the countries is significant, though trade volumes vary significantly. In 2017, the median total exported among surveyed countries was US\$ 1.6 billion however, US\$ 2.9 billion was imported from China. Angola exported the most to China in 2017 (US\$ 15 billion) whilst Mauritius exported the least at US\$ 30 million. South Africa received the most imports from China at US\$ 15 billion and Zimbabwe received the least at US\$ 318 million.

21 AFRICAN COUNTRIES' TRADE WITH CHINA, 2017, US\$ BILLIONS



All but four countries have trade deficits with China – i.e. their imports from China exceeded the exports to China. The only four countries with trade surpluses are Zambia, Gabon, South Africa and Angola, which primarily export primary goods such as oil, timber and metals to China. Increased local manufacturing, including of health products, in all the 21 countries could shift this balance significantly. Foreign Direct Investment (FDI) from China for the countries similarly varies significantly, with South Africa and Egypt being major destinations for Chinese FDI historically, but recent trends showing more diversification across the rest of the continent.

3. PHARMACEUTICAL MARKET SIZE

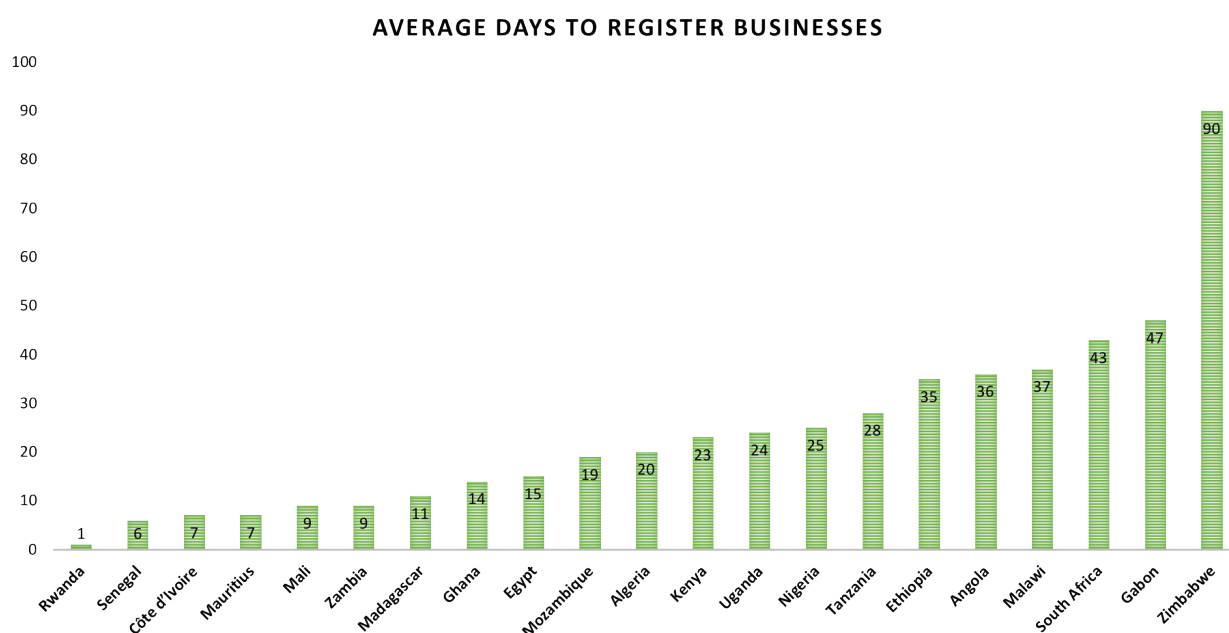
In all countries except for Malawi, Mali and Mozambique, pharmaceutical production is considered a national priority, highlighting the demand for and commitment to local production among most surveyed countries.

However, despite clear interest in local production, information on the pharmaceutical market size in surveyed countries is relatively scarce. For instance, of the 21 countries, only Uganda and Zimbabwe have complete information on annual purchases of drugs by the government, the private sector and donors. Many other countries have incomplete information on their pharmaceutical market sizes.

4. INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

The processes involved with setting up pharmaceutical production in surveyed countries as well as business and government incentives differ across the 21 countries.

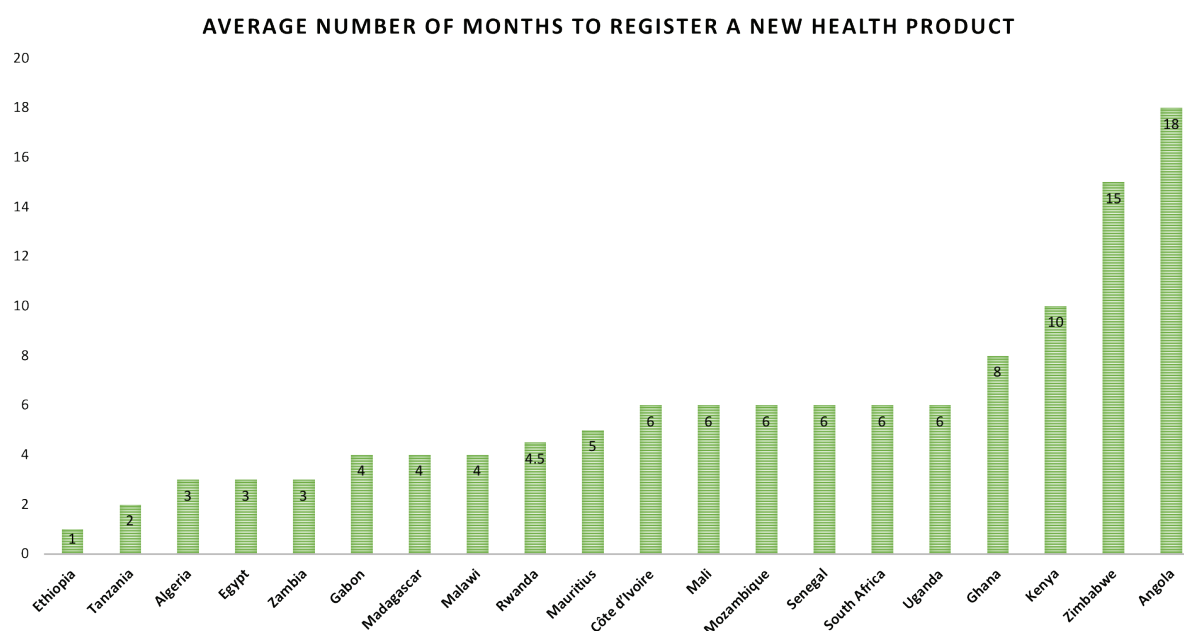
While doing business is considerably more complex than just initial registration, the time it takes to register a new business can be an interesting initial indicator. On average, it takes 24 days to register a business in the surveyed countries. On the most efficient scale of the spectrum, it takes 1-9 days to register a business in Rwanda, Senegal, Mali, Mauritius and Côte d'Ivoire. On the least efficient end of the spectrum, it takes 90 days to register a business in Zimbabwe. Most countries are working hard to improve these statistics.



Furthermore, 100% foreign ownership of businesses is permitted in over 60% of the surveyed countries, including in Egypt, Ethiopia, Gabon, Ghana, Kenya, Madagascar, Malawi, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia. Nevertheless, joint ventures can be very helpful for ensuring understanding of local markets and processes, so this should not necessarily be seen as a barrier to entry. On the other hand, in some of these countries, there is a minimum investment in order for a company to qualify for 100% foreign ownership. For example, in Ghana and Tanzania the minimum investment is \$500,000.

In addition, in relation to setting up pharmaceutical production, we found that in over 60% of surveyed countries, there is free allocation of land and/or a plan for a pharmaceutical industrial park. These countries include Algeria, Côte d'Ivoire, Egypt, Ethiopia, Gabon, Ghana, Kenya, Madagascar, Mauritius, Rwanda, Senegal, Uganda and Zambia. In some other countries, there is interest but a lack of concrete planning.

On average, it takes 6 months to register a new product across the surveyed countries. However, in some countries – including those where opening a business is fairly quick and easy – there can be significant delays in this process. Some countries provide accelerated registration for special circumstances. For instance, Ethiopia has a 1-month fast track for local manufacturers while Kenya has a 3-month fast track for locally manufactured or priority medicines. No surveyed countries provide accelerated registration for Chinese FDA approved products. However, in Zimbabwe WHO PQ products receive accelerated registration.



Over 80% of countries provide tax incentives for local production. For example, Uganda provides import duty exemption for machinery used for local production, Zambia provides tax holidays for up to 10 years if investment thresholds are met, and Algeria prohibits the importing of any drug that can be manufactured locally.

Further, over 60% of surveyed countries impose import duties for drugs produced outside of the country. Some countries provide import duty exemption for certain drugs. For example, Madagascar exempts drugs for HIV/AIDS, TB and Malaria from import duty.

Moreover, 90% of surveyed countries provide import incentives for APIs, excipients and machinery for production. However, some countries require taxes to be paid on APIs, excipients and/or machinery. In some cases, import incentives depends on investment size.

Unfortunately, however, most countries neither guarantee purchase from local manufacturers nor offer pooled procurement. Only 3 of 21 countries surveyed guarantee purchase and/or offer pooled procurement. These countries are Algeria, Kenya and South Africa. Additionally, Ghana offers a 15% price preference for local suppliers in public procurement.

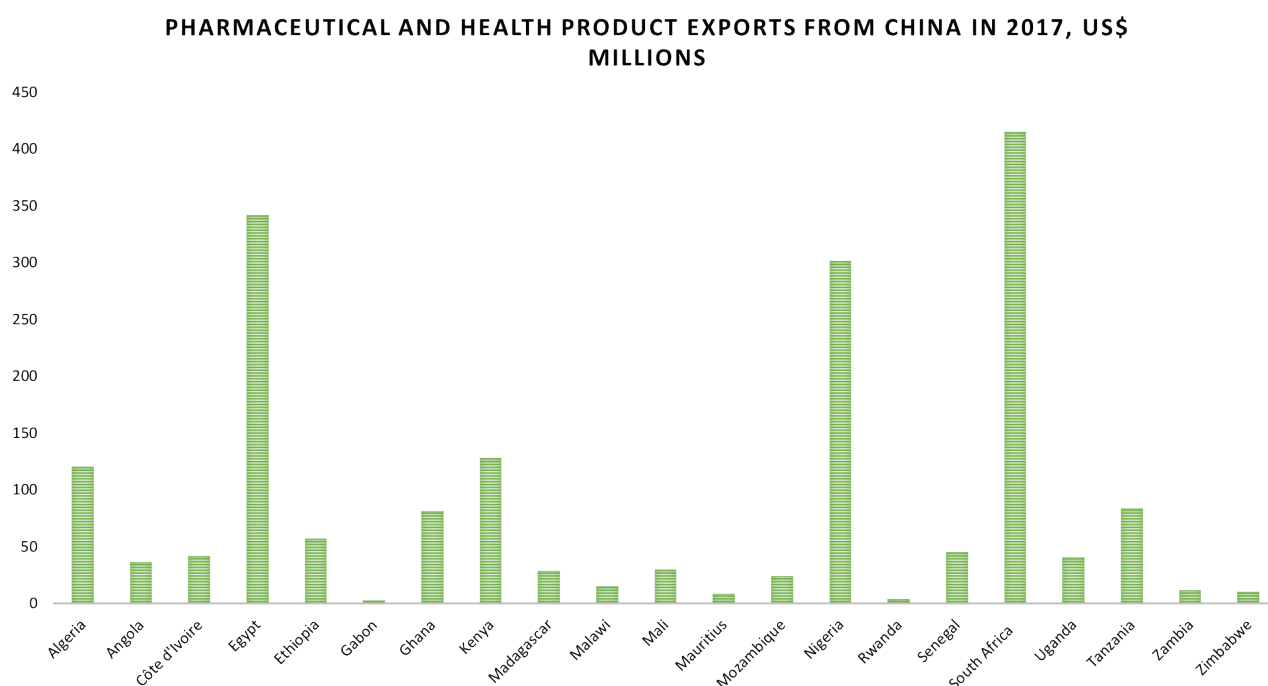
62% of surveyed countries allow free inflow of capital and remittance of profits (foreign currency).

Other countries, such as Algeria, Côte d'Ivoire, Egypt, Ethiopia, Mozambique and Nigeria, have strict to moderate foreign currency control.

Finally, with regards to substandard and falsified prevention: most countries do not have strong capabilities in preventing substandard and falsified products from entering the market. Only two countries—Mauritius and South Africa—have strong capabilities in substandard and falsified prevention. Senegal and Zimbabwe have moderate capabilities but some substandard and falsified products are still able to enter the market. Our analysis suggests that substandard and falsified prevention is an important area of improvement for almost all surveyed countries.

5. CURRENT CHINESE MARKETS IN COUNTRY

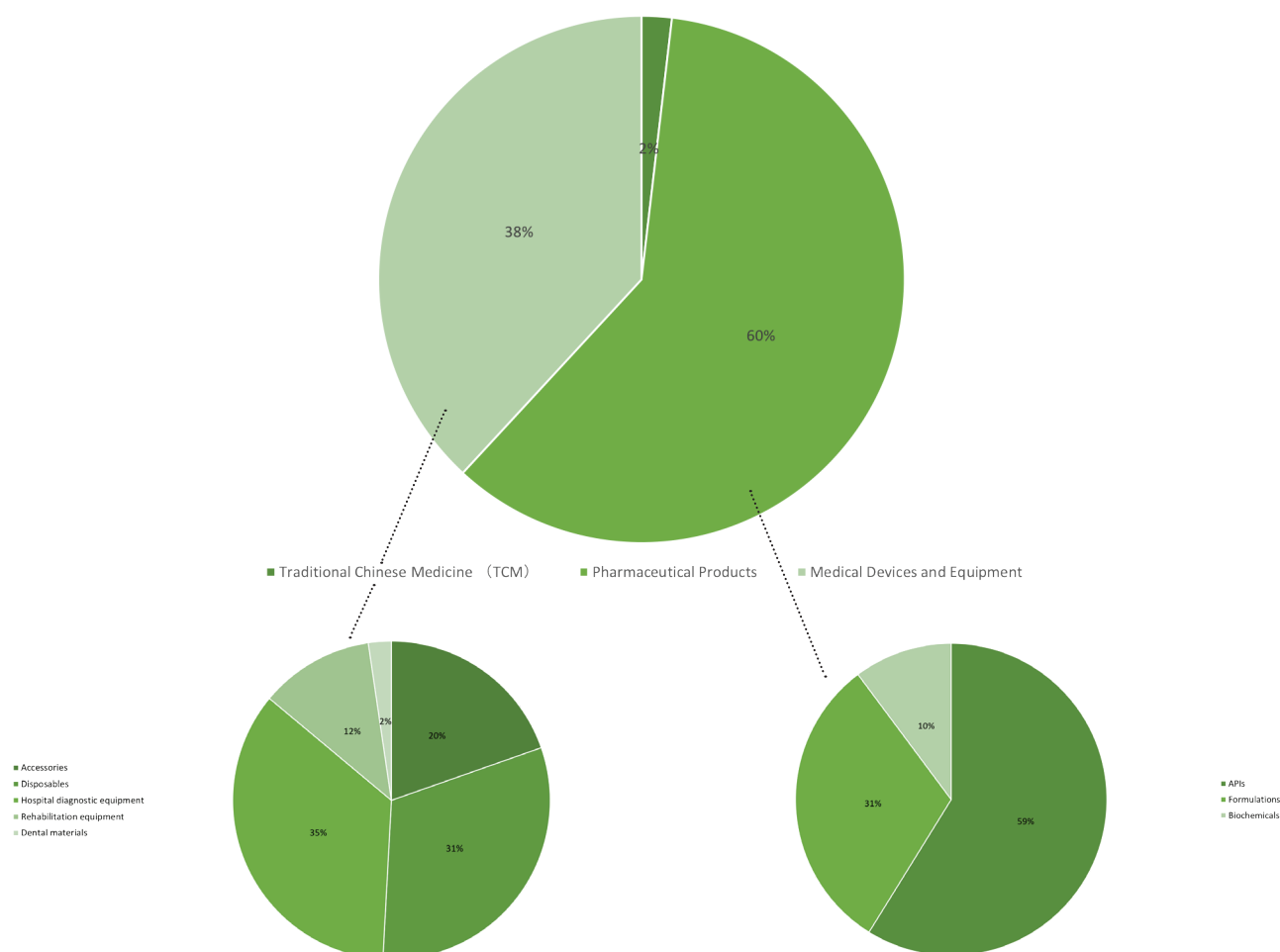
From the analysis, it appears that all surveyed countries import Chinese pharmaceutical products, although total import values vary significantly among the countries. South Africa, Egypt and Nigeria are top importers of Chinese pharma products among surveyed countries, with a 2017 value of over \$300 million per country. Gabon, Rwanda and Mauritius imported the least Chinese products in 2017.



The data suggests that in 2017, on average the pharmaceutical and health product sector in these 21 countries accounted for 3% of total exports from China. Mali imported the most pharmaceutical and health products as a percentage of its imports from China at 5%.

In terms of what is exported from China, Modern medicine accounts for 60% of the total, followed by medical equipment (38%). Within this category, 60% are APIs. Within the category of medical equipment, hospital diagnosis and treatment equipment account for 35% and disposables 31%. Finally, Traditional Chinese Medicine (TCM) occupies a slim 2% of all pharmaceutical and health exports from China. However, all these figures differ greatly across countries, as they have differing demands and health market structures. For instance, 5% of Ghana's pharmaceutical and health product imports from China are TCM.

Types of pharmaceutical and health products exported from china to 21 African countries, 2017



Overall, the Profiles highlight that all African countries have a growing market opportunity due to growing needs in essential medicines, medical devices and health services. Many are part of continental and regional policy frameworks to create conducive environment for upgrading the local pharmaceutical capacity. Some African countries are giving their local pharmaceutical industries a national priority, aligning the sector's objective with those of the country's industry development policy.

While our comparative analysis is only a starting point, these profiles provide a consistent means to assess them as a starting point for decisions with regards to exploratory visits, deeper investigation, and hopefully market entry. Further support is available to have a deeper understanding on developments in African pharmaceutical markets and to highlight cooperation opportunities between African countries and their partners, especially China.

UNAIDS and CCCMHPIE together, as the joint partners behind this report, stand ready to play an important role in facilitating existing opportunities in African countries, and in particular with regards to Chinese companies.

The background of the entire page is a photograph of various pharmaceuticals, including capsules and tablets, scattered across a light-colored surface. The image is covered with a semi-transparent green filter. The text '21' is prominently displayed in the center-left area.

21

COUNTRY PROFILES

Country Profile 1:

ALGERIA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | Middle East and North Africa |
| Political Stability | -0.96; Rank: 180 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$170.37 billion 1.7% |
| Human Development Index (2017) | 0.754, No. 85 (<i>high human development</i>) |
| General Government Dept Stock (2017) | US \$ 5.699 million, (<i>external debt % of GDP (2017) :2.3</i>) |
| Availability of Basic Infrastructure (water, electricity) | 84% of the population have access to water; electric power consumption is 1,356 Kwh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1958

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
Yes, signed in 2014.

Belt and Road Initiative (BRI) country? MOU signed Sept. 2018.

Bilateral investment Agreement?
Yes, signed in 1996, in force 2003.

Double Taxation Agreement?
Yes, signed in 2006.

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$8.3 billion;
- *Exports (2017):* US \$0.69 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$12.05 million; year-on -year growth rate: 10.84.

Top 3 Key products from China (% of total value of 2017 imports):

- APIs (34%)
- Hospital diagnostic equipment (20%)
- Formulations (9%)

Local manufacturing by Chinese companies (specify product and scale):

Light industry, construction material production, oil and gas processing.

What has been China's major economic impact in country to date?

Importation of oil and gas products, infrastructure development (e.g. Great mosque of Algiers), manufacturing industry.

What could development partners (incl. China) contribute to for future development impact in the country?

Importation of machines, financing for big infrastructure projects, industrialization

Is Pharmaceutical production in top 5 priorities for country?

Yes. Algeria's five-year plan (2014-19) has Healthcare as a high priority area. Since 2015, the government has allocated €4.85bn for the sector's development. Until 2025, 20 billion USD are allocated for the advancement of the entire health care sector.

PHARMACEUTICAL MARKET SIZE

Population (2017): 41.3 million.

GNI per capita Atlas (2017): US \$ 3,960.

Per capita spending on Health- PPP (2016):
US \$ 292.

Healthcare spending in % of GDP (2016): 7.4%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$):

Pharmaceutical Market size: 4.2bn USD (2016).
Algeria imported a total of 1.9 billion USD packaged medicaments in 2016.

Unmet need (disease, numbers, drug, potential funder):

Non-communicable diseases Cardiovascular diseases and diabetes, other communicable diseases (non-malignant neoplasms; endocrine, blood and immune disorders; sense organ, digestive, genitourinary, and skin diseases; oral conditions; and congenital anomalies) mother and child health.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Algerian pharmaceutical companies export pharmaceutical products to many countries in North and West Africa.

Harmonization in region:

Algeria is part of the African Medicine Regulatory Harmonization scheme, but it has not yet joined any

regional MRH organization.

- *Clinical guidelines for common diseases:* Yes. There is a common disease treatment guideline and essential medicine list in Algeria.
- *GMP or other manufacturing certification:* Yes, there are several pharmaceutical companies fulfilling GMP standards. Algeria has, in African countries context, a rather developed pharmaceutical industry.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Current information suggests no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 20 days.

100% foreign ownership permitted?

NO. There is a 49-51% Joint Venture rule in the pharmaceutical sector. The law requires majority Algerian ownership of most businesses. The Algerian tax law requires foreign investors to re-invest within four years the value of any investment tax incentives received.

Free allocation of land? Plan for Pharma Industrial Park?

Yes. Under country's investment law it's possible to receive land for setting-up manufacturing space. The area called Sidi Abdellah has become a pharmaceutical cluster in Algeria.

Regulatory Process:

- *Average length of time to register new product:* 3 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Weak but improving, there is a grey market, especially for branded products. The Directorate of Pharmacy and Medicine oversee the registrations and licensing management for market access.

Tax incentives for local manufacturing?

Yes. To encourage local manufacturing, Algeria prohibits the importing of any drug that can be manufactured locally. Government offers tax exemptions, reduced land prices, and other incentives to encourage pharmaceutical companies to build manufacturing plants in the country. National production strategy: every time a product has three manufacturers operating locally, imports of that product are banned.

Import duty for drugs produced outside country?

Yes. Algerian government has implemented an importation ban on over 360 medicines and medical devices, in order to stimulate domestic pharmaceutical production.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement? Yes, government buys from local producers, however, still a lot of imports of medicines occur

Free inflow of capital & remittance of profits (Foreign Currency):

Limited remittance of profit with strict foreign exchange controls.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Around 30 major drug manufacturers operate in the local market, among them are:

- Sanofi (France, US \$480 million), vaccines, generics and cardiovascular medicines;
- GlaxoSmithKline (Great Britain, US\$221 million), Vaccines and generics, cardiovascular medicines;
- Hikma Pharmaceuticals (Jordan, US\$213 million): Generics, Anti-infectives, cardiovascular medicines;
- NovoNordisk (Denmark, US\$209 million): Diabetes medicines;
- El Kendi (Algeria, US\$173 million): Diabetes and cardiovascular medicines, Anti-Infectives and other medications;
- Saidal (Algeria, US\$144 million): Anti-inflammatoryies, diabetes and cardiovascular medication, antaligics - exports to 13 other African countries;
- Biopharm (Algeria, US\$44 million) anti inflammatories, anti-infectious, cardioloascular medication - exports 15 products to 3 African countries (Mauritania, Mali, and Niger).

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture.

Algeria's Market size is the second biggest with ca. US \$4,2 billion turnover in 2016. Total Healthcare spending reached 11,84 billion USD in 2016.

Over the past three years, Algeria has registered more than 140 new pharmaceutical investment projects with an average of three to four manufacturing units that are being developed annually. It is expected that the Algerian medical devise market is growing as the population is aging and the NCD related disease burden is growing.

CONCLUSION

What is the biggest pharma opportunity in the country?

Algeria is North Africa's largest pharmaceutical market. It is becoming a pharmaceutical production hub in Africa. 75% of locally produced products are Generics, 15 % are originators. Pharmaceuticals for Non-Communicable Diseases (NCDs) are becoming increasingly important. Algeria is in the process of constructing 172 public hospitals, 377 private clinics and 45 specialized heath units in the next decade.

What is the biggest hurdle to local production of drugs in the country?

- Human resources can be difficult to recruit, manage, and retain in Algeria, both at the skilled and unskilled levels.
- Delays of weeks and months in clearing goods from Algerian customs.

Country Profile 2:

ANGOLA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | Southern Africa |
| Political Stability | -0.29; Rank: 139 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$124 billion 0.7% |
| Human Development Index (2017) | 0.581; Rank: 147 (<i>low human development</i>) |
| General Government Debt Stock (2017) | US \$37.201 million |
| Availability of Basic Infrastructure (water, electricity) | 49% of the population has access to fresh water, electricity consumption is 312 kwh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1983

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes, signed in 2010.

Belt and Road Initiative (BRI) country?
Not yet, interest expressed.

Bilateral investment Agreement?
No.

Double Taxation Agreement?
Yes, signed in October 2018 (not in force).

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
Yes.

Trade with China:

- *Imports (2017):* US \$2.28 billion;
- *Exports (2017):* US \$15.91 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$3.67 million; year-on-year growth rate: 40.23.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (39%)

- Medical accessories (24%)
- Hospital diagnostic equipment (11%)

Local manufacturing by Chinese companies (specify product and scale):

Construction materials, light industry and agricultural processing.

What has been China's major economic impact in country to date?

Oil and fuel production, real estate development, agricultural development, mining.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment into oil industry, real estate development, manufacturing and agriculture.

Is Pharmaceutical production in top 5 priorities for country?

Increasing local manufacturing of basic primary pharmaceuticals is a government priority per country's National Pharmaceutical Policy.

PHARMACEUTICAL MARKET SIZE

Population (2017): 29.8 million.

GNI per capita Atlas (2017): US \$ 3,330.

Per capita spending on Health-PPP (2014): US \$320.

Healthcare spending in % of GDP (2014): 3.3%.

Annual purchase of drugs – government (\$):

According to Angola's Ministry of Health, the country spends US \$60 million p.a. for pharmaceutical import. Total government's healthcare budget for 2017 is US \$1.87 billion.

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$):

Unmet need (disease, numbers, drug, potential funder):

Major health concerns in Angola include malaria, typhoid, tuberculosis, infectious and parasitic diseases, respiratory and diarrheal diseases, cholera, rabies, measles, sickle cell anaemia, and chronic non-communicable diseases.

Angola's National Development Plan for 2013-2017 (PND) and National Health Strategic Plan for 2012-2025 (PNDS) outline the government's priorities. The PNDS projected that about \$5.2 billion would be invested in the public system per year for the period 2013 to 2025.

Angolan government procurement of pharmaceuticals for treatment of malaria and tuberculosis is funded 50% by the Angolan government, the other funding coming

from The Global Fund (25%), and 25% from the U.S. government.

HIV related commodities are funded 60% by the Angolan government and 40% by The Global Fund.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Harmonization in region:

Within the African Medicines Regulatory Harmonisation (AMRH) programme, Angola is participating in a rapid MRH assessment exercise within SADC and ECCAS RECs.

- *Clinical guidelines for common diseases:* There is a guideline for common diseases in the country.
- *GMP or other manufacturing certification:* Angola has WHO guidelines on GMP, but is not used.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production? Current information suggestions no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 36 days.

100% foreign ownership permitted?

No, there is minimum 35% local participation required.

Free allocation of land? Plan for Pharma Industrial Park?

No.

Regulatory Process:

Angola has a National Pharmaceutical Policy, adopted in 2010 to guide the pharmaceutical sector. The Ministry of Health, under the Health Inspection Office (IGS) is responsible for monitoring the quality of imported pharmaceuticals and medical equipment, and ensuring that medical devices imported into the country meet WHO norms and Angolan regulations.

The Ministry's National Directorate for Pharmaceuticals and Equipment (DNME) is the regulatory body responsible for establishing the criteria for pharmaceuticals and medical equipment entry into Angola. DNME has developed a New Medicines Regulatory Unit to regulate and guide product registration.

- *Average length of time to register new product:* 18 months or longer.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

The National Institute for Consumer Protection (INADEC) with DNME are responsible for regulating

medicines and other pharmaceutical products in Angola in collaboration with the Inspectorate General of Health. However, reports suggest the regulatory system is not fully functional or operating effectively. Angola did not have a national quality control laboratory for medicines, although plans were in place to develop a level I laboratory with the capacity to do basic testing (2013).

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

No.

Guarantee to purchase from local manufacturer? Pooled procurement?

Public sector depends on the central government medical procurement center (CECOMA) which centralizes all orders and manages stocks for all public health institutions nationwide. Since beginning 2016, CECOMA began to use the UN Development Program for procurement of pharmaceuticals, taking-up primarily a distribution and logistics role.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- Nova Angoméica; (anti-anemic, analgesic, antimalarial, anti-inflammatories, anti-tuberculosis, anti-allergic (in pill and syrup forms), as well as saline solution and ointments);
- Price Farma (works with MNCs) imports and distributes pharmaceuticals in Angola;
- Other providers of pharmaceuticals in Angola include big pharmacies such as Mecofarma, Moniz Silva, Novassol, Central, Mediang and Tandu-Far;
- GlaxoSmithKline and Bayer Healthcare Pharmaceuticals have their own distributor in the country.

Lower cost pharmaceuticals are often imported from India and China.

Chinese companies mostly involved in setting-up/building health infrastructure such as health centres and hospitals.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment,

Laboratory reagents, Hospital furniture?

Angola relies on imported medical equipment, devices, supplies and consumables to meet local demand. CECOMA and Parastatal Angopharma are the two official procurement agencies. Most imports of medical equipment are managed by the Angolan private sector.

CONCLUSION

What is the biggest pharma opportunity in the country?

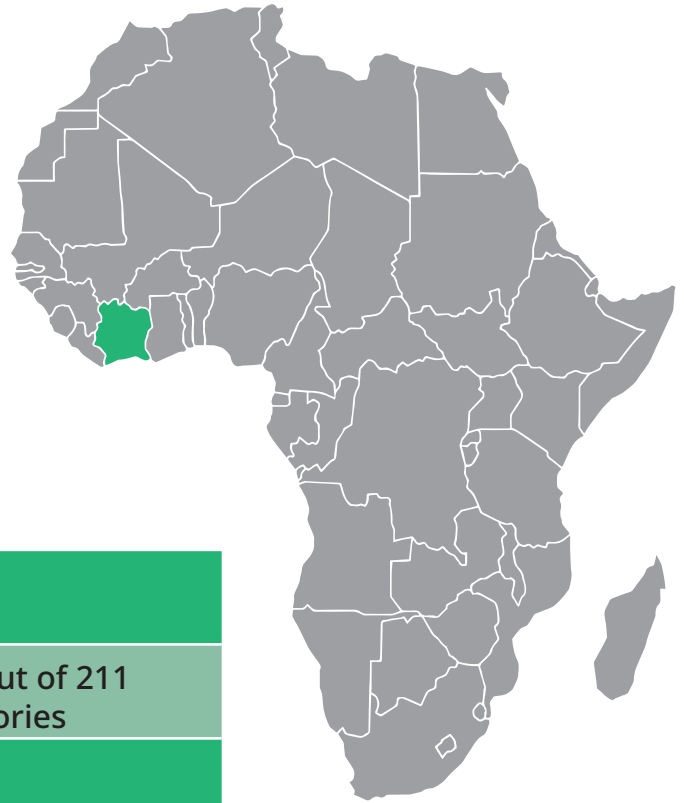
The lack of sufficient pharmaceuticals and medical supplies is negatively impacting patient health and at the same time provides good opportunity for new entrants to the market. Child and maternal care provides a good market opportunity and Antimalarial production.

What is the biggest hurdle to local production of drugs in the country?

Lack of foreign currency, human resource and poor control mechanisms on fraudulent medicines pose a problem. Further, cumbersome customs process, lack of transparency in government procurement, and complex investment climate are further challenges.

Country Profile 3:

CÔTE D'IVOIRE



GENERAL OVERVIEW:

| | |
|--|--|
| Region | West Africa |
| Political Stability | -1.09; Rank: 186 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$40.3 billion 7.8% |
| Human Development Index (2107) | 0.492, Rank: 170 (<i>low human development</i>) |
| General Government Debt Stock (2017) | US \$ 13.433 million (<i>external debt % of GDP (2017): 24</i>) |
| Availability of Basic Infrastructure (water, electricity) | 83% of the population has access to water, 64.3% of the population has access to electricity (2016), <i>electric power consumption is 276 Kwh /capita (2014)</i> |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1983

High Level Visits from Chinese leadership since 2007: 1

Comprehensive Strategic Partnership?
Not yet.

Belt and Road Initiative (BRI) country?
Not yet, interest expressed.

Bilateral investment Agreement?
Yes, signed in 2002 (not in force).

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
No.

Trade with China (in \$):

- *Imports (2017):* US \$ 1.05 billion;
- *Exports (2017):* US \$ 0.09 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$4.17 million (2017); year-on-year growth rate: 33.93.

Top 3 Key products from China (% of total value of 2017 imports):

- APIs (42%)

- Medical disposables (20%)
- Hospital diagnostic equipment (13%)

Local manufacturing by Chinese companies (specify product and scale):

There are around 100 China companies in CDI producing construction materials and agriculture processing.

What has been China's major economic impact in country to date?

Energy development, trade.

What could development partners (incl. China) contribute to for future development impact in the country?

Financial support, infrastructure development.

Is Pharmaceutical production in top 5 priorities for country?

Yes, in line with fighting HIV/ADS, Malaria and TB.

PHARMACEUTICAL MARKET SIZE

Population (2017): 24.3 million.

GNI per capita Atlas (2017): US \$ 1,540.

Per capita spending on Health-PPP (2015):
US \$ 189.6.

Healthcare spending in % of GDP: 5.4% (2015).

Annual purchase of drugs – government (\$):
14 million.

Annual purchase of drugs – private (\$):
300 million.

Annual Purchase of drugs – donors (\$):
62 million.

In 2015 Côte d'Ivoire imported \$291 million worth of pharmaceuticals.

Unmet need (disease, numbers, drug, potential funder): \$424 million.

High maternal and under-5 mortality rate, Malaria, HIV/AIDS, TB. NDCs are on the rise.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Côte d'Ivoire is a member of Economic Community of West African States (ECOWAS/CEDEAO) and The West African Economic and Monetary Union (WAEMU/UEMOA). It is also member of the West African Pharmaceutical Manufacturers Association (WAPMA). African Medicines Regulatory Harmonization (AMRH) programme, CDI started the Medicine Regulatory Harmonization programme in 2015.

Harmonization in region:

The West Africa Medicines Regulatory Harmonization

(MRH) programme was launched in 2015. Ivory Coast participated in the establishment of the joint MRH Project Steering Committee and formation of 7 Technical Working Groups.

- *Clinical guidelines for common diseases:* Aligned under ECOWAS and WAEMU Common Technical Document (CTD). CDI is in the process of developing harmonization strategy based on CTD. The national health commodity supply chain system is led by three entities. The GOCI National Pharmaceutical Agency (Programme National de Développement de l'Activité Pharmaceutique (PNDAP) develops and enforces health commodity policy, and designs standard operation procedures (SOPs) for the health supply chain. The Nouvelle Pharmacie de la Santé Publique (NPSP) is a nonprofit, nongovernmental organization (NGO) under contract with the GOCI to manage all implementation aspects of the national public health commodity supply chain system. In this regard, NPSP functions as the primary procurement agency for the GOCI health commodity supply chain. The Ivorian Authority for Pharmaceutical Regulation (Autorité Ivoirienne de Régulation Pharmaceutique, AIRP) has been established (Law No. 2017-541 on the regulation of the pharmaceutical sector, promulgated on August 3, 2017, and published in the Official Journal n° 80 of October 5, 2017) and is an essential element to ensure effective regulation of the Ivorian pharmaceutical sector.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Current information suggests no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 7 days.

100% foreign ownership permitted?
No.

Free allocation of land? Plan for Pharma Industrial Park?

There is no free allocation of land. There is a special zone dedicated for biotechnology and pharmaceutical industry development.

Regulatory Process:

- *Average length of time to register new product:* 6 Month.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers suggests is weak. The GOCI National Medicines Authority (Direction de la

Pharmacie du Médicament et des Laboratoires (DPML) is responsible for the registration of pharmaceuticals and for the approval of health commodities. Some drug laboratories have been tested by the WHO-AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Currently, local manufacturing is not receiving any special measures or incentives other than specified in the investment code.

According to the ordinance 2012-487 of June 07, 2012 relative to the investment code, there is a tax exemption on finished pharmaceutical products as well as on raw materials.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

No guarantee, however, essential medicines are procured through centralized institutions such as NPSP and private wholesale distributors (COPHARMED, LABOREX).

Free inflow of capital & remittance of profits (Foreign Currency):

No. Exchange-control exists in CDI for financial remittances outside ECOWAS.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- Cipharm (local), 5 billion CFAF; exports 50% of its production to neighboring countries. Produces anti-malarials, syrups, generics;
- S-terre (local);
- Olea (local);
- Lic Pharma (local);
- Pharmivoire Nouvelle SA (local);
- Rougier-Pharma (local);
- Galefomy (local);
- Lpci (local);
- Dermopharma (local);
- Sun Pharma (India);
- Novartis Pharma Service (Swiss)

Exchange platforms are in place, such as the Association of Pharmaceutical Producers of Côte d'Ivoire (APPCI), the State-Private Sector Consultation Committee (CCESP), the inter-ministerial platform (MSHP - Ministry of Industry, Mines and Trade), and the LIPA association bringing together pharmaceutical

companies from sub-Saharan Africa.

OTHER INTERESTS IN HEALTH INVESTMENTS

Market size: \$800 million.

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Based on its latest National Health Plan, CDI plans to extend the availability of health care to all its citizens and requires adequate medical devices and equipment. The sector is planned to grow in the coming years.

CONCLUSION

What is the biggest pharma opportunity in the country?

Local production of pharmaceuticals for Malaria, HIV/AIDS and TB. Most of these medicines are being imported and oftentimes run out of stock. There is an increase of non-transmissible diseases that need to be covered with medicine.

What is the biggest hurdle to local production of drugs in the country?

Local production is currently not sufficiently protected by laws and government measures; it cannot compete with big foreign pharmaceutical producers and the most important threat is the permeability of the market by substandard imported drugs.

Country Profile 4:

EGYPT



GENERAL OVERVIEW:

| | |
|--|---|
| Region | North Africa |
| Political Stability | -1.42; Rank: 192 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$235.3 billion 4.2% |
| Human Development Index (2107) | 0.696, No. 115 (<i>medium human development</i>) |
| General Government Debt Stock (2017) | US \$82.886 million, (<i>external debt % GDP (2017): 36.1</i>) |
| Availability of Basic Infrastructure (water, electricity) | 99% of the population has access to drinking water; Electricity consumption in Egypt is 1.658 Kwh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1983

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes.

Belt and Road Initiative (BRI) country?
Yes.

Bilateral investment Agreement?
Yes, signed in 1994 (in force 1996).

Double Taxation Agreement?
Yes.

Asian Infrastructure Investment Bank (AIIB) member?

Yes.

Priority country for industrial cooperation?
Yes.

Trade with China:

- *Imports (2017):* US \$7.83 billion;
- *Exports (2017):* US \$0.86 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$34.21 million; year-on-year growth rate: 0.83.

Top 3 Key products from China (% of total value of 2017 imports):

- APIs (56%)

- Hospital diagnostic equipment (15%)
- Biochemicals (6%)

Local manufacturing by Chinese companies (specify product and scale):

Automobile production for local and export;
Agriculture, IT and fiberglass production, textile factories, home appliance manufacturing for local.

What has been China's major economic impact in country to date?

Infrastructure development, light manufacturing, special economic zones development.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment in infrastructure development, industrialization and development of manufacturing for export.

Is Pharmaceutical production in top 5 priorities for country?

Yes, Egypt want to develop further the pharmaceutical sector and expand its effectiveness for the local market.

PHARMACEUTICAL MARKET SIZE

Population: 97.6 million (2017).

GNI per capita Atlas (2017): US \$ 3,010.

Per capita spending on Health – PPP (2014): US \$ 594.1.

Healthcare expenditure in % of GDP (2017): 6.5%

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): In 2016, Egypt imported pharmaceutical products worth US \$1.8 billion and exported US \$304 million.

Unmet need (disease, numbers, drug, potential funder):

Egypt has high out-of-pocket spending for pharmaceuticals. 56% of health expenditure. Pharmaceutical purchases at pharmacies accounting for nearly half of out-of-pocket payments. Drug prices are regulated by the health ministry's Central Administration of Pharmaceutical Affairs (CAPA), which sets compulsory product retail prices. Egypt has a large pharmaceutical industry, but it also relies on imported ingredients. Nearly all ingredients for local manufacturing need to be imported. Multinational pharmaceutical suppliers like Pfizer, Novartis, GlaxoSmithKline and Sanofi cover 40% of the market in Egypt, while 60% of the market belongs to domestic suppliers. Egypt imports about \$600 million in finished medicines per year and \$1.8 billion in active ingredients. Multinationals have local factories set up but 15-20% of drugs are imported, while 80-85% are produced locally. About 70% of all drugs in Egypt are

generic and domestic-made.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Egypt exports pharmaceutical products to neighboring countries, it is expected that the export market will grow to US \$300 million by 2020.

Harmonization in region:

Egypt is part of the Common Market for Eastern and Southern Africa ("COMESA") and part of the African Medicines regulatory Harmonisation scheme. Egypt is also part of The Arab Union of the Manufacturers of Pharmaceuticals & Medical Appliances (AUPAM), a sub-organization of the Arab League, which has begun the development of a regional drug registration process in the region.

- *Clinical guidelines for common diseases:*
- *Medicines registration:* Procedures for registration of pharmaceutical products, whether locally manufactured or imported, are listed in the Ministerial Decree no. 425 of 2015. Requirements and procedures differ according to the following categories of products:
 - * *Imported fully finished products;*
 - * *Imported semi-finished products (Bulk), which are manufactured outside but packaged in Egypt;*
 - * *Locally manufactured products by licensed manufacturing factory in Egypt.*

GMP or other manufacturing certification:

Egypt has adopted the WHO Good Manufacturing Practices for Pharmaceutical Products (GMP) as the Egyptian guide for good manufacturing standards. Several companies, such as Hefny Pharma, are compliant with it.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No. However, Egypt became fully TRIPS compliant in January 2005, when legislation enacted in 2002 came into effect.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 15 days.

100% foreign ownership permitted?

Yes. The Egyptian law allows 100% foreign ownership of investment projects and guarantees the right to remit income earned in Egypt and to repatriate capital.

Free allocation of land? Plan for Pharma Industrial Park?

There are free zones that are allocated for pharmaceutical producing companies.

Regulatory Process:

- *Average length of time to register new product:*

Three months according to CAPA, however there are long delays in approval process of two to three years.

- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers suggests is weak. The Egyptian Drug Authority (EDA) is the pharmaceutical regulatory body of the Egyptian Ministry of Health (MOH) responsible for the regulation & legislation of pharmacy practice including counterfeit substandard and falsified drugs.

Tax incentives for local manufacturing?

Yes. Local manufacturing is encouraged through tax incentives to set up local manufacturing.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes. Pharmaceutical products may not be imported or released by the customs unless registered and approved by Ministry of Industry (MoI). In order to register in the Importers Register, an importation company must be fully owned and managed by Egyptian nationals. Importation of pharmaceutical products is allowed only from manufacturing companies which are registered at MoI.

Guarantee to purchase from local manufacturer? Pooled procurement?

No.

Free inflow of capital & remittance of profits (Foreign Currency):

No.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Egypt has ca. 120 local pharmaceutical companies. Ca. 10% are MNCs operating in the country. In 2016 the following companies were the leading producer of pharmaceuticals.

- Novartis, (US \$193m) (international): Top product: Cataflam [Diclofenac Potassium], Catafast, Voltaren;
- Glaxo Smith Kline (US \$170m): Top Product: Augmentin;
- Egyptian International Pharmaceutical Industries (EIPICO), (US\$100m) Cefotax, Flumox Pharco Pharmaceutical (US \$113m);
- Amoun Pharmaceutical, (US \$96 m);
- Evapharma (US \$79 m);
- Pfizer (US \$73 m);
- Global NAPI Pharmaceuticals (GNP) (US \$49,3 m);
- Hikma Pharmaceuticals (US \$48 m);

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical devices, laboratory equipment, laboratory reagents, hospital furniture?

Egypt's medical device market is the second largest in the Middle East. Sales in medical devices totalled US \$25 million in 2016.

CONCLUSION

What is the biggest pharma opportunity in the country?

In line with the country's healthcare system upgrade, there are opportunities in the following areas: construction, management, and rehabilitation of hospitals and rural healthcare facilities; emergency care (ambulatory) services; training programs for nurses and physicians; establishment of quality control of biological and laboratory centers, development of quality standards for hospitals, laboratories, and healthcare institutions.

The Government is aggressively trying to reduce import of medicines into the country and give more support to local production, tackling trade deficit.

What is the biggest hurdle to local production of drugs in the country?

Red tape and lengthy registration process Not clear market regulations and fixed price structure.

Country Profile 5:

ETHIOPIA



GENERAL OVERVIEW:

| | |
|--|---|
| Region | East Africa |
| Political Stability | -1.69; Rank: 195 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$80.5 billion 10.2% |
| Human Development Index (2107) | 0.463, Rank: 173 (<i>low human development</i>) |
| General Government Dept Stock (2017) | US \$26.562 million |
| Availability of Basic Infrastructure (water, electricity) | 66% of the population has access to drinking water ⁷⁶ ; electric power consumption is 70 kWh per capita; (<i>in 2014/2015, 60% of the population had access to electricity services</i>) ⁷⁷ |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1983

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes, since May 2017.

Belt and Road Initiative (BRI) country?
Yes.

Bilateral investment Agreement?
Yes, signed in 1998 (in force 2000).

Double Taxation Agreement?
Yes, since 2015.

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
Yes.

Trade with China:

- *Imports (2017):* US \$5.06 billion;
- *Exports (2017):* US \$0.33 billion;

Imports of Chinese pharmaceutical and health products Total (2017): US \$5.71 million; year-on-year growth rate: -2.98.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (36%)
- Hospital diagnostic equipment (17%)
- Medical disposables (15%)

Local manufacturing by Chinese companies (specify product and scale):

Investment from China to Ethiopia has started from almost zero in mid-2000s its current level (stock) of more than US \$4 billion (1.171 projects) and it is increasing steadily. Light manufacturing, footwear, textile and garment, automotive and electric manufacturing, construction, telecommunication.

What has been China's major economic impact in country to date?

Industrial manufacturing, textile and garment, transportation and construction, pharmaceutical production.

What could development partners (incl. China) contribute to for future development impact in the country?

Capital goods, infrastructure, transportation and telecommunication, industrialization.

Is Pharmaceutical production in top 5 priorities for country?

Yes.

PHARMACEUTICAL MARKET SIZE

Population (2017): 105.0 million.

GDP per capita Atlas (2017): US \$ 740.

Per capita spending on Health –PPP (2014): US \$73.0.

Healthcare expenditure in % of GDP (2014): 4.9%

Annual purchase of drugs – government (\$): Government owned PFSA is biggest importer of pharmaceuticals in the country. Imports pharmaceuticals worth ca. US\$ 40 million (2016) into the country. Government owned Pharmaceuticals Fund and Supplies Agency (PFSA), procures almost 70% of all the medicines consumed in Ethiopia. PFSA procurement was US\$ 310 million in 2014.

Annual purchase of drugs – private (\$): The annual private pharmaceutical market in Ethiopia is estimated at US\$ 100 million. This is because there is still significant out-of-pocket expenditure on health, estimated at 46% by the Ethiopian Food, Medicines, Healthcare Administration and Control Authority (FMHACA).

Annual Purchase of drugs – donors (\$): Ethiopia's pharmaceutical market is estimated to be worth US\$ 400 to US\$ 500 million per year.

Unmet need (disease, numbers, drug, potential funder): Health services coverage is around 98%. Lower respiratory infections, HIV/AIDS, Diarrhoea diseases, Birth asphyxia and birth trauma, protein-energy malnutrition.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: No. However, Ethiopia exports to neighboring countries. 2015 (US \$2 million).

Harmonization in region:

Ethiopia is part of the African Medicine Regulatory Harmonization scheme. In 2015, it participated in the IGAD member states National Medicine Regulation Authorities' meeting and signed agreement to implement the regional medicines Regulatory Harmonization programme.

In 2016, Ethiopia agreed to establish an IGAD MRH steering committee, technical working groups and a coordination unit to oversee the implementation.

- *Clinical guidelines for common diseases:* There is a medical essential list available o Medicines registration: Registration for local manufacturing is around one month. Food, Medicine and Health Care Administration and Control Authority (EFMHACA) of Ethiopia responsible for registration procedure.
- *GMP or other manufacturing certification:* Yes, Ethiopia is actively working to establish GMP certified production centres. EFMHACA has formulated a GMP Roadmap (2013-2018) being implemented by all pharmaceutical industries with the primary objective of improving access to quality medicines.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No. However, Ethiopia agreed to reform IP to align with TRIP Flexibilities as outlined by WTO by 2021.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 35 days.

100% foreign ownership permitted?

Yes, in non-strategically areas and above a certain investment level. Certain sectors are closed to foreign investments.

Free allocation of land? Plan for Pharma Industrial Park?

Yes. There is a dedicated Pharma Industrial Park, which offers serviced land, incl. essential infrastructure (e.g. wastewater treatment plant, water supply, power substation plus one-stop shop, Joint warehousing, calibration and testing services, etc).

Regulatory Process:

- *Average length of time to register new product:* One month for local manufacturer. Note also that there is a list of fast track products (HIV/ AIDs, Malaria, TB, Vaccine, and reproductive health products) which is being updated to include anticancer, orphan medicines, and other rarely used medicines for orphan diseases. Otherwise, the designation for priority of medicine registration

follows the principle of service fee payment to expedite the registration process.

- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers suggests is weak. The Food, Medicine and Health Care Administration and Control Authority of Ethiopia (EFMHACA), is responsible for regulating drugs and preventing substandard and falsified drugs entering the market. Some drug laboratories have been tested by the WHO-AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Yes. Income tax exemptions for formulation/final medicine (from 6-12 years) and Active Pharmaceutical Ingredient (API) manufacturers (8-14 years) inside industrial parks depending on the location of the park and the extent of export orientation of the company.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

Pharmaceuticals Fund and Supply Agency (PFSA) offers a 25% price preference and prepayment of 30% of the tender value to manufacturers operating in Ethiopia that have been awarded a contract by PFSA.

The Ethiopian Government is planning to provide a framework for long-term procurement guarantees in exchange for strategically important investment.

Free inflow of capital & remittance of profits (Foreign Currency):

No, foreign investors can make some remittances in convertible foreign currencies in some areas (e.g. profits).

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Currently, there are 32 plants (small and large scale) involved in the manufacturing of pharmaceuticals and related products, 12 are manufacturers of generic finished pharmaceutical dosage forms.

- Gulf Pharmaceutical Industries (Julphar) (UAE: international): produces antibiotics, insulin, suspension and syrup. A JV with local manufacturing company, Medtech, products also

prepared for export. Plant is cGMP compliant.

- Ethiopian Pharmaceuticals Manufacturing Sh. Company (EPHARM) (local): produces Antibiotics, infusions, Tropical Drugs, anti-allergics, Analgesics
- Addis Pharmaceutical Factory (local) (local): produces generic drugs, such as anti-inflammatories, Analgesics, Antmalarials. Company is cGMP compatible.
- Humanwell Pharmaceuticals (China) (China: international): Produces generics for local use, antibiotics, anti-inflammatories
- Sansheng (Ethio) Pharmaceutical (China: international): Produces anti-pain drugs and antibiotics;
- Cadila Pharmaceuticals (India: International): Produces tablets, capsules, oral liquids and powders
- Sino-Ethiopia Associate Africa (Joint Venture): produces empty gelatin capsules.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Ethiopia's medical device market is growing fast and requires all sorts of equipment and laboratory equipment. It is expected that this section will grow in line with the growth of the pharmaceutical sector.

CONCLUSION

What is the biggest pharma opportunity in the country?

The country's pharmaceutical industry is still underdeveloped and the government is determined to establish a functioning industry until 2025. Dedicated incentives for local production of generics and branded medicine. Population is growing fast and the need for medicines is growing. There is a rapid economic development taking place in the country.

What is the biggest hurdle to local production of drugs in the country?

Underdeveloped market, lack of adequate human resources and difficulties for importation of products due to foreign currency shortage.

Country Profile 6:

GABON



GENERAL OVERVIEW:

| | |
|--|--|
| Region | Central Africa |
| Political Stability | 0.09; Rank: 123 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$14.62 billion 1.1% |
| Human Development Index (2107) | 0.702, No. 110 (<i>medium human development</i>) |
| General Government Debt Stock (2017) | US \$6.166 million |
| Availability of Basic Infrastructure (water, electricity) | 93% of the population has access to clean water, electricity consumption is 1,173 kwh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1974

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
Yes, since May 2016.

Belt and Road Initiative (BRI) country?
No, but interest expressed.

Bilateral investment Agreement?
Yes, signed in 1997 (in force 2009) .

Double Taxation Agreement?
Signed in Sept. 2018 (not in force).

Asian Infrastructure Investment Bank (AIIB) member?
No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.43 billion;
- *Exports (2017):* US \$0.68 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$0.28 million (2017); year-on-year growth rate: -4.73.

Top 3 Key products from China (% of total value of 2017 imports):

- Hospital diagnostic equipment (43%)

- Medical disposables (15%)
- Medical accessories (14%)

Local manufacturing by Chinese companies (specify product and scale):

Currently there are approx. 30 Chinese companies operating in Gabon, mostly in timber production and infrastructure development.

What has been China's major economic impact in country to date?

Infrastructure construction, oil and gas, wood and timber products, manganese, agriculture, tourism, finance and telecommunications.

What could development partners (incl. China) contribute to for future development impact in the country?

Infrastructure development, industrialization, manufacturing.

Is Pharmaceutical production in top 5 priorities for country?

Yes, Government wants to advance health care system to new level.

PHARMACEUTICAL MARKET SIZE

Population: 2.0 million (2017).

GNI per capita Atlas (2017): US \$ 6.610.

Healthcare expenditure in % of GDP: 2.7 %

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$):

Unmet need (disease, numbers, drug, potential funder):

Mother and Child Mortality, HIV/AIDS, TB, malaria, non-communicable diseases, cancer.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Gabon does not export to neighbouring countries. As a member of CEMAC, Gabon's trade with other CEMAC member countries (Cameroon, Central African Republic, Chad, Republic of Congo, and Equatorial Guinea) has low or no customs duties.

Harmonization in region:

Gabon is part of the African Medicines Regulatory Harmonization (AMRH) scheme. Gabon is participating in a mapping exercise since 2016 to establish regulatory systems that will guide ECCAS and OCEAC Member States. In 2014 ECCAS countries started common pharmaceutical policies.

- *Clinical guidelines for common diseases:* Gabon has an Essential Medicines List available.
- *GMP or other manufacturing certification:* No.

Are any Intellectual Property flexibilities

incorporated in the national legislation to favour local production?

Current information suggests no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 47 days.

100% foreign ownership permitted?

Yes.

Free allocation of land? Plan for Pharma Industrial Park?

Yes.

Regulatory Process:

- *Average length of time to register new product:* 4 Month, but with delays in the approval process it might take longer.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers and other evidence suggests is very weak. Currently no information on a dedicated authority monitoring substandard and falsified drugs.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

No.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

There are no manufacturing companies. Government is actively looking for investment in the pharmaceutical manufacturing sector. There are currently ca. 75 Pharmacies and distributors.

- I'office Pharmaceutic National (OPN) (government buyer and distributor) responsible for buying and distributing antiretrovirals and TB medicaments;
- Sanofi Gabon (distributor), Main products:

antimalarial, diabetes: Amarel; Antibioticas: Amoxirex and vaccines;

- Pharmagabon- distributor.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

The country has introduced a National Health Development strategy that aims to provide universal health coverage to the entire population by 2025.

Investments into modern health care equipment and medical devices are part of the Health strategy.

CONCLUSION

What is the biggest pharma opportunity in the country?

Government plans to bring the healthcare system to international standards by 2025. Non-communicable diseases are increasing in Gabon and placing an increasing burden on the country's society and economy. All pharmaceuticals dealing with Non-communicable diseases, e.g. diabetes medicines are a big opportunity. Cancer treatment is another big opportunity in Gabon.

What is the biggest hurdle to local production of drugs in the country?

- No adequate infrastructure and human resources fit for the pharmaceutical sector.
- Market size is too small.



GENERAL OVERVIEW:

| | |
|--|--|
| Region | West Africa |
| Political Stability | 0.09; Rank: 107 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$47.62 billion 8.5% |
| Human Development Index (2107) | 0.592, No. 140 (<i>medium human development</i>) |
| General Government Dept Stock (2017) | US \$ 22.022 million |
| Availability of Basic Infrastructure (water, electricity) | 89% of the population has access to drinking water; electric power consumption is 355 kWh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1960

High Level Visits from Chinese leadership since 2007: 1

Comprehensive Strategic Partnership?
Yes, since May 2016.

Belt and Road Initiative (BRI) country?
Yes – since Sept. 2018.

Bilateral investment Agreement?
Yes, signed in 1989 (in force 1991).

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$3.15 billion;
- *Exports (2017):* US \$2.16 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$8.16 million; year-on-year growth rate: 7.49.

Top 3 Key products from China (% of total value of 2017 imports):

- Medical disposables (28%)

- API (24%)
- Medical accessories (13%)

Local manufacturing by Chinese companies (specify product and scale):

Mining, pharmaceuticals, plastic recycling, light manufacturing.

What has been China's major economic impact in country to date?

Mining and manufacturing, infrastructure development.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment in light manufacturing, agriculture and infrastructure development.

Is Pharmaceutical production in top 5 priorities for country?

Yes, improvement and expansion of health care is one of the priorities of the Ghana's human development agenda. Pharmaceutical sector selected as 10 strategic anchor sectors.

PHARMACEUTICAL MARKET SIZE

Population (2017): 28.8 million.

GNI per capita (2017): US \$ 1,490.

Per capita spending on Health- PPP (2017): US \$ 146.

Healthcare spending in % of GDP (2014): 3.5%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): In 2016, Ghana's pharmaceutical market is estimated to be around (GHS 1.3 billion) US \$289.7 million big. 115 US \$200 million is being imported and remaining supplied by local manufacturer.

Unmet need (disease, numbers, drug, potential funder): Malaria, lower and upper respiratory infections, HIV/AIDS, Diarrhoea disease.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Ghana serves as the regional hub for pharmaceutical manufacturing and distribution to over 300 million people who live within the Economic Community of West African States (ECOWAS).

Harmonization in region:

Ghana is part of the West Africa Medicines Regulatory Harmonization (MRH) programme since 2015.

- *Clinical guidelines for common diseases:* Yes, for Malaria treatment and there is Standard Treatment Guidelines for common diseases.
- *GMP or other manufacturing certification:* No.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Ghana has updated patent laws and discussions are ongoing regarding the most effective method to make drugs more accessible for those most in need.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 14 days.

100% foreign ownership permitted?

Yes, with minimum of 500k foreign equity investment.

Free allocation of land? Plan for Pharma Industrial Park?

Yes, Free Zones are used for pharmaceutical production facilities. New zones are under construction.

Regulatory Process:

- *Average length of time to register new product:*
- 6-10 months.
- *Accelerated registration of drugs approved by Chinese FDA?*

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers suggests is weak. The Food and Drugs Authority (FDA) formerly the Food and Drugs Board (FDB) is mandated by the public Health Act, 2012 (Act 851) to regulate food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines & medical devices. Some drug laboratories have been tested by the WHO- AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

Ghana offers 15% price preference for local suppliers in public procurement. In addition, 49 Pharmaceutical products are banned from importation due to sufficient local capacity to produce.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES

CURRENTLY MANUFACTURING IN COUNTRY

Ghana has currently 38 registered pharmaceutical manufactures including:

- Danadams Pharmaceuticals (local): manufacturing antiretroviral, anti-malaria, anti-TB;
- Ernest Chemist (local): produces tablets, powders, capsules, oral liquids and suspensions;
- Sanbao Pharmaceutical (China: international), located within the TemaZone, competition more from Indian companies than locally;
- Adcock Ingram (South Africa);
- Guilin Pharmaceutical (China) part of FOSUN Pharmaceuticals; produces anti-malaria medicine artesunate and generic pharmaceuticals;
- UniChem Industries (local);
- Kinapharma (local);
- Tobinco (local);
- M&G Pharmaceuticals (local).

Local companies cover 40% of market demand. ca. 35% are OTC (over-the-counter medications. Rest is prescription medication. 2/3 of drug purchases are financed through out-of pocket expenditure. Remaining being financed through government (public procurement) and donor funded purchases.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Ghana medical device market is estimated to be US \$20 million big with growing demand for sophisticated equipment due to growing middle class in the country.

CONCLUSION

What is the biggest pharma opportunity in the country?

Anti-malarial products, cardio-vascular treatment. Ghana's pharmaceutical market is set to grow to US \$365 million market by 2019. Government is actively helping local pharmaceutical companies through banning the importation of widely used products such as ampiciline, tetracycline, chlorthalidone, indomethacin, paracetamol, aspirin and diazepam.¹²⁶ Ghana's National Health Insurance Scheme (NHIS) will raise the demand for pharmaceutical products.

What is the biggest hurdle to local production of drugs in the country?

Access to funds and Cost of funds for manufacturers to borrow to upgrade their facilities to WHO GMP levels. Rise in the amount of substandard and falsified pharmaceutical products, especially widely available substandard and/or falsified malaria medications is a big concern Unclear regulatory situation and unavailability of adequate workforce is a problem.

Country Profile 8:

KENYA



GENERAL OVERVIEW:

| | |
|--|---|
| Region | East Africa |
| Political Stability | -1.08; Rank: 184 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$74.93 billion 4.5% |
| Human Development Index (2107) | 0.590, Rank: 142 (<i>medium human development</i>) |
| General Government Debt Stock (2017) | US \$26.424 million; (<i>external debt % GDP (2017): 30.3</i>) |
| Availability of Basic Infrastructure (water, electricity) | 63% have access to drinking water; electricity power consumption 167 kWh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1963

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes, since May 2017.

Belt and Road Initiative (BRI) country?
Yes.

Bilateral investment Agreement?
Signed in 2001 (not in force).

Double Taxation Agreement?
Yes, since Sept 2017 (not in force).

Asian Infrastructure Investment Bank (AIIB) member? Yes (prospective).
Priority country for industrial cooperation? Yes.

Trade with China:

- *Imports (2017):* US \$4.20 billion;
- *Exports (2017):* US \$0.13 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$12.82 million; year-on-year growth rate: 5.59.

Top 3 Key products from China (% of total value of 2017 imports):

- API (26%)
- Hospital diagnostic equipment (24%)
- Formulations (17%)

Local manufacturing by Chinese companies (specify product and scale):

Automobile, machinery, home appliances, consumable products, ceramics.

What has been China's major economic impact in country to date?

Manufacturing, industrial cooperation, infrastructure development.

What could development partners (incl. China) contribute to for future development impact in the country?

Industrial capacity cooperation, investments in infrastructure and manufacturing.

Is Pharmaceutical production in top 5 priorities for country?

Yes, Kenya wants to establish universal health care system until 2030. Availability of locally produced medicine is one part of the universal health care system.

PHARMACEUTICAL MARKET SIZE

Population: 49.7 million.

GNI per capita (2017): US \$ 1.440.

Per capita spending on Health-PPP (2014): US \$169.

Healthcare spending in % of GDP (2014): 5.7%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): Kenya's pharmaceutical and health market has been estimated to be around \$797 million in 2015 and to reach US \$1.2 billion by 2020.

Unmet need (disease, numbers, drug, potential funder):

Non-communicable diseases, Malaria, Tuberculosis, HIV/AIDS.

Harmonization in region:

As member of the East African Community, Kenya has approved harmonized standards under African Medicines Regulatory Harmonization (AMHR) since January 2015 for Registration of Medicines, Good Manufacturing Practices (GMP), Quality Management System (QMS) and Information Management System (IMS). Under the ECA umbrella, Kenya plans to harmonize the regulatory functions in Pharmacovigilance (PV), Medical devices & diagnostic, Clinical Trials Oversight and Vaccine registration. Kenya has a comprehensive list of Clinical guidelines for common diseases.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production? No. However, Kenyan IP laws include regulation to enforce quality standards and to prevent the registration of medicines bearing labels

that mislead patients as to the characteristics of a drug.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business (2017): 23 days.

100% foreign ownership permitted?

Yes, investors are free to choose to operate their business with either 100% ownership or in partnership with local investor except in the Insurance, ICT, Air services and investments in the stock market.

Free allocation of land? Plan for Pharma Industrial Park?

Yes. Pharmaceutical manufacturers are encouraged to set-up in Kenya's Special Economic Zones.

Regulatory Process:

- *Average length of time to register new product:* Around 8-12 months under harmonized registration system. 3 months for fast-track registration of locally manufactured and priority medicines.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers suggests is weak. The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act is responsible for all regulatory measures to support the safety and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of consumers.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes, under country's investment rules.

Guarantee to purchase from local manufacturer? Pooled procurement?

Yes, through The Kenya Medical Supplies Authority (KEMSA).

Free inflow of capital & remittance of profits (Foreign Currency):

No restrictions.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Kenya has currently 35 licensed pharmaceutical manufacturers including:

- Cosmos pharmaceutical (sales volume 2017: US \$9.1 million) (local);
- GlaxoSmithKline (US \$8.1 million) (international): Main product: Pandol;
- Laborate (2.9 million) (local);
- Glenmark (2.9 million) (local);
- Ajanta Pharma (2.7 million) (local);
- Cipla Ltd (2.2 million) (local);
- Beta Healthcare (local);
- Universal Corporation Ltd. (local) (WHO pre-qualified)

- and distribution;
 - Need for the importation of APIs and essential medicines.
-

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

The medical device market in Kenya is estimated at US \$130 million.

Large device manufacturers dominate the market: GE Africa, Philips, Guided Therapeutics.

Interest in investment in health equipment manufacturing is growing. The Government of

Kenya plans to invest up to 600 million USD in procurement of health care devices until 2020.

CONCLUSION

What is the biggest pharma opportunity in the country?

Kenya's health sector is dominated by the public sector and the sector is expected to grow by 10.8% annually through 2019. Reasons are: increased government spending in line with Vision 2030, growing population, growing economic growth, growing trend in non-communicable and communicable disease. Growth trends in CDs and NCDs and insufficient provisions of health products provides opportunities for local health product production.

There is a huge need for investment in medical equipment and diagnostic equipment to support the health sector Vision 2030 plan.

Kenya requires a sophisticated health information system. There is a need for systems that can collect, validate and analyze health information.

Kenya plans to create health centres in the entire country with a need for furniture and medical devices.

Kenya is planning to increase the countries ARV users from 900k patients to 2,9 million patients until 2021 under a government program.

What is the biggest hurdle to local production of drugs in the country?

- Lack of specialized human resource for the pharmaceutical industry;
- Uneven distribution of healthcare infrastructure

Country Profile 9:

MADAGASCAR



| GENERAL OVERVIEW: | |
|--|---|
| Region | Southern Africa (Indian Ocean Islands) |
| Political Stability | -0.33; Rank: 142 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$11,49 billion 4.2% |
| Human Development Index (2107) | 0.519, No. 161 (<i>low human development</i>) |
| General Government Dept Stock (2017) | US \$ 3.376 million |
| Availability of Basic Infrastructure (water, electricity) | 52% have access to drinking water |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1972

High Level Visits from Chinese leadership since 2007: 1

Comprehensive Strategic Partnership?
Yes, since May 2017.

Belt and Road Initiative (BRI) country?
Yes.

Bilateral investment Agreement?
Signed in 2005 (in force 2007).

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?

Yes, since June 2018.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.86 billion;
- *Exports (2017):* US \$0.19 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$2.91 million (2017); year-on-year growth rate: 11.13.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (75%)

- Medical disposables (7%)
- Hospital diagnostic equipment (6%)

Local manufacturing by Chinese companies (specify product and scale):

Significant textile production, marine-based industries, mining.

What has been China's major economic impact in country to date?

Investment in Mining, fishing and marine industries.

What could development partners (incl. China) contribute to for future development impact in the country?

Further Investment in the marine industries, infrastructure development, support for textile industry development.

Is Pharmaceutical production in top 5 priorities for country?

Yes.

PHARMACEUTICAL MARKET SIZE

Population (2017): 25.6 million.

GNI per capita Atlas (2017): US \$ 400.

Per capita spending on Health –PPP (2014):
US \$ 43.7.

Healthcare spending in % of GDP (2014): 3.0% (2014).

Annual purchase of drugs – government (\$): US \$60 million (2015).

Annual purchase of drugs – private (\$):
Annual Purchase of drugs – donors (\$): in 2016, The Global Fund spent around US \$223 million for malaria and US \$44 million on HIV/AIDS and US \$24 million on Tuberculosis programs, including medicines.

Unmet need (disease, numbers, drug, potential funder): Maternal and child treatment, HIV, TB, Malaria, Cardiovascular diseases.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines. Madagascar only exports pharmaceutical products to the island of Comoros.

Harmonization in region:

Madagascar is not yet part of the African Medicine Regulatory Harmonization Scheme. Madagascar is part of the SADC protocols on health harmonization programmes.

- *Clinical guidelines for common diseases:* No
- *Medicines registration:* No.
- *GMP or other manufacturing certification:* Yes, there is a list of essential medicines (Liste Nationale des Medicaments Essentiels (LME) in Madagascar.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No. It is recommended that the country can increase its future access to medicines by maximizing these TRIPS flexibilities in the national Patent Act.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 11 days.

100% foreign ownership permitted?
Yes.

Free allocation of land? Plan for Pharma Industrial Park?

Yes.

Regulatory Process:

- *Average length of time to register new product:* 4 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines? There is an inspection service available, but feedback from distributors suggests is quite weak. The Medicines

Agency of Madagascar and the Ministry of Health & Family Planning is responsible for quality control of pharmaceutical products.

Tax incentives for local manufacturing?
Yes.

Import duty for drugs produced outside country?

No import duty for HIV/AIDS, TB, Malaria medicine.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

Public procurement of pharmaceuticals is done through the public agency, Centrale d'achat de médicaments essentiels et de consommables médicaux (SALAMA), buys mostly generics from India and China.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

There is no local production in Madagascar, instead there are a number of large distributors supplying essential medicines, in particular:

- Office Pharmaceutical Malagache (Opham)

- Farmad Pharmaceutical
- Salfa
- Somaphar
- Sopharmad

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

According to the Ministry of Health, Madagascar requires medical devices and laboratory equipment to strengthen the health sector delivery. All devices are currently being imported from abroad.

CONCLUSION

What is the biggest pharma opportunity in the country? Production of affordable medicines, especially generics for HIV/AIDS, TB and Malaria treatment.

What is the biggest hurdle to local production of drugs in the country?

- No adequate infrastructure; nearly all of Madagascar's pharmaceutical needs are derived from import.
 - No adequate human resource available.
-

Country Profile 10:

MALAWI



GENERAL OVERVIEW:

| | |
|--|---|
| Region | Southern Africa |
| Political Stability | -0.27; Rank: 137 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$6.303 billion 4.0% |
| Human Development Index (2107) | 0.477; Rank: 171 (low human development) |
| General Government Debt Stock (2017) | US \$ 2.160 million; (external debt % GDP (2014): 39.4) |
| Availability of Basic Infrastructure (water, electricity) | 90% of the population has access to drinking water |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 2007 (initially 1964).

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
No.

Belt and Road Initiative (BRI) country?
No.

Bilateral investment Agreement?
No.

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
No.

Trade with China:

- Imports (2017): US \$0.35 billion;
- Exports (2017): US \$0.04 billion;

Imports of Chinese pharmaceutical and health products:

- Total (2017): US \$1.56 million; year-on-year growth rate: 61.12.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (74%)

- Hospital diagnostic equipment (8%)
- Medical accessories (7%)

Local manufacturing by Chinese companies (specify product and scale):

Agriculture, fishing, construction materials.

What has been China's major economic impact in country to date?

Agriculture, Mining, Manufacturing (fertilizer), construction.

What could development partners (incl. China) contribute to for future development impact in the country?

Infrastructure development, agricultural development.

Is Pharmaceutical production in top 5 priorities for country?

No. Pharmaceutical production is currently not a major priority in the country.

PHARMACEUTICAL MARKET SIZE

Population (2017): 18,6 million.

GNI per capita Atlas (2017): US \$ 320.

Per capita spending on Health- PPP (2014): US \$ 93.5.

Healthcare spending in % of GDP (2014): 11.4%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): In

2016, The Global Fund distributed US \$676 million on fighting HIV/AIDS and US \$162 million to fight Malaria in the country.

Unmet need (disease, numbers, drug, potential funder):

Malaria, HIV/AIDS, Tuberculosis, Hypertension and cancer.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

No MOUs with neighboring countries on approval, registration, and distribution of medicines have been signed.

Harmonization in region:

Malawi is not part of the African Medicine Regulatory Harmonization Scheme.

- *Clinical guidelines for common diseases:* The Health Protocol issued by SADC in 1999 has clarified the common health concerns in the region, including Malaria, HIV, communicable disease and other common disease in the region.
- *Medicines registration:* Malawi is not yet part of a common medicine registration system.
- *GMP or other manufacturing certification:* It is currently not available.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No. However, pressure increased from the African Regional Intellectual Property Organization (ARIPO) in 2017, to utilize flexibilities in intellectual property law in Malawi to ensure that people can access medicines and other essential health technologies.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 37 days.

100% foreign ownership permitted?

Yes.

Free allocation of land? Plan for Pharma Industrial Park?

No.

Regulatory Process:

- *Average length of time to register new product:* 3–4 months, however there are frequent delays in the registration process.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from manufacturers and distributors suggests is weak. Fake anti-Malaria medicines are reportedly being sold by street vendors in Malawi. The Pharmacy, Medicines & Poisons Board (PMPB) provide regulatory mechanisms that promotes the availability and use of safe and good quality medicines. The National Drug Quality Control Laboratory (NDQCL) provides support to the PMPB for the testing of drugs. Assessment in 2011 stated NDQCL was not accredited by WHO, however the lab would send some samples to a WHO accredited lab in South Africa.

Tax incentives for local manufacturing?

No.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Yes. Under the Industrial Rebate Scheme, raw materials for the manufacture of pharmaceuticals are both import and VAT free.

Guarantee to purchase from local manufacturer? Pooled procurement?

No guarantees are provided to local manufacturers.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes, it is possible to bring in and take out capital

without restrictions.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- Crown pharmaceuticals (local): produces antibiotics, paracetamol, ibuprofen;
- Pharmanova Ltd. (local) produces Panado, Cafemol and Novaspirin;
- Kentam Ltd (local); produces Bufen, Kilpain, Kilpain Pc;
- SADM Pharmaceuticals Ltd. (local).

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Currently, Malawi imports all medical devices and laboratory equipment. There is a need for all sorts of devices and equipment.

CONCLUSION

What is the biggest pharma opportunity in the country? In Malawi, there is a huge need for medicine for both chronic and non-chronic diseases, especially those affordable and effective medicines for local people. Medicines for an

Public health institutions are often running out of medicine. The largest purchaser of medicines in Malawi is the Central Medicine Store (CMS). Medicines purchased by the CMS makes up 70-90% of all medicine consumed in Malawi. Hence providing a steady stream of supply of essential medicine to this institution is a big opportunity.

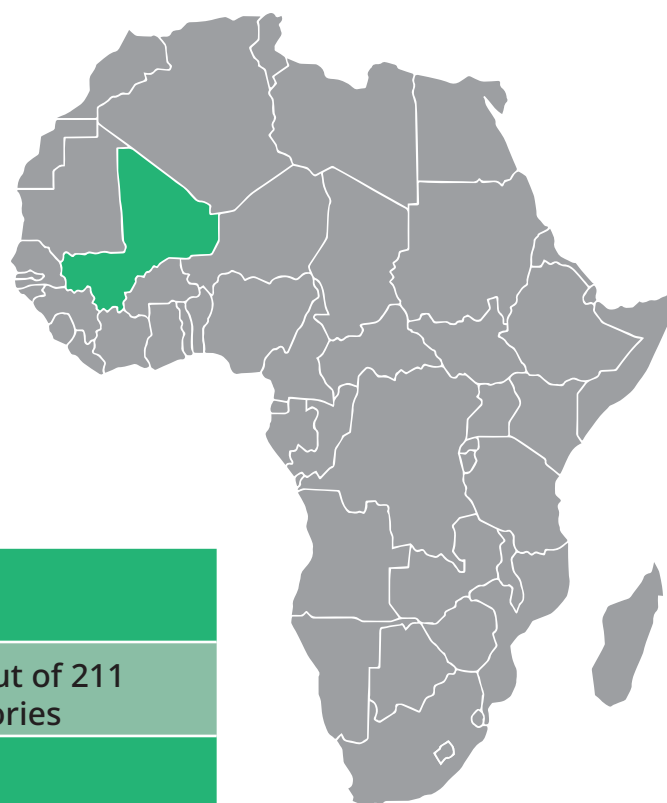
Producing and selling generics in Malawi provides for a good opportunity.

What is the biggest hurdle to local production of drugs in the country?

- Poor infrastructure that makes production and distribution of medicines very expensive and time consuming.
- There is a weak institutional capacity and a booming trade in substandard and falsified drugs.

Country Profile 11:

MALI



| GENERAL OVERVIEW: | |
|--|---|
| Region | West Africa |
| Political Stability | -1.91; Rank: 198 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$15.28 billion 5.3% |
| Human Development Index (2107) | 0.427; Rank: 182 (<i>low human development</i>) |
| General Government Dept Stock (2017) | US \$ 4.368 million |
| Availability of Basic Infrastructure (water, electricity) | 77% of the population has access to drinking water |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1960

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?

No – although in 2010 a joint committee for Economic, Trade and Technological Joint Committee was established.

Belt and Road Initiative (BRI) country?

No.

Bilateral Investment Agreement?

Yes – since 2009.

Double Taxation Agreement?

No.

Asian Infrastructure Investment Bank (AIIB) member? No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.58 billion;
- *Exports (2017):* US \$0.10 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$3.02 million (2017); year-on-year growth rate: -5.11.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (84%)
- Medical accessories (6%)
- Medical disposables (5%)

Local manufacturing by Chinese companies (specify product and scale):

Sugar production, construction companies, agro-industry (cotton).

What has been China's major economic impact in country to date?

Infrastructure development, esp. railway development, mineral resources (esp. Iron Ore and bauxite development), and security cooperation.

What could development partners (incl. China) contribute to for future development impact in the country?

Infrastructure development and investment into power projects.

Is Pharmaceutical production in top 5 priorities for country?

No.

PHARMACEUTICAL MARKET SIZE

Population (2017): 17,46 million.

GNI per capita Atlas (2017): US \$ 770.

Per capita spending on Health- PPP (2014): US \$ 108.

Healthcare spending in % of GDP: 6.9%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): US \$10 million USD (Malaria Initiative) Mali has a CFA 60 billion pharmaceutical Market. Mostly wholesale business with branded pharmaceutical products sourced from European suppliers.

Unmet need (disease, numbers, drug, potential funder): Lower respiratory infections, HIV/TB/ Malaria, preterm birth complications.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: No MOUs with neighboring countries.

Harmonization in region:

Mali is part of the West African Medicine Harmonization Programme.

- *Clinical guidelines for common diseases:* Mali has an essential medicines list in place.
- *GMP or other manufacturing certification:* No GMP certification in place, Humanwell (see below) is a GMP compliant plant.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Current information suggests no flexibilities have

been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 9 days.

100% foreign ownership permitted?

No.

Free allocation of land? Plan for Pharma Industrial Park?

No.

Regulatory Process:

- *Average length of time to register new product:* 6 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from distributors and manufacturers suggests it is quite weak. Substandard and falsified pharmaceutical products pose real problems in Mali and represent about 55-60% of the market or CFA 60 billion according to the Ordre des Pharmaciens du Mali (National Association of Pharmacists).

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

No, it is revised every two years.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

Private wholesaler provide most of the Malian government pharmaceutical needs through the Pharmacie Populaire du Mali (PPM) through a three-year contract.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Mali imports the majority of pharmaceutical products, due to lack of local production.

Humanwell Health Care Group is a Chinese pharmaceutical company which benefitted from China Africa Development Fund (CADFund) support to establish local production in Mali. It is GMP standard and provides the local market with medicine products

that are part of the essential list.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Medical devices in Mali are provided through imports. There is a need for laboratory equipment and medical devices as medical institutions lack basic instruments. Local production of basic equipment could alleviate current shortage. Due to unavailability of essential devices, second-hand market for medical devices is growing in Mali.

CONCLUSION

What is the biggest pharma opportunity in the country? Mali has a good supply chain system and imports most of its essential pharmaceutical products from Europe (France). A local production for essential medicine would help to make medicine readily available.

What is the biggest hurdle to local production of drugs in the country?

Illegal imports and the import of substandard and falsified pharmaceutical products pose real problems in Mali.

Country Profile 12:

MAURITIUS



GENERAL OVERVIEW:

| | |
|--|---|
| Region | East/Southern Africa; Indian Ocean Island |
| Political Stability | 0.99; Rank: 39 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$13,33 billion 3.8% |
| Human Development Index (2107) | 0.790, No. 65 (<i>high human development</i>) |
| General Government Debt Stock (2017) | US \$ 21.067 million |
| Availability of Basic Infrastructure (water, electricity) | 100% of the population has access to drinking water; electric power consumption (kWh per capita) is 2,183 |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1972

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?

No – but is only African country to have a Free Trade Agreement with China (since Sept. 2018).

Belt and Road Initiative (BRI) country?

No.

Bilateral Investment Agreement?

Yes – since 1996 (in force 1997).

Double Taxation Agreement?

Yes – since 1994 (amended 2006).

Asian Infrastructure Investment Bank (AIIB) member? No.

Priority country for industrial cooperation? No.

Trade with China:

- *Imports (2017):* US \$0.86 billion;
- *Exports (2017):* US\$ 0.03 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$0.88 million (2017); year-on-year growth rate: -16.54.

Top 3 Key products from China (% of total value of 2017 imports):

- Hospital diagnostic equipment (18%)
- Medical disposables (21%)

- Medical accessories (6%)

Local manufacturing by Chinese companies (specify product and scale):

Tourism, financial services, industrial zone and Smart City development.

What has been China's major economic impact in country to date?

Mauritius so far been a top destination for Chinese finance on the African continent. There has been some development of the hospitality, tourism and health industry specifically for upper-class Chinese clients.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment is needed into education/skills (to stimulate competitiveness in the manufacturing sector) as well as climate change management (as a small island).

Is Pharmaceutical production in top 5 priorities for country?

Yes.

PHARMACEUTICAL MARKET SIZE

Population (2017): 1.25 million.

GNI per capita Atlas (2017): US \$ 10,140.

Per capita spending on Health- PPP (2014): US \$ 896.2.

Healthcare spending in % of GDP: 4.8% (2014).

Annual purchase of drugs – government (\$): US \$20 million (2014).

Annual purchase of drugs – private (\$): Out of pocket spending on drugs US \$94.15 million (2014).

Annual Purchase of drugs – donors (\$): In 2016, Global Fund disbursed cumulative US \$10 million for treatment of HIV/TB/Malaria. In 2015, total pharmaceutical market size in Mauritius is 122 million USD.

Unmet need (disease, numbers, drug, potential funder):

Non-communicable diseases, diabetes, hypertension.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Mauritius is part of the SADC medicine regulatory harmonization scheme. It is working closely within the SDAC framework to establish registration guidelines for medicines.

Harmonization in region:

- *Clinical guidelines for common diseases:* Essential Medicine Lists are available in Mauritius and Mauritius uses treatment guidelines for common

diseases.

- *Medicines registration:* The Medicine Regulatory Authority is responsible for medicine registration in Mauritius.
- *GMP or other manufacturing certification:* Yes. There are manufacturer that have GMP certification.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No – the country is no longer eligible for TRIPS flexibilities. However, in 2009 Mauritius adopted a National IP Policy to support the importance of the role that IP plays in the sustainable economic and cultural development of the country.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 7 days.

Free allocation of land? Plan for Pharma Industrial Park?

Yes. Mauritius is establishing a pharmaceutical village in the southern part of the island.

Regulatory Process:

- *Average length of time to register new product:* 4-6 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from distributors and manufacturers suggests is strong. The Medicines Regulatory Authority (MRA) under the Ministry of Health and Quality of Life is responsible for quality and market control of drugs. Laboratory testing exists in Mauritius for Quality Control yet this laboratory is not a functional part of the MRA. As of 2011, existing national laboratory facilities were not yet accepted for collaboration with the WHO pre-qualification Programme.

Tax incentives for local manufacturing?

Yes. The Government of Mauritius has established an investment tax credit of 15% over three years for manufacturers of pharmaceuticals and eight years of tax holidays for new companies entering into production of medicine on the island.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Yes, there are incentives in place to encourage local production.

Guarantee to purchase from local manufacturer? Pooled procurement?

There is no explicit guarantee, however, the government purchases mostly generic medications through tenders issued throughout the year according to an established annual procurement plan.

**Free inflow of capital & remittance of profits
(Foreign Currency):**

Yes. There are 35 registered wholesalers of Pharmaceutical products. Only wholesalers are allowed to import medicine into the country and they control the market.

There is some limited local production – e.g.

- Ajanta Pharma (local), produces Over The Counter (OTC) medications for the local market.

OTHER INTERESTS IN HEALTH INVESTMENTS

**Medical Devices, Laboratory equipment,
Laboratory reagents, Hospital furniture?**

Medical devices and laboratory equipment are mostly imported from Europe and USA. There is a growing need for devices used for treatment of NDCs, specifically cancer diagnosis. Out of pocket spending on medical supplies and disposables was US \$70 million in 2014.

CONCLUSION

What is the biggest pharma opportunity in the country?

A lot of medicine in Mauritius is imported- especially medicines for diabetes, cancer and cardio vascular treatment. A production (packaging) site targeting import-substitution of these products could be a good opportunity. Mauritius is also becoming a new destination for bio-medicine development on the African continent. Mauritius is also a growing medical tourism destination.

What is the biggest hurdle to local production of drugs in the country?

The market size is very small, however, the island can be seen as a gateway or a destination for other African countries, especially in East Africa with closer/more frequent air links.

Country Profile 13:

MOZAMBIQUE



| GENERAL OVERVIEW: | |
|--|---|
| Region | Southern Africa |
| Political Stability | -0.98; Rank: 181 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | \$12.33 billion 3.7% |
| Human Development Index (2107) | 0.437, No. 180 (<i>low human development</i>) |
| General Government Dept Stock (2017) | USD \$ 12.010 million |
| Availability of Basic Infrastructure (water, electricity) | 62% of the population have access to water; electric power consumption: 462 Kwh per capita (2014) |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1975.

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
Yes – since 2016.

Belt and Road Initiative (BRI) country?
No.

Bilateral Investment Agreement?
Yes – since 2001 (in force 2002).

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?
No.

Priority country for industrial cooperation?
Yes.

Trade with China (in \$, use 2016 or latest data)
Trade with China:

- *Imports (2017):* \$0.71 billion;
- *Exports (2017):* \$0.35 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$2.43 million; year-on-year growth rate: -10.18.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (23%)
- Medical disposables (21%)
- Medical accessories (18%)

Local manufacturing by Chinese companies (specify product and scale):

agriculture, fisheries, construction, mining and off shore processing of liquefied natural gas.

What has been China's major economic impact in country to date?

Infrastructure development, ocean economy development, agriculture and mining.

What could development partners (incl. China) contribute to for future development impact in the country?

Importation of machines for agriculture, construction and manufacturing industry, funding for industrialization and infrastructure development.

Is Pharmaceutical production in top 5 priorities for country?

No.

PHARMACEUTICAL MARKET SIZE

Population (2016): 29.7 million.

GNI per capita Atlas (2017): US \$ 420.

Per capita spending on Health- PPP (2015): US \$28.

Healthcare spending in % of GDP (2014): 3.9%.

Annual purchase of drugs – government (\$): ca. \$122 million. The Central de Medicamentos e Artigos Medicos (Central Medical Store Administration – CMAM) is responsible for the procurement of essential medicines and pharmaceuticals for the government health system.

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): The Ministry of Health relies heavily on assistance from foreign donors. Global Fund, the World Bank and USAID are active in addressing HIV/AIDS. The Global Fund has so far disbursed US \$716,8 million for HIV/ Malaria and TB programmes (2016).

Unmet need (disease, numbers, drug, potential funder):

HIV/AIDS, Malaria, tuberculosis, NDCs such as hypertension, diabetes and cancer, are on the rise, affecting a considerable portion of the population.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: Yes, through SADC.

Harmonization in region:

Yes, as a SADC member, Mozambique is part of the ongoing activity to create a harmonization strategy

in the region, as well as a collective Registration of Medicines among SADC countries.

- *Clinical guidelines for common diseases:* Yes. There is a common disease treatment guideline and essential medicine list in Mozambique.
- *GMP or other manufacturing certification:* Yes; two pharmaceutical companies are GMP certified by the local Pharmaceutical Regulatory Body.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

No. A 2012 Musungu report mentions that the Patent Act does not allow parallel import (National exhaustion only, Art. 68(b)), does not have a Bolar clause and only offers a compulsory license on the grounds of non-working or an emergency. The country can increase its future access to medicines by maximizing these TRIPS flexibilities in its national Patent Act.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 19 days.

100% foreign ownership permitted?

No.

Free allocation of land? Plan for Pharma Industrial Park?

No.

Regulatory Process:

- *Average length of time to register new product:* Up to 12 months for medical registration. Market authorization is obtained from the Ministry of Health to sell medicine.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from distributors and manufacturers suggests is very weak. USAid under the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program has been working with the Ministry of Health (MOH) of Mozambique to strengthen the functionality of the pharmaceutical sector by building institutional and individual capacity however prevention of substandard and falsified drugs remains minimal. Some drug laboratories have been tested by the WHO- AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

No. Government often invites foreign companies to bid for tenders of medical devices as well as pharmaceutical drugs. The procurement management unit (UGEA) is the agency responsible for purchasing material for the Ministry of Health, including all medical equipment and supplies for all public health care centres in the country.

Free inflow of capital & remittance of profits (Foreign Currency):

No. There are foreign currency controls in place.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

The market is dominated by the public sector that imports drugs through the Ministry of Health's Central Drugs and Medical Supplies Agency (CMAM) and by a highly concentrated group of private importers/wholesalers selling to a retailing network of 264 private pharmacies, 40 publicly owned retailers. Stride Pharma (origin: India, 100% private) and Sociedade Mocambicana de Medicamentos (SMM – Mozambique state-owned) are the only medicines manufacturers within the country. Both of them produce for the Government (MoH). Otherwise, the country imports most of its pharmaceutical drugs and it often faces supply shortages, especially for high-end antibiotics and vitamins. Particular companies in this space are:

- Farmac (state-owned pharmaceutical company supplying the pharmacies);
- Medimoc (responsible for importing of medicines);
- Utomi
- Dra L Fung
- Director Geral

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

The medical device industry in Mozambique is highly dominated by Indian, Brazilian and Chinese suppliers. Most of the diagnosis equipment are from Europe. There is very little local production of medical devices. There is a high demand for used medical equipment, such as hospital beds for small and mid-sized private health clinics, diagnostic centres and laboratories. Population growth is fuelling the demand for medical devices and diagnostic equipment.

CONCLUSION

What is the biggest pharma opportunity in the country?

Growth in Mozambique's pharmaceutical market will be driven by a growing chronic disease burden and

the government's efforts to achieve universal health coverage through its 2014-2019 Health Sector Strategic Plan.

Large-scale projects in the mining, oil and gas sectors are driving demand for well-equipped healthcare facilities in remote areas.

Government plans to develop healthcare infrastructure with the aid of foreign investors is opening new opportunities.

What is the biggest hurdle to local production of drugs in the country?

- Theft of medicines and equipment and abundance of substandard and falsified drugs.
- Lack of health infrastructure.
- Lack of regulation for traditional medicine practices and products.

Country Profile 14:

NIGERIA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | West Africa |
| Political Stability | -1.94; Rank: 200 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$375.77 billion 0.8% |
| Human Development Index (2107) | 0.532, Rank 157 (<i>low human development</i>) |
| General Government Debt Stock (2017) | US \$ 40.238 million (<i>external debt % GDP (2017): 5.1</i>) |
| Availability of Basic Infrastructure (water, electricity) | 69% of the population has access to drinking water; electric power consumption in 2016 is 144 kWh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1971.

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes – since 2005.

Belt and Road Initiative (BRI) country?
No, but interest expressed.

Bilateral Investment Agreement?
Yes – since 1997 (updated 2001).

Double Taxation Agreement?
Yes – since 2002 (effective 2010).

Asian Infrastructure Investment Bank (AIIB) member? No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$12.36 billion;
- *Exports (2017):* US \$1.74 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$30.21 million; year-on-year growth rate: 18.98.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (36%)
- API (31%)

- Biochemicals (8%)

Local manufacturing by Chinese companies (specify product and scale):

Home appliances, construction materials, car and motorcycle assembly, pharmaceutical production, furniture and wood products, plastic industry.

What has been China's major economic impact in country to date?

Oil and Gas industry, infrastructure development, light manufacturing.

What could development partners (incl. China) contribute to for future development impact in the country?

Financing, infrastructure development, investment into light manufacturing.

Is Pharmaceutical production in top 5 priorities for country?

Yes, Nigeria want to advance the pharmaceutical industry into new level with increasingly efficient and GMP approved production sites.

PHARMACEUTICAL MARKET SIZE

Population (2017): 190.9 million.

GNI per capita Atlas 2017: US \$ 2.080.

Per capita spending on Health- PPP (2014): US \$216.9.

Healthcare spending in % of GDP: 3.7%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): In 2016, The Global Fund spent US \$944 million on malaria, US \$713 million on HIV/AIDS and US \$186 million on tuberculosis treatment in Nigeria, including on medications.

Unmet need (disease, numbers, drug, potential funder):

Nigeria's pharmaceutical market size was 889 million USD in 2015. Unmet needs include in particular Lower Respiratory Infections, HIV/AIDS, Tuberculosis, Malaria, Diarrheal diseases.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: Nigeria exports locally-produced pharmaceutical within ECOWAS as well as WAEMU regions.

Harmonization in region:

Nigeria is part of The West African Medicines Regulatory Harmonization (MRH) programme since 2015. Together with other West African countries, it has established Technical working groups to develop guidelines for the MRH programme.

- *Clinical guidelines for common diseases:* There is a common medicine list and guidelines for common

diseases.

- *GMP or other manufacturing certification:* Yes. Nigeria has several GMP approved pharmaceutical companies (see further below).

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Current information suggestions no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 25 days.

100% foreign ownership permitted? Yes.

Free allocation of land? Plan for Pharma Industrial Park?

No. However, pharmaceutical companies can invest in existing Special economic zones in the country.

Regulatory Process:

- *Average length of time to register new product:* 4 months up to 3 years.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

The National Agency for Food and Drug Administration (NAFDAC) under the Ministry of Health is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of drugs. This body was reformed in 2001 however it still remains weak in preventing substandard and falsified drugs.

Tax incentives for local manufacturing? Yes, but very weak.

Import duty for drugs produced outside country?

Yes. A Minimum 20% tariff must be paid on imported products.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

No guarantee to buy from local manufacturers.

Free inflow of capital & remittance of profits (Foreign Currency):

No. But there is some degree of foreign currency control in Nigeria.

PHARMACEUTICAL

COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- Swiss Pharma Nigeria Ltd (WHO GMP certified);
- Evans Medical Plc (WHO GMP certified);
- Chi Pharmaceutical Ltd (WHO GMP certified);
- GlaxoSmithKline (GSK) vaccines and anti-viral drugs; May and Baker Nigeria Plc (GMP certified);
- Agari (GMP certified);
- Juhel (in the process to get GMP certification);
- Phamatex (in the process to get GMP certification);
- Afrabchem (in the process to get GMP certification);

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Nearly all market needs for medical devices are supplied by imports. There is a strong demand for diagnostic equipment such as Magnetic Resonance Imaging (MRI), Computed Tomography scan (CT), Digital X-Ray, Ultrasound, Mammography and Ultrasound Scans, and other diagnostic technologies. The market for medical devices is estimated at \$100 million. There is also a need for building more adequate hospitals and health centres.

CONCLUSION

What is the biggest pharma opportunity in the country?

Low-cost generic and OTC drugs are in high demand as the purchasing power of the population is weak and government is looking for a cheap way to provide essential medicines.

Production of generic antiretroviral drugs for a high number of HIV/ AIDS patients.

Medical disposables especially for testing for malaria parasites, drug abuse, and infectious diseases such as HIV/AIDS and tuberculosis are needed.

Anesthesia equipment, infant and maternal care technologies.

Hospital administration, management and consulting services.

What is the biggest hurdle to local production of drugs in the country?

- Lack of facilities for the management of cold-chain products, including standard warehouses for storing.
- Lack of effective regulatory framework and policies, corruption, scarcity and poor distribution of healthcare professionals.

Country Profile 15:

RWANDA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | East Africa |
| Political Stability | 0.04; Rank: 111 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$9,13 billion 6.1% |
| Human Development Index (2107) | 0.524; Rank: 158 (<i>low human development</i>) |
| General Government Dept Stock (2017) | US \$ 3.338 million |
| Availability of Basic Infrastructure (water, electricity) | 76% of the population has access to drinking water |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1971

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
No.

Belt and Road Initiative (BRI) country?
Yes – since July 2018.

Bilateral Investment Agreement?
No.

Double Taxation Agreement?
Yes.

Asian Infrastructure Investment Bank (AIIB) member? No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.28 billion;
- *Exports (2017):* US \$0.04 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$0.42 million; year-on-year growth rate: 5.29.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (51%)
- Hospital diagnostic equipment (20%)

- Medical accessories (11%)

Local manufacturing by Chinese companies (specify product and scale):

Light Manufacturing, garment and textiles, construction materials.

What has been China's major economic impact in country to date?

Infrastructure building (roads in particular), early textiles manufacturing.

What could development partners (incl. China) contribute to for future development impact in the country?

Further investment in Rwanda's industrialization, especially in industrial parks (clusters), and textile and garments and light industries. Also welcome investment in infrastructure development, ICT and education.

Is Pharmaceutical production in top 5 priorities for country?

To some degree - the sector is considered an important driver of Rwanda's industrialization process.

PHARMACEUTICAL MARKET SIZE

Population (2017): 12.2 million.

GNI per capita Atlas (2017): US \$ 720.

Per capita spending on Health –PPP (2014): US \$ 125.

Healthcare spending in % of GDP (2014): 7.5%.

Annual purchase of drugs – government (\$): US \$22 million (2015).

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): Rwanda imports annually approx. US \$100 million worth of pharmaceutical products. 95% of medicines are imported mainly from India, China, Malaysia and Europe.

Unmet need (disease, numbers, drug, potential funder): Acute Respiratory Infections, HIV/TB/ Malaria, Diarrhea diseases.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: Rwanda and Uganda have signed import and distribution rights for medicines in 2014.

Harmonization in region:

Rwanda is part of the East African Countries (EAC) Medicines Regulatory Harmonization (MRH) programme since 2012 and has adopted the harmonized technical guidelines by the EAC Council in 2014. Rwanda has also approved selected products through the World Health Organization Medicines Prequalification Program (WHO-PQP) and the EAC Joint Assessments and Inspections programme.

- *Clinical guidelines for common diseases:* Yes, there is a National Essential Medicines list and different guidelines dealing with common diseases.
- *GMP or other manufacturing certification:* All medicines that are imported to Rwanda need to have GMP certification. Rwanda also follows the Eastern African countries common medicine registration scheme.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

In 2006 the Government of Rwanda passed a law requiring generic medicines to be used for all treatment programmes when available and in 2007 Rwanda became the first country to announce its intention to use the WTO 30 August 2003 decision to import a generic fixed-dose combination of zidovudine, lamivudine and nevirapine from a Canadian generic manufacturing company. To date, Rwanda is the only country to have used this flexibility.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business:

According to government sources - 6 hours, online application, free of charge.

100% foreign ownership permitted?

Yes.

Free allocation of land? Plan for Pharma Industrial Park?

Yes – for instance Cooper Pharma (see further) received land free of charge.

Regulatory Process:

- *Average length of time to register new product:* 3-6 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

There is a system in place however, feedback from distributors and manufacturers suggests is quite weak. In 2018, Rwanda passed a regulation establishing the Food and Drugs Authority. This body will be responsible for regulating compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of drugs. Some drug laboratories have been tested by the WHO-AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes. No taxes are levied on such ingredients.

Guarantee to purchase from local manufacturer? Pooled procurement?

Rwanda buys essential medicine through the “Coordinated Procurement and Distribution System” by the Medical Production and Procurement Division.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes, there are no legal restrictions for repatriation of profits.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

SOPHAR Ltd is a big pharmaceutical importer and distributor that consist of 58 different pharmacies under the Association of Pharmacists in Rwanda. It imports branded drugs, medical equipment, consumables and laboratory reagents. Cooper Pharma, a Moroccan pharmaceutical company, plans to build a US\$6 million worth pharmaceutical plant in Kigali Special Economic Zone. This will be the first local pharmaceutical manufacturing plant that is also GMP approved.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Rwanda is importing almost all medical devices and laboratory equipment. There is a growing market with the establishment of a functioning health insurance system.

CONCLUSION

What is the biggest pharma opportunity in the country?

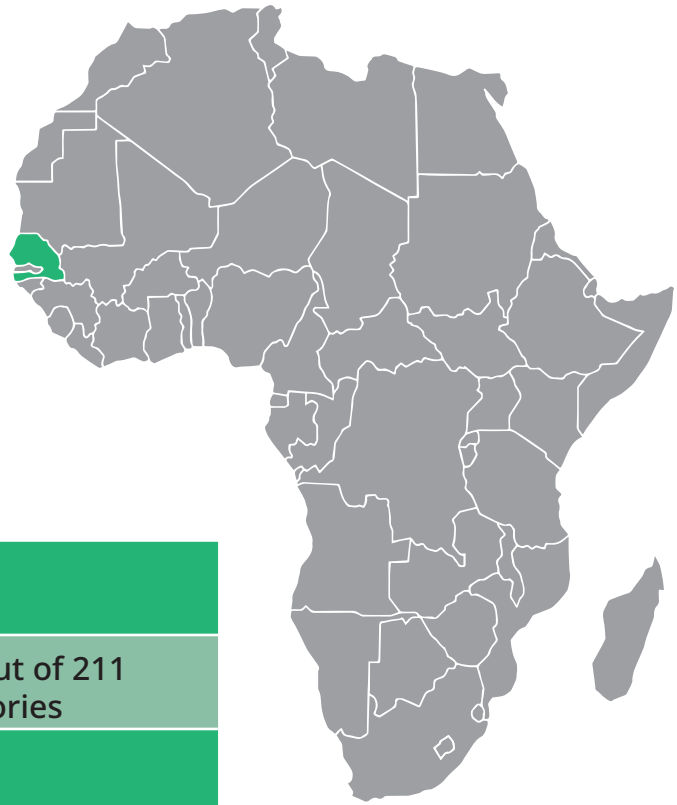
Pharmaceutical manufacturing presents a good investment opportunity, largely due to the growing market for pharmaceutical products as shown by the growth of pharmaceutical imports. Rwanda is increasingly considered a hub for the region, especially DRC and EAC countries. Health insurance scheme guarantees growing market for pharmaceutical products.

What is the biggest hurdle to local production of drugs in the country?

- Insufficiently trained personnel in the pharmaceutical sector.
- No adequate infrastructure for production, the first local manufacturing to be operational only in 2019.

Country Profile 16:

SENEGAL



GENERAL OVERVIEW:

| | |
|--|---|
| Region | West Africa |
| Political Stability | -0.04; Rank: 120 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$16.37 billion 6.8% |
| Human Development Index (2107) | 0.505; Rank: 164 (low human development) |
| General Government Debt Stock (2017) | US\$ 8.886 million |
| Availability of Basic Infrastructure (water, electricity) | 79% of the population has access to drinking water; electricity consumption (Kwh per capita) is 223 |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 2005 (initially 1973)

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
Yes, since 2016.

Belt and Road Initiative (BRI) country?
Yes, since July 2018.

Bilateral investment Agreement?
No.

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?
No.

Priority country for industrial cooperation?
No.

Trade with China:

- Imports (2017): US \$1.12 billion;
- Exports (2017): US \$0.12 billion;

Imports of Chinese pharmaceutical and health products:

- Total (2017): US \$4.57 million; year-on-year growth rate: -4.32.

Top 3 Key products from China (% of total value of 2017 imports):

- API (32%)

- Medical Disposables (23%)
- Hospital diagnostic equipment (18%)

Local manufacturing by Chinese companies (specify product and scale):

Garment and textiles, fish processing industry, wholesale trade in consumable products.

What has been China's major economic impact in country to date?

Light manufacturing, agriculture and fisheries, security cooperation.

What could development partners (incl. China) contribute to for future development impact in the country?

Infrastructure development, agricultural modernization and industrialization.

Is Pharmaceutical production in top 5 priorities for country?

Yes. Senegal addresses public health issues through the Plan National de Développement Sanitaire within which pharmaceutical production plays a role.

PHARMACEUTICAL MARKET SIZE

Population (2017): 15.9 million.

GNI per capita Atlas (2017): US \$ 950.

Per capita spending on Health –PPP (2016): US \$ 106.

Healthcare spending in % of GDP (2014): 4.7%.

Annual purchase of drugs – government (\$):

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$): In 2016, The Global Fund spent US \$121 million on HIV/AIDS, US \$118 million on malaria and US \$23 million on TB treatment, including medication. In 2014, Senegal imported 193 million worth of pharmaceutical products, and exported 13 million worth of products to countries in West Africa.

Unmet need (disease, numbers, drug, potential funder): Malaria, HIV, Tuberculosis, maternal mortality, Acute Respiratory Infections and neglected tropical diseases.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Senegal exports to neighboring countries.

Harmonization in region:

Senegal is part of the West Africa Medicines Regulatory Harmonization (MRH) programme since 2015. It participated in the establishment of the joint MRH Project Steering Committee and formation of 7 Technical Working Groups (TWG's) that are developing technical guidelines of the MRH programme. There is a list of Essential Medicines that is being revised every

two years.

- *GMP or other manufacturing certification:* Senegal uses GMP certification to procure pharmaceutical products.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Current information suggests no flexibilities have been incorporated in the national legislation or have been used in the past.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 6 days.

100% foreign ownership permitted?

No.

Free allocation of land? Plan for Pharma Industrial Park?

The Diamniadio Special Economic Zone is being built to attract investment, including from the pharmaceutical sector.

Regulatory Process:

Direction de la Pharmacie et Médicament (DPM) is responsible for the registration of medicament.

- *Average length of time to register new product:* 6 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

There is quality assurance systems in place however, feedback from distributors and manufacturers suggests some weaknesses. The Pharmacie Nationale d'Approvisionnement (PNA) is responsible for regulating drugs.

Tax incentives for local manufacturing?

Yes, available.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes.

Guarantee to purchase from local manufacturer? Pooled procurement?

The technical arm of the Ministry of Health of Senegal Pharmacie Nationale d'Approvisionnement (PNA) is the main public institution for procurement of pharmaceuticals. It procures every two years medicaments through international tenders. 90% are sourced internationally and 10% from local manufacturer. It also provides medicaments to the six approved wholesalers.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes. Most of the drugs (approx. 90%) used in Senegal are imported- mostly from France, India and China by big wholesale companies. There are in total 6 authorized wholesalers, in particular: Laborex (approx. 49% market share) Cophase (30% market share) Sodipharm (17% market share).

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

There is some local manufacturing in Senegal. All local manufacturers produce licensed and generic pharmaceuticals such as antimalarials, antibiotics, analgesics, anti-tuberculosis, vaccines, vitamins and other essential medicines. All also export to other West African countries. Key names include:

- Sanofi West Africa (international)
- Pasteur Institute in Dakar manufactures the vaccine against yellow fever (anti-amaril vaccine) and makes Senegal one of the three largest producers in the world of this vaccine;
- Médis (international) - bought Wintrop Pharma Senegal from Sanofi to produce for the French speaking African countries. It supplies West African countries with essential medicines;
- The Cannone SA Vladafrigue (local) manufactures powders and creams * West Africa Pharma (local).

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Medical devices are mostly provided through public procurement. State procurement requires that the medical devices are new, and mostly European Standards. However, private companies do import some used medical devices. There is a strict demand by the regulator to have aftersales services for medical devices imported into the country.

CONCLUSION

What is the biggest pharma opportunity in the country?

Currently, local production only covers 10% of the needs. Market proximity could play role to start local production to save importation cost. The Growing population signals a growing need for medication. The Senegal Emerging Plan (PSE) provides huge incentives for pharma opportunity and aims to build a hub for the sub-region.

What is the biggest hurdle to local production of drugs in the country?

- The Senegalese market is small – so any local manufacturing needs to focus more broadly on West African country markets. Strong private sector supply chain involvement in pharmaceutical supply.
- Lack of adequate human resources.

Country Profile 17:

SOUTH AFRICA



| GENERAL OVERVIEW: | |
|--|--|
| Region | Southern Africa |
| Political Stability | -0.27; Rank 136 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | \$349.41 billion 1.3% |
| Human Development Index (2107) | 0.699, Rank: 113; (<i>medium human development</i>) |
| General Government Dept Stock (2017) | US \$ 176.335 million; (<i>external debt % GDP (2017): 49.6</i>) |
| Availability of Basic Infrastructure (water, electricity) | 84% of the population have access to water; electric power consumption: 1,356 Kwh per capita |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1998

High Level Visits from Chinese leadership since 2007: 7

Comprehensive Strategic Partnership?
Yes, since 2010.

Belt and Road Initiative (BRI) country?
Yes, since 2015.

Bilateral investment Agreement?
Yes, since 1997 (in force 1998).

Double Taxation Agreement?
Yes - since 2001.

Asian Infrastructure Investment Bank (AIIB) member? Yes (prospective).

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$15.22 billion;
- *Exports (2017):* US \$8.67 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$41.56 million; year-on-year growth rate: 18.62.

Top 3 Key products from China (% of total value of 2017 imports):
API (48%)
Hospital diagnostic equipment (12%)

Medical Disposables (11%)

Local manufacturing by Chinese companies (specify product and scale):

Light industry, construction material production, mining, renewable energy, car manufacturing, telecommunications.

What has been China's major economic impact in country to date?

Mining raw materials, infrastructure development, manufacturing telecommunication and renewable energy industry.

What could development partners (incl. China) contribute to for future development impact in the country?

Machines, manufactured products, renewable energy equipment and appliances and industrialization.

Is Pharmaceutical production in top 5 priorities for country?

Yes – although focus is on universal health coverage to be achieved in a variety of ways.

PHARMACEUTICAL MARKET SIZE

Population: 56.7 million.

GNI per capita Atlas (2017): US \$ 5,430.

Per capita spending on Health –PPP (2014): US \$1148.

Healthcare spending in % of GDP (2014): 8.8%.

Annual purchase of drugs – government (\$): ca. \$502 million (2015).

Annual purchase of drugs – private (\$): ca. \$2.7 billion (2015).

Annual Purchase of drugs – donors (\$): The Global Fund spent cumulatively around \$694,5 million on HIV/AIDS and Tuberculosis programmes until 2016. South Africa has a two-tier healthcare system:

- *Public sector:* Serves 82% of the population (46 million people), financed by government through taxes. Main goal is creating access to affordable essential medicines for the population.
- *Private sector:* Serves 16% of the population (7 million people), provides access to medical insurance, generally higher priced than public sector. Imports of pharmaceutical products remain important in South Africa as the pharmaceutical market focus of the local manufacturers is on antiretroviral (ARVs) and other essential (generic) medicines. South Africa has the largest anti-retroviral treatment programme in the world. The African continent is the main destination for South African exports of pharmaceutical products and many multi-national corporations (MNCs) are using South Africa as a platform to explore the opportunities in other African markets.

Unmet need (disease, numbers, drug, potential funder):

Tuberculosis, influenza and pneumonia, intestinal infectious diseases, heart diseases, diabetes, HIV/AIDS.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines.

Harmonization in region:

The SADC free trade area ensures tariff free exports of pharmaceuticals in the region. South Africa remains the main source of pharmaceutical products for various African states in SADC and beyond.

- *Clinical guidelines for common diseases:* Yes. There is a common disease treatment guideline and essential medicine list in South Africa.
- *GMP or other manufacturing certification:* South Africa is the only country in the SADC that meets the Good Manufacturing Practices standards of the World Health Organization.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

This is an unclear area. South Africa has some laws aligned with the TRIPS Flexibilities into to promote public health (a bolar provision to allow a generic to be registered during the period when the originator medicine is still patent protected, and provisions to allow parallel importation). South Africa also has Section 56 of the Patents Act 57 of 1958- a compulsory license to be granted when an abuse by the patent holder of their rights is proven. However, this is a contentious area as South Africa's patent law has not been amended since the 2001 Doha Declaration.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 43 days.

100% foreign ownership permitted?
Yes.

Free allocation of land? Plan for Pharma Industrial Park?
No.

Regulatory Process:

- *Average length of time to register new product:* 6 months and more.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Medicine prices are tightly controlled by the Department of Health and companies are usually only allowed one price raise a year.

Ability to prevent substandard and falsified medicines?

Strong. South Africa has a sophisticated pharmaceutical market and effective control mechanisms in place. The Medicines Control Council (Under the South African

Health Products regulating Authority) applies standards laid down by the Medicines and Related Substances Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. South Africa is one of few countries with internationally accredited laboratories for drug testing (ISO 15189). Of the 340 in Africa (both private and public) 312 are in South Africa however, fewer than 10% of these are public sector laboratories.

Tax incentives for local manufacturing?

Yes.

Import duty for drugs produced outside country?

Yes.

Import incentives for APIs, excipients and machinery for production?

Yes. South Africa has started to produce API's in the country.

Guarantee to purchase from local manufacturer? Pooled procurement?

Yes.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Approximately 276 companies are licensed to manufacture, import, export or distribute pharmaceuticals in South Africa. With about \$2.8 billion it is the biggest pharmaceutical market in Sub-Saharan Africa. Domestic manufacturing pharmaceutical companies almost exclusively produce generic products.

In 2015, the generics market in South Africa was valued at \$800 million. Biggest producers of generic medicines are Aspen Pharmaceuticals and Adcock Ingram. Most of the world's leading pharmaceutical companies have set-up representation and R&D offices in South Africa. However, all originator drugs are imported into the market. Prescription drugs comprise ca. 88% of the domestic pharmaceutical market. Leading companies are:

- Aspen
- Adcock Ingram
- Sanofi
- Novartis
- Pfizer
- Cipla
- Johnson&Johnson
- Merck
- Roche
- Wrapsa
- CPT Pharma

OTHER INTERESTS

IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

The South African medical device market is estimated to be worth around \$1.5 billion. In the coming years, extensive upgrades and development of hospital infrastructure is being considered in the country. This provides a very good opportunity for medical device providers, especially in the areas of diagnostic imaging equipment, dental equipment and patient aids. The device market is dominated by imports from the US, followed by Germany, Switzerland and China.

CONCLUSION

What is the biggest pharma opportunity in the country?

High disease burden ensures increasing demand for drugs, especially anti-retroviral drugs – e.g. there are currently 4.2 million people receiving treatment for HIV in the country.

South Africa's rapid urbanization, change in lifestyle and dietary trends create long-term demand for pharmaceuticals that target chronic, lifestyle-related diseases (NDCs). E.g. 20% and 12% of 18-35 year olds have hypertension and diabetes respectively.

National Health Insurance (NHI) has started implementation, with a full roll-out expected by 2025.

Increasing local production of medicines is a clear opportunity in South Africa.

What is the biggest hurdle to local production of drugs in the country?

- Shortage of skills in the Medicines Control Council and the very long period required for the registration of medicines, lengthy process required for the approval of clinical trials.
- Currency fluctuation.

Country Profile 18:

TANZANIA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | East Africa |
| Political Stability | -0.58; Rank 157 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$52.09 billion 7.1% |
| Human Development Index (2107) | 0.538; Rank: 154 (<i>low human development</i>) |
| General Government Debt Stock (2017) | US \$18.242 million |
| Availability of Basic Infrastructure (water, electricity) | 56% of the population has access to drinking water; electric Power Consumption is 99 Kwh per capita (2014) |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1961

High Level Visits from Chinese leadership since 2007: 4

Comprehensive Strategic Partnership?
Yes, since 2010.

Belt and Road Initiative (BRI) country?
No.

Bilateral investment Agreement?
Signed in 2013 (not in force).

Double Taxation Agreement?
No.

Asian Infrastructure Investment Bank (AIIB) member?
No.

Priority country for industrial cooperation?
Yes.

Trade with China:

- *Imports (2017):* US \$2.62 billion;
- *Exports (2017):* US \$0.23 billion;

Imports of Chinese pharmaceutical and health products:

- Total (2017): US \$8.39 million; year-on-year growth rate: 13.55.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (33%)

- Medical Disposables (32%)
- Hospital diagnostic equipment (14%)

Local manufacturing by Chinese companies:

Agricultural processing, light industry, construction material.

What has been China's major economic impact in country to date?

Infrastructure development, agricultural demonstration, light industry, tourism, mining and fishing.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment in infrastructure, strengthening of Special Economic Zones, agriculture development.

Is Pharmaceutical production in top 5 priorities for country?

Yes, Tanzanian government has a strong interest to develop the pharmaceutical market in the coming years.

PHARMACEUTICAL MARKET SIZE

Population (2017): 57.3 million.

GNI per capita Atlas (2017): US \$ 910.

Per capita spending on Health –PPP (2014): US \$ 137.5.

Healthcare spending in % of GDP (2016): 11.3%.

Annual purchase of drugs – government

(\$): Annual purchase of drugs – private

(\$): Tanzania's pharmaceutical sales were 463 million in 2016. The country imported ca. 293 million from abroad.

Annual Purchase of drugs – donors (\$): The Global Fund has disbursed 1.9 billion USD in Tanzania to date. In 2016, The Global Fund spent US \$947 million on HIV/AIDS and US \$493 million on Malaria prevention in Tanzania. Other Donor organizations are: NORAD, UNITAID and AXIOS and Crown Agents.

Unmet need (disease, numbers, drug, potential funder): HIV/AIDS, tuberculosis and malaria are the main disease burden. Non-communicable diseases such as diabetes and cancer are on the rise.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: Tanzania exports medicines to neighboring countries, especially to Kenya and Rwanda.

Harmonization in region:

Tanzania is part of the East African Community Medicine Regulatory Harmonization Programme.

- *Clinical guidelines for common diseases:* Tanzania has standard treatment guidelines for common diseases and National Essential Medicines List.

- *Medicines registration o GMP or other manufacturing certification:* Yes. Tanzania adheres to GMP standard for all imported or produced pharmaceutical products.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Is eligible as an LDC but TRIPS flexibilities are currently not included in the Tanzanian law and therefore the country is not able to make use of these flexibilities.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 28 days.

100% foreign ownership permitted?

Yes - if more than US \$500k is invested.

Free allocation of land? Plan for Pharma Industrial Park?

No.

Regulatory Process:

- *Average length of time to register new product:* 2 months, but in the past there have been delays of up to 2 years. Recent crack-down on red tape and corruption may have a positive impact.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from distributors and manufacturers suggests is very weak. The Tanzania Food and Drugs Authority (TFDA), under the MOH, is regulatory body responsible for control of quality and safety of food, drugs (including herbal drugs), cosmetics, and medical devices. A TFDA laboratory was established in 2000 that is working towards international accreditation, in 2005 it was assessed by the WHO-AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in an effort to improve the testing of drugs in the country.

Tax incentives for local manufacturing?

No, but government is considering.

Import duty for drugs produced outside country?

No, but VAT needs to be paid.

Import incentives for APIs, excipients and machinery for production?

No tax is levied on APIs and other raw materials.

Guarantee to purchase from local manufacturer? Pooled procurement?

No guarantee, but there is a 15% discount for local manufacturers.

Free inflow of capital & remittance of profits

(Foreign Currency):

Yes.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- Shelys Pharmaceuticals (local): produces penicillin, (ciprofloxacin) anti-infectives, nutraceuticals, anti-malarials, gastro intestinal, pain management, fever and topical inflammation, disinfectants;
- Tanzania Pharmaceutical Industries (TPIs): generic medicine producer, anti-retrovirals (ARVs) for HIV
- Mansoor Daya Chemicals (local): Paracetamol, painkillers, folic acid, and supplies directly to MSD.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

The Medical Stores Department of Tanzania is actively collaborating with private sector to open local manufacturing industries to enable the country to source essential medicines and medical supplies locally and reduce importation costs and lead-time as well as storage costs.

CONCLUSION

What is the biggest pharma opportunity in the country?

Providing diabetes medicines as well as other non-communicable disease medicines to the market. Population growth will create conducive environment for drug producers in the country.

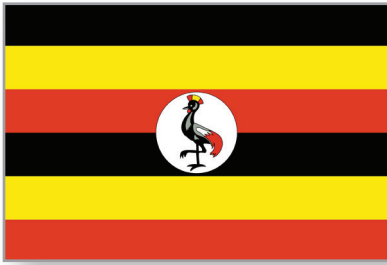
Planned health care system will increase need for more pharmaceuticals OTC market very popular as many Tanzanians buy their own medicines From 2017, MSD procures its medicines and medical supplies direct from manufacturers instead of suppliers

What is the biggest hurdle to local production of drugs in the country?

- Limited health care facilities and lack of adequate human resources in the country.
- Underdeveloped pharmaceutical procurement system Heavy reliance on importation of raw materials.

Country Profile 19:

UGANDA



GENERAL OVERVIEW:

| | |
|--|---|
| Region | East Africa |
| Political Stability | -0.56; Rank 154 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$25.89 billion 4.0% |
| Human Development Index (2107) | 0.516; Rank: 162 (<i>low human development</i>) |
| General Government Dept Stock (2017) | USD\$ 11.189 million |
| Availability of Basic Infrastructure (water, electricity) | 39% of the population has access to drinking water; electric Power Consumption is 215 Kwh per capita (2014) |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1962

High Level Visits from Chinese leadership since 2007: 1

Comprehensive Strategic Partnership?
No.

Belt and Road Initiative (BRI) country?
Yes, since 2018.

Bilateral investment Agreement?
Signed in 2004 (not in force).

Double Taxation Agreement?
Signed in 2012 (not in force).

Asian Infrastructure Investment Bank (AIIB) member?

No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.99 billion.
- *Exports (2017):* US \$0.03 billion.

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$4.06 million; year-on-year growth rate: 22.84.

Top 3 Key products from China (% of total value of 2017 imports):

- Formulations (44%)

- API (21%)
 - Medical Accessories (10%)
- Local manufacturing by Chinese companies: Reportedly 83 companies operating in the country, including:
- Sino Africa Medical Devices: Mosquito nets, medicines & equipment;
 - Zhongman Petroleum Natural Gas Group Company Ltd: Oil drilling;
 - China Communications Construction company: Infrastructure.

What has been China's major economic impact in country to date?

Infrastructure development, (esp. roads).

What could development partners (incl. China) contribute to for future development impact in the country?

Infrastructure development, mining and extractive industries, pharmaceuticals and health technologies, and hydropower development.

Is Pharmaceutical production in top 5 priorities for country?

Indirectly via infrastructure and Human capital development (including efforts to reduce morbidity and mortality).

PHARMACEUTICAL MARKET SIZE

Population (2017): 42.9 million.

GNI per capita Atlas (2017): US \$ 600.

Per capita spending on Health: US\$ 51.85.

Annual purchase of drugs – government (\$): 28.6 million (NHA 2013/2014).

Annual purchase of drugs – private (\$): 97.3 million (NHA 2013/2014).

Annual Purchase of drugs – donors (\$): 6.7 million (NHA 2013/2014). In 2015, US Government spent US \$474 million for health programs, facilities, purchasing pharmaceuticals, and purchasing medical equipment. In 2015, Uganda imported medical and pharmaceutical products worth US \$373 million.

Unmet need (disease, numbers, drug, potential funder):

HIV/AIDS. Lower respiratory infections, Malaria, TB, NDCs Global Fund spent in 2016: USD 419 million on HIV/AIDS and US \$370 million on Malaria programme.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines: Not yet in place, work is in progress to harmonize registration in the East African Community regional block.

Harmonization in region:

- *Clinical guidelines for common diseases:* Available.

And essential medicine list is available in the country.

- *Medicines registration:* In progress.
- *GMP or other manufacturing certification:* Yes, GMP guidelines for medical products is in place.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production?

Uganda is a LDC country, and, as such, they are not obliged to comply with TRIPS. Most recently there has been calls for greater use of IP flexibilities to ensure there is access to essential, better and improved medicines for HIV.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 24 days.

100% foreign ownership permitted?
Yes.

Free allocation of land? Plan for Pharma Industrial Park?

Yes, however it is not regulated and ad hoc.

Regulatory Process:

- *Average length of time to register new product:* 6 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

is expected to do so, however, feedback from distributors and manufacturers suggests is quite weak. The National Drug Quality Control Laboratory (Kampala) is ISO/IEC 17025: 2005 accredited.

Tax incentives for local manufacturing?

Plant and machinery exempted from import duties.

Import duty for drugs produced outside country?

Yes, at 12% since 2017 on selected drugs.

Import incentives for APIs, excipients and machinery for production?

Yes. Under Uganda's Investment Code Act, pharmaceutical investment is seen as priority area and receives incentives on imports for machinery and inputs.

Guarantee to purchase from local manufacturer? Pooled procurement?

No.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes.

PHARMACEUTICAL

COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

- CIPLA Quality Chemicals Industries Limited, joint venture between a local and international pharmaceutical company, manufactures Anti-retroviral, anti-malarial and hepatitis B medicines, exports to Sub-Saharan countries and supplies drugs to the Global Fund. Total Revenues for 2016: USD 49 Million. Certification: current Good Manufacturing Practices (cGMP).
- Kampala Pharmaceutical Industries (1996) Limited, local manufacturer and an affiliate of the Aga Khan development network. Product range includes analgesics, anti-asthma, anti-diabetic, anti-malarial, anti-parasites, antibiotics, cardiovascular drugs, cold remedies, Nutraceuticals.
- Beta HealthCare Uganda Limited, an affiliate of Aspen Group. Exports its products to Tanzania, Rwanda, Burundi, Ethiopia, Sudan, Somalia, Mauritius and West Africa.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Uganda requires medical devices and laboratory equipment most of which is tax exempted.

CONCLUSION

What is the biggest pharma opportunity in the country?

The Ugandan pharmaceutical market is dominated by Asian imports, which supply up to 90% of the country's medicine needs. Any reduction through local production could be a big opportunity.

What is the biggest hurdle to local production of drugs in the country?

The market is fairly small. If investing in Uganda, then the wider East African region needs to be targeted. Inadequate human resources.

Country Profile 20:

ZAMBIA



GENERAL OVERVIEW:

| | |
|--|--|
| Region | Southern Africa |
| Political Stability | 0.11; Rank 105 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | USD 25.80 billion 4.1% |
| Human Development Index (2107) | 0.588; 144 (<i>medium human development</i>) |
| General Government Debt Stock (2017) | USD 16.309 million |
| Availability of Basic Infrastructure (water, electricity) | 65% of the population has access to drinking water; electric power consumption kwh per capita is 707 |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1964

High Level Visits from Chinese leadership since 2007: 3

Comprehensive Strategic Partnership?
No.

Belt and Road Initiative (BRI) country?
No.

Bilateral investment Agreement?
Signed in 1996 (not in force).

Double Taxation Agreement?
Yes, signed 2010 (effective 2012).

Asian Infrastructure Investment Bank (AIIB) member?
No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.97 billion;
- *Exports (2017):* US \$ 2.27 billion;

Imports of Chinese pharmaceutical and health products:

- *Total:* US \$1.18million (2017); year-on-year growth rate: 62.57.

Top 3 Key products from China (% of total value of 2017 imports):

- Medical Disposables (30%)

- Formulations (19%)
- Hospital diagnostic equipment (17%)

Local manufacturing by Chinese companies:

Light manufacturing in Lusaka-based MFEZs; Copper and other mining operations in the Chambeshi (MFEZ).

What has been China's major economic impact in country to date?

Mining, especially copper and zinc.

What could development partners (incl. China) contribute to for future development impact in the country?

Investment into manufacturing, renewable energy and job creation.

Is Pharmaceutical production in top 5 priorities for country?

Yes. Production of pharmaceutical products is a priority area for Zambia.

PHARMACEUTICAL MARKET SIZE

Population (2017): 17.1 million.

GNI per capita Atlas (2017): US \$ 1,300.

Per capita spending on Health – PPP (2016): US\$ 194.7.

Healthcare spending in % of GDP (2016): 8.3%. Most of the buying of medicines and medical supplies is channelled through the Ministry of Health. Nearly all medicines are imported, putting pressure on foreign exchange reserves.

Annual purchase of drugs – government (\$):

In 2017 government was estimated to spend US \$390 million on drug and medical supplies incl. ARV Therapy, TB Drugs, Vaccines, RH commodities, Malaria Com-modities, NTDs, MDAs, Viral Hepatitis vaccines, and Cancer supplies and drugs.

Annual purchase of drugs – private (\$):

Annual Purchase of drugs – donors (\$):

Unmet need (disease, numbers, drug, potential funder):

In Zambia, Malaria, Respiratory infection, Diarrhoea, HIV/AIDS and Tuberculosis are the main disease burdens. Zambia puts eliminating malaria as a national priority through achieving universal access to malaria prevention and mass drug administration. The most common NCDs in the country include chronic respiratory diseases, CVDs, diabetes mellitus (Type II), cancer and sickle cell anemia. In 2016, it was estimated that NCDs caused 23% of all deaths in the country.

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

Zambia has signed the SADC Model BIT in 2012.

Harmonization in region:

- *Medicines registration:* Zambia is member of the African Medicines Regulatory Harmonization (AMRH). Under the AMRH and the Zazibona scheme, Zambia, as a member of SADC has registered 11 products. ZAZIBONA scheme is part of SADC Framework for Regulatory Harmonization in the region.
- *GMP or other manufacturing certification:* No.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production? No. The Zambian IP law predates TRIPS and does not include the necessary TRIPS flexibilities. Zambia started a review of its IP laws in 2010. However, in 2004 the government did use TRIPS flexibilities to issue compulsory licenses for the production of ARVs.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 9 days.

100% foreign ownership permitted?

Yes.

Free allocation of land? Plan for Pharma Industrial Park?

Pharmaceutical companies can produce inside existing Multi-facility Economic Zones (MFEZ) and can enjoy the same tax preferential treatment.

Regulatory Process:

- *Average length of time to register new product:* 3 months.
- *Accelerated registration of drugs approved by Chinese FDA?* No.

Ability to prevent substandard and falsified medicines?

Feedback from distributors and manufacturers suggests is very weak. The Zambia Medicines Regulatory Authority regulates and controls the manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances and is responsible for prevention of substandard and falsified drugs. A number of Zambian laboratories were tested by the WHO- AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) program in 2015 in an effort to support improvements towards international accreditation.

Tax incentives for local manufacturing?

Yes, in line with ZDA Act incentives provided to other manufacturing investment in the country. If investment requirement thresholds are fulfilled, there are tax holidays up to 10 years.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Possible, based on the investment size. If above 500k there will be zero import duty.

Guarantee to purchase from local manufacturer? Pooled procurement?

No.

Free inflow of capital & remittance of profits (Foreign Currency):

Yes. 100% of repatriation of capital allowed.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

Zambia's pharmaceutical market is estimated at US\$ 241 million (2014). Zambia's pharmaceutical industry is largely dominated by Indian companies, and there is very little local and state investment. Licensed pharmaceutical manufacturing companies in Zambia include:

- Teejay pharmaceuticals;
- Pharmanova Zambia Ltd.;
- Baxy pharmaceuticals;
- International Drug Company;
- NRB Pharma Zambia Ltd. main products anti-bacterial, anti-panadomic, anti-biotics, anti-tuberculosis tablets etc. Plan to manufacture anti-malarial, anti-retroviral drugs for HIV / AIDS.

There are approx. 117 approved wholesale providers.

CONCLUSION

What is the biggest pharma opportunity in the country?

Zambia plans to strengthen quantification and increased procurement of essential drugs and diagnostic supplies; encourage public-private partnerships and other stakeholders in improving access to and affordability of medicines for NCDs - especially cancer and diabetes treatment.

What is the biggest hurdle to local production of drugs in the country?

- Human resource challenges: there are inadequate pharmaceutical personnel at production and service delivery points.
- Inadequate infrastructure.

Country Profile 21:

ZIMBABWE



GENERAL OVERVIEW:

| | |
|--|---|
| Region | Southern Africa |
| Political Stability | 0.77; Rank 173 out of 211 countries & territories |
| GDP (2017) & GDP Growth Rate | US \$17,84 billion 3.4% |
| Human Development Index (2107) | 0.535; 156 (low human development) |
| General Government Dept Stock (2017) | US\$ 9.330 million |
| Availability of Basic Infrastructure (water, electricity) | 65% of the population has access to drinking water. electric power consumption kwh per capita is 707 |

GOVERNMENT RELATIONS WITH CHINA

Diplomatic relations since: 1980

High Level Visits from Chinese leadership since 2007: 2

Comprehensive Strategic Partnership?
Yes, from April 2018.

Belt and Road Initiative (BRI) country?
Yes, since 2018.

Bilateral investment Agreement?
Yes, since 1996 (in force 1998).

Double Taxation Agreement?
Yes, since 2015 (effective 2017).

Asian Infrastructure Investment Bank (AIIB) member? No.

Priority country for industrial cooperation?
No.

Trade with China:

- *Imports (2017):* US \$0.32 billion;
- *Exports (2017):* US \$0.88 billion;

Imports of Chinese pharmaceutical and health products:

- *Total (2017):* US \$1.03 million; year-on-year growth rate: -5.06.

Top 3 Key products from China (% of total value of 2017 imports):

- Hospital diagnostic equipment (27%)
- API (18%)

- Medical Disposables (17%)

Local manufacturing by Chinese companies: Cement; textiles; mid-sized and targeted at local market.

What has been China's major economic impact in country to date?

Mining, power generation, manufacturing; infrastructure, large and petty trade.

What could development partners (incl. China) contribute to for future development impact in the country?

Renewable energy, mining, Trade, local manufacturing, education, health systems, ICT, and tourism.

Is Pharmaceutical production in top 5 priorities for country?

Yes, it has been for a long time. For instance it was a priority sector for development in the country's Industrial Development Policy (2012-2016) and the Zimbabwe Agenda for Sustainable Socio-Economic Transformation (2013-2018).

PHARMACEUTICAL MARKET SIZE

Population (2017): 16.5 million.

GNI per capita Atlas (2017): US \$ 910.

Per capita spending on Health- PPP (2014): US \$ 58.

Healthcare spending in % of GDP: 5.0%.

Annual purchase of drugs – government (\$): US \$ 19.5 million (2014). Treasury allocation + AIDS Levy.

Annual purchase of drugs – private (\$): US \$128.2 million (2014).

Annual purchase of drugs – donors (\$): US \$96.8 million (2014).

Unmet need (disease, numbers, drug, potential funder):

Communicable and infectious diseases: Malaria (anti-malarials), TB (anti-TB drugs) HIV/AIDS (ARVs and related commodities), other diseases (basic drugs, injectables) Non-Communicable Diseases - Cancer (chemotherapeutic agents), Diabetes (anti-diabetics) and Hypertension (anti-hypertensives) – growing burden.

- *Funders/buyers:* Government, Medical Insurance, Donors, Bilaterals and Individuals (out of pocket).

MOUs agreements with neighboring countries on approval, registration, and distribution of medicines:

In the case of registration, there is a move for common registration of medicines in entire SADC region, but this is at an early stage. It started out in the ZaZiBoNa countries (Zambia, Zimbabwe, Botswana, and Namibia), but will be extended to all of SADC.

Harmonization in region:

- *Clinical guidelines for common diseases:* There is no harmonization in region as such, but all countries in the region tend to follow WHO Standard Treatment Guidelines.
- *GMP or other manufacturing certification:* No.

Are any Intellectual Property flexibilities incorporated in the national legislation to favour local production? No. However, as an LDC in the past Zimbabwe has used TRIPS flexibilities during emergencies, such as in 2002 when the Government declared a state of emergency and authorised government departments to use any patented invention for the service of the state.

INCENTIVES FOR LOCAL PRODUCTION OF PHARMACEUTICALS

Average time to register business: 90 days.

100% foreign ownership permitted?

No. Must be less than 50% foreign owned.

Free allocation of land?

Not yet clear, but there is some indication of interest in that area. The infrastructural design in Zimbabwe is slightly different than most other countries where industrial locations are chosen by closeness to raw material. Mass industrial parks are not yet a common concept.

Regulatory process:

- *Average length of time to register new product:* 12-18 months – 6 months for locally-manufactured products.
- *Accelerated registration of drugs approved by Chinese FDA?* No, but WHO PQ products get accelerated registration.

Ability to prevent substandard and falsified medicines?

Local regulatory authority (MCAZ) is responsible for drug regulation and has a WHO- AFRO Stepwise Laboratory (SLIPTA) prequalified laboratory testing facility.

Tax incentives for local manufacturing?

In planning stage – Special Economic Zone being considered by the government.

Import duty for drugs produced outside country?

No.

Import incentives for APIs, excipients and machinery for production?

Zero import duty and VAT for import of certain APIs and excipients.

Guarantee to purchase from local manufacturer? Pooled procurement?

No, NatPharm will implement preference for procurement from local manufacturers for part of the procurement funded by national AIDS levy.

Free inflow of capital & remittance of profits (Foreign Currency):

This continues to be a challenge for the country as it has adopted the USD as its local currency. This had created a situation where many foreign investments in the country are used as planted access to the USD and thus capital flight is very high.

PHARMACEUTICAL COMPANIES CURRENTLY MANUFACTURING IN COUNTRY

There are a number of local manufacturers – for instance: Varichem, US \$9.9 million turnover (2014): Zidovudine 300mg/ Lamivudine 150mg/ Nevirapine 200mg Tablets, Fluconazole 200mg Caps, Nevirapine Tablets. Exports to neighbouring countries. Plus Five, US \$5.9 million turnover (2014): Paracetamol 120mg/5ml syrup 100ml, Griseofulvin 12mg/5ml Suspension 100ml, Metformin 500mg Tablets- 1000's. Exports to neighboring countries. DatLabs, US \$4.1 million turnover (2014): Caffeine, Codeine Phosphate, Paracetamol, Doxylamine Succinate combination, Ammonium chloride, Diphenylpyraline hydrochloride, Etophylline, Menthol, Sodium citrate, Theophylline combination, Aspirin + Caffeine tablets. Exports to neighbouring countries. Company gross profit margins range from 30-60%, depending on capacity utilization.

OTHER INTERESTS IN HEALTH INVESTMENTS

Medical Devices, Laboratory equipment, Laboratory reagents, Hospital furniture?

Health sector is engaged on increasing cooperation with other partners (incl. China) around rehabilitation of health centres, purchase and installation of medical equipment, training of medical technologists, supply of doctors, supply of laboratory items and reagents.

CONCLUSION

What is the biggest pharma opportunity in the country?

Import substitution for local market, and export into the SADC regional markets.

What is the biggest hurdle to local production of drugs in the country?

Perceived country/economic risk; could be mitigated by investment agreements.