UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

Improving the investment landscape for local production of essential antibiotics in Kenya

An Advisory Report

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NOTES

The United Nations Conference on Trade and Development (UNCTAD) serves as the focal point of the United Nations for the integrated treatment of trade and development and interrelated issues in the areas of finance, investment, technology and sustainable development. UNCTAD's work is carried out through intergovernmental deliberations, research and policy analysis, and technical assistance.

Since 2006, UNCTAD has pursued a programme for the promotion of local pharmaceutical production in developing countries. In May 2020 UNCTAD launched a project on "Investment incentives for local production of essential antibiotics in East Africa."

I. Public health policies and measures to mitigate antimicrobial resistance per se are within the remits of the World Health Organization (WHO) and national health policies. UNCTAD specializes in the integrated treatment of investment and trade policies for the promotion of sustainable development. This report is not intended to advise on public health polices. Occasional references to health policies and regulations are made only to the extent that they shape, guide or otherwise influence the production and supply of antibiotics.

II. Investors assess the feasibility of their investment project in local production taking into account multiple factors. These factors include, importantly, the degree of dependence on imports of Active Pharmaceutical Ingredients, the production of which is concentrated in China and India. A comprehensive and granular assessment of the investment case for local production of antibiotics is necessarily case-specific and beyond the scope of this report. This advisory report focuses on investment incentives, as one of the investment drivers, addressing the question of what Kenya can do to foster a conducive investment environment for local production of antibiotics.

III. To address concerns about the economic feasibility of local production (item II above), UNCTAD is preparing a paper discussing the "Business Case for Local Pharmaceutical Production in Africa, with Focus on Antibiotics". The objective of the paper is to critically assess the argument for the economic viability of local production of antibiotics in Africa, including historical evidence, business rationales and (country-specific) enabling factors. While not focusing specifically on Kenya, general aspects of the framework developed in the paper have contributed to inform and shape the discussion and recommendations presented in this Report. A summary of key messages of the paper is added as Annex (3) to this Report, for the benefit of interested Kenyan stakeholders.

CONTENTS

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A first draft of the advisory report was presented during an international expert meeting organized by UNCTAD on 17 May 2021. The report team is grateful for the feedback received from experts and to all participants who gave interviews that provided important inputs to this report.

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LIST OF ACRONYMS

AMR	Antimicrobial Resistance
AMS	Antimicrobial Stewardship
API	Active Pharmaceutical Ingredient
AWaRe	Access, Watch and Reserve
CET	Common External Tariff
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
EML	Essential Medicines List
EPZ	Export processing zones
FDCs	Fixed dose combinations
FEAPM	Federation of East African Pharmaceutical Manufacturers
GMP	Good Manufacturing Practices
HIV and AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
MEDS	Mission for Essential Drugs and Supplies
NAP	National Action Plan for the Prevention and Containment of Antimicrobial Resistance
NCD	Non-Communicable Diseases
NHIF	National Hospital Insurance Fund
NQCL	The National Quality Control Laboratory
PEPFAR	President's Emergency Plan for AIDS Relief
PPB	Pharmacy and Poisons Board
R&D	Research and Development
SDG	Sustainable Development Goals
SEZ	Special economic zones
UHC	Universal Health Coverage
UNCTAD	United Nations Conference on Trade and Development
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this advisory report is to (i) examine the current status of the manufacturing of antibiotics in Kenya and the relevant investment framework and (ii) propose recommendations for enhancing it, with particular reference to incentives for promoting investment in local manufacturing.

Local pharmaceutical production in Africa has attracted considerable policy attention for more than a decade – and with increased focus since the COVID-19 pandemic. Yet there has been little analysis of specific therapeutic categories. Antibiotics are of particular interest because they are essential medicines with major relevance for public health due to concerns over antimicrobial resistance (AMR).

It is imperative that every patient has access to the right antibiotics at the right time, no matter where they live. While the narrative around AMR is often associated with abuse of antibiotics, their misuse due to lack of access is equally harmful. If the appropriate treatment is not available, alternative suboptimal treatments may give pathogens increased opportunities to develop resistance. Lack of access to antibiotics is particularly severe in developing countries, particularly Least Developed Countries (LDCs), where antibiotics are often not even registered by pharmaceutical companies with national regulatory bodies, preventing entirely their access. As a result, the population who face the highest risk of infection and the highest rates of drug resistance also face the highest barriers to access the antibiotics they need to survive potentially deadly infections and to properly manage AMR. Both risks of infections and AMR hit hardest the most vulnerable segments of population, including in particular children and women, for example in connection to infections that developed during childbirth or early stages of life.

This is why it is particularly critical in the case of antibiotics that pharmaceutical companies, governments and procurers take action to ensure (not only access but) appropriate access to antibiotics. Local production – the focus of this study – is one possible way to achieve this objective.

Based on a mix of policy and literature review, secondary data analysis, and primary data analysis of field survey and interviews with various stakeholders including local producers, government, the private sector and civil society, this report provides some key insights into the trends and issues of local production of antibiotics in Kenya:

- A relatively large number of local manufacturers of pharmaceuticals are present, including in the production of antibiotics. Antibiotics is a key segment for pharmaceutical local production in Kenya. Foreign investment and partnership with multinational enterprises is currently very limited but growing.
- Locally-produced antibiotics are marginally cheaper (for patients in the public sector) or have similar prices (private and mission sector) to imported products, and generally are more available across the different sectors.
- Pharma-wide incentives are in place, including production facilitating incentives (notably via Special Economic Zones and Export Processing Zones) and market shaping incentives (public procurement preferences); yet no specific incentives are designed for antibiotics.
- According to stakeholders interviewed, implementation of incentives for local pharmaceutical production is weak and variable. Lack of effective regulatory enforcement inhibits local production, while greater coordination is needed across stakeholders. Competitive challenge from imported antibiotics is a main factor undermining the expansion of local production.

Based on these insights, this report further provides ten recommendations for improving the investment framework for local production of antibiotics, with a specific focus on investment incentives.

Notwithstanding the specific recommendations provided in this Report for the antibiotics Kenyan industry, general guidelines for strengthening the overall governance of investment incentives also apply – as

defined by UNCTAD Investment Promotion Framework for Sustainable Development (UNCTAD, 2015). In particular,

i. Incentives should be granted on *the basis of a set of pre-determined, objective, clear and transparent criteria.*

ii. Their *long-term costs and benefits should be carefully assessed* prior to implementation, and they should be *periodically reviewed to ensure continued effectiveness* in achieving the desired objectives.

Main policy recommendations

1. Focus on partnership with MNEs and integration in global production networks
2. Review and modernize fiscal incentives
3. Re-assess market shaping incentives (preferential procurement), including on a cost-benefit basis
4. Consider refining pharma sector-wide incentive system through product-specific incentives
5. Enhance the SEZ/EPZ model
6. Use streamlined regulation to facilitate investment.
7. Develop a collaborative mechanism among local manufacturers for procurement, storage and supply of APIs and other critical inputs.
8. Continue to pursue regional integration and make sure national and regional policies are aligned and synergetic.
9. Enhance information systems regarding production and supply
10. Continue to strengthen governance and coordination between health and investment authorities.

INTRODUCTION

In March 2020, UNCTAD launched a project funded under the United Nations Development Account on "Investment incentives for local production of essential antibiotics in East Africa." The project was designed to respond to technical assistance requests from the governments of Ethiopia, Kenya and Uganda to review the current state of domestic production of antibiotics, assessing the investment framework and identifying proposals to improve production and sustainable supply of antibiotics.

Local pharmaceutical production is a priority development policy issue at national, regional and continental levels in Africa. Such initiatives involve, with different levels of emphasis, three main aims: improving access to medicines (i.e., public health), national health sovereignty/security of supply (i.e., strategic) and growth, jobs, trade balance (i.e., economic development) (African Development Bank 2022, 4). Promoting local pharmaceutical production is a long-standing policy objective in Kenya, from the Kenya National Drug Policy 1994 to the Kenya National Pharmaceutical Policy 2012 and the Kenya Pharmaceutical Sector Development Strategy released in 2012.

This report approaches the issue of local pharmaceutical production in Kenya through a specific focus on antibiotics, part of a wider category of antimicrobials with enormous significance for public health. The O'Neill-chaired Review on Antimicrobial Resistance noted that globally 700,000 people die every year from drug resistance in common bacterial infections, HIV and malaria. They forecast that more than 10 million people will die because of AMR in 2050 if appropriate interventions are not implemented (O'Neill J., 2016).

While AMR is an issue of global concern, initiatives have been taken at various levels to address the problem. Kenya has had a "National action plan on prevention and containment of antimicrobial resistance, 2017-22", and related programmes. However, despite the recent interventions, studies show that AMR continues to be a major concern and it is increasing in Kenya (Omulo et al., 2021; OneHealthTrust, 2015).

It is imperative that every patient has access to the right antibiotics at the right time, no matter where they live. While the narrative around AMR is often associated with abuse of antibiotics, their misuse due to lack of access is equally harmful. If the appropriate treatment is not available, alternative suboptimal treatments may give pathogens increased opportunities to develop resistance. Lack of access to antibiotics is particularly severe in developing countries, particularly Least Developed Countries (LDCs), where antibiotics are often not even registered by pharmaceutical companies with national regulatory bodies, preventing entirely their access. As a result, the population who face the highest risk of infection and the highest rates of drug resistance also face the highest barriers to access the antibiotics they need to survive potentially deadly infections and to properly manage AMR. Both risks of infections and AMR hit hardest the most vulnerable segments of population, including in particular children and women, for example in connection to infections that developed during childbirth or early stages of life.

This is why it is particularly critical in the case of antibiotics that pharmaceutical companies, governments and procurers take action to ensure (not only access but) appropriate access to antibiotics. Local production – the focus of this study – is one possible way to achieve this objective.

Antibiotics currently have greater involvement of, and prospects for, local production in Africa than other major antimicrobials. Access to antivirals, antimalarials and drugs for treatment of tuberculosis is facilitated through international cooperation and financing mechanisms, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and President's Emergency Plan for AIDS Relief (PEPFAR) of the United States. Local African producers have struggled to break into these markets, which mostly operate through bulk procurement of WHO pre-qualified products at the lowest price possible that are usually provided by large generic companies, especially from India.

Instead, antibiotics are more widely consumed, and are produced in a wider range of developing countries, including as a result of significant public health interest. They are more likely to be used unnecessarily

(leading to drug resistance), due to the prevalence of bacterial infections that require medical intervention compared to those caused by parasites or fungi (Greenwood, Michael, 2021). The focus on antibiotics for human consumption is without prejudice to the role of other antimicrobials for public health and the importance of the broader issues of AMR, such as in agriculture and environmental regulation. Nevertheless, the COVID-19 pandemic has led to disruption and shortages of supply of antibiotics for human consumption in many developing countries.

The Kenyan government has frequently expressed a goal to increase the share of local pharmaceutical production. The Kenya National Drug Policy (1994) included a specific objective "to encourage self-sufficiency through local manufacture of drugs for consumption and export" (1994, 5). The subsequent Kenya National Pharmaceutical Policy 2012 similarly includes an objective to "Encourage local manufacture of essential medicines for self-sufficiency in the domestic market and to promote growth in pharmaceutical exports" (Ministry of Medical Services 2012, 3). Pharmaceuticals is one of the sectors listed under the medium to high technology sectors as a priority alongside labour intensive sectors and advanced manufacturing industries in Kenya's National Industrialization Policy Framework 2012-2030. The Kenya Pharmaceutical Sector Development Strategy, developed by UNIDO in collaboration with various Kenyan governmental stakeholders as well as the Federation of Kenya Pharmaceutical Manufacturers, was released in 2012. The 2020-2025 Strategic Plan of the Pharmacy and Poisons Board includes promotion of local production as a strategic objective.

Pharmaceuticals is also listed in the EAC Industrialization Strategy 2012-2032 as one of six strategic industries to be promoted. There is an EAC Regional Pharmaceutical Manufacturing Plan of Action 2012-2016, followed up by the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027. Regulatory harmonization has been ongoing. Kenya has become part of the 2015 Medicines Regulation Harmonization Guidelines of EAC. It is also participating in joint evaluations and inspections together with other National Medicines Regulatory Authorities of EAC partner states.

The purpose of this study is to examine the current situation and the investment framework for the manufacturing and supply of antibiotics in Kenya. The study of this particular therapeutic category can inform the opportunities and challenges facing wider initiatives concerning local pharmaceutical production in Kenya. In addition, the project outcomes may inform the design of incentives to promote production and supply of other essential medicines lacking sufficient market incentives. The investment and trade perspective offered here into the incentives for local production of antibiotics may also inform policymakers concerned with tackling AMR, in Kenya and other countries.

As part of the analysis, the project involved an extensive stakeholder assessment and consultation involving:

(i) Policy makers covering investment policy, health policy, trade and procurement.

(ii) Regulatory agencies.

(iii) Public procurement agencies, and health service providers (referral hospitals).

(iv) Pharmaceutical companies and

(v) Donor agencies and civil society.

After delays due to COVID-19, the project started in July 2020. Representatives of a total of 35 organizations were interviewed. The list of interviewees is detailed in Annex I. In addition to the interviews, the study involved extensive collection and analysis of empirical data on local production of antibiotics and the associated relevant investment policy framework. The key findings and recommendations of the draft advisory report were presented for review on May 2021 during an international expert meeting organized by UNCTAD. This final report incorporates the comments received from international experts and national stakeholders.

A number of challenges were encountered during the preparation of this advisory report. One critical challenge was the difficulty of getting access to all the relevant data. In particular, production volumes

and sales data were not forthcoming from manufacturers and distributors. The COVID-19 pandemic also posed delays in meeting with stakeholders and receiving certain data. Nevertheless, most key stakeholders provided time and gladly offered their insights and perspectives.

UNCTAD is the focal point of the United Nations for the integrated treatment of trade and development and interrelated issues in the areas of finance, investment, technology and sustainable development. This report focuses on this dimension of antibiotics production and supply. At the same time, pharmaceuticals issues are of crucial significance for public health, and those of antibiotics for AMR. Health policymakers play key roles in shaping the policy context facing pharmaceutical production and supply, especially through regulation and procurement. It is thus anticipated that the findings will be of interest and relevance to national health authorities, the WHO and civil society organizations concerned with public health.

As an additional deliverable to the project, the project team coordinated by UNCTAD is preparing a paper, discussing the "Business Case for Local Pharmaceutical Production in Africa, with Focus on Antibiotics". The objective of the paper is to assess the argument for the economic viability of local production of antibiotics in Africa, including historical evidence, business rationales and (country-specific) enabling factors. While not focusing specifically on Kenya, some general aspects of the framework presented in the paper have been informing and shaping the material presented here. To the benefits of the interested Kenya stakeholders, a pre-view excerpt of the key findings of the study is added as Annex (3) to this Report.

The remaining part of this report is organized as follows. The next section provides brief background on the socio-economic context of Kenya. Section 2 assesses the pharmaceutical industry landscape, with a particular focus on local production of antibiotics. Section 3 examines prices and availability of locally produced relative to imported antibiotics. Section 4 illustrates investment incentives currently in place to support local production in Kenya. Section 5 reports the results from interviews with Kenyan stakeholders regarding their perceptions on antibiotics local production and on the investment environment. The last section summarizes the main findings and provides some policy recommendations.

1. SOCIO-ECONOMIC CONTEXT

Kenya is a middle-income East African country with a fast-growing population, estimated at 53 million in 2021[1]. With a Gross Domestic Product (GDP) of USD 110.347 billion in 2021, Kenya is considered a leading economy in East Africa. Agriculture has the largest share of the economy, contributing about one-third of its GDP. Tourism, manufacturing, building and construction and retail industry are the other important contributors of the national GDP.

Kenya's 2030 Vision provides the developmental blueprint for the country, with the aim of making Kenya "a newly-industrializing, middle income country providing high quality life to all its citizens" by the year 2030 (Kenya, 2021). It is being implemented through medium term plans that include the "Big 4 Agenda" (2018-2022). The Big 4 agenda targets two strategic areas with direct impact on pharmaceutical manufacturing, increasing the share of manufacturing in the economy from 8.5% to 15% and achieving 100% Universal Health Coverage (UHC). Both under Vision 2030 and the Big 4 Agenda, Kenya implemented the development of special economic zones (SEZ) and export processing zones (EPZ). The EPZs and SEZs are expected to attract foreign direct investments and provide opportunities for partnerships. The Buy Kenya Build Kenya strategy, encouraging purchasing and consumption of locally produced goods and services, was launched by the Ministry of Industrialization, Trade and Enterprise Development in 2017.

A member of the EAC, Kenya is not subject to tariffs against imports and exports with its six partners, Burundi, Kenya, Rwanda, South Sudan, Uganda and Tanzania. It also applies a Common External Tariff (CET), covering most of Kenya's exports and imports. Kenya is part of the EAC Industrialization Policy 2012-2032 and associated Strategy. Kenya is also a member of COMESA – a free trade block consisting of 21 member states across Africa. Kenya is a member of the African Continental Free Trade Area (AfCFTA), with an objective of reducing or eliminating tariffs for 90% of tariff lines between African Countries by 2030 latest followed by elimination of an additional 7% of tariff lines.

Healthcare is financed through direct public funding by the government and donor organizations, the National Hospital Insurance Fund (NHIF), private health insurance, and out-of-pocket expenditure by consumers. Public funding is by far the largest source, accounting for 60% of expenditures, followed by out-of-pocket expenditure at 27%. Private insurance and NHIF account for 13% of expenditures (Ministry of Health. 2017). Around 19% of the population have health insurance, out of which 16% are covered under the NHIF (Barasa, Edwine, et al, 2018). Lack of comprehensive and affordable insurance has an impact on health-related behaviors, and access to healthcare and treatments that require antibiotics.

[1] World Bank World Development Indicators.

2. THE KENYAN PHARMACEUTICAL INDUSTRY, WITH FOCUS ON LOCAL PRODUCTION OF ANTIBIOTICS

2.1. Pharmaceutical industry landscape

Kenya's pharmaceutical market has been growing steadily with the expansion of the economy, a growing population, urbanization and an increase in life expectancy. The pharmaceutical market was estimated at approximately $1 billion in 2018 showing a significant rise from $826 million in 2016 and $919 million in 2017 according to the PPB. It is expected to grow at an estimated compound annual growth rate of 7.6%– 12% for the next five years starting from 2021 (Kenya Investment Authority, 2020). Generics comprise the major share of the market, with the patented drug market – at US$ 108 mn (KES 10.9 bn) – at marginally over 10% of the total. COVID-19 might affect some of these projections as it continues to affect all sectors including the pharmaceutical sector.

There are 3 distinct segments to the market – private, public and mission (Government of Kenya 2020, 53) – with a similar market share (Figure 1). Public procurement is coordinated by KEMSA (the Kenya Medical Supplies Authority), which is estimated to account for about 30% of the medicines in the country (Ministry of Health 2020, 45). The Mission for Essential Drugs and Supplies is a Christian not-for-profit organization which procures medicines for faith-based organizations and mission hospitals, but also sell to NGOs, private hospitals and government outlets (Ewen et al. 2018, 7).

Kenya has 35 registered pharmaceutical companies that manufacture medicines for both the local and export market. Both Universal Corporation and Dawa Pharmaceuticals are WHO-prequalified. 5,744 people were employed in manufacturing of basic pharma products and preparations in 2017 (Ministry of Health 2020, 21). Local production is estimated to supply about 20- 30% of the pharmaceuticals on the Kenyan market. Key characteristics of local manufacturers include similar product portfolios, variation in GMP standards and low-capacity utilization (usually between 50% and 66%) (UNIDO 2010, 5).

Foreign investment in local pharmaceutical manufacturing is low, but growing following a series of investment announcements since 2016. UNIDO (2010, 42) noted only one multinational, GlaxoSmithKline, to be amongst the local manufacturers in Kenya. Although, in 2022, GlaxoSmithKline announced it would pull out of Kenya in order to adopt a distributor-led model to supply the country, the factory will remain open under its affiliate Haleon (Healthcare Africa 2022). Strides Pharma (from India) acquired Universal Corporation, one of Kenya's leading local pharmaceutical manufacturers, in 2016 (KIA 2020, 16). B. Braun Pharmaceuticals from Germany took an existing factory in Nairobi in 2017 and substantially renovated the facility to commence local manufacturing. A series of greenfield FDI projects have also been announced including Square Pharmaceuticals (from Bangladesh) in Athi River EPZ, Dinlas Pharma EPZ Ltd. (from India) in Machakos County, and Tasa from the UK (KIA 2020, 16). South Korea's Kolon Pharmaceuticals is also reported to have entered (Kenya 2020, 30).

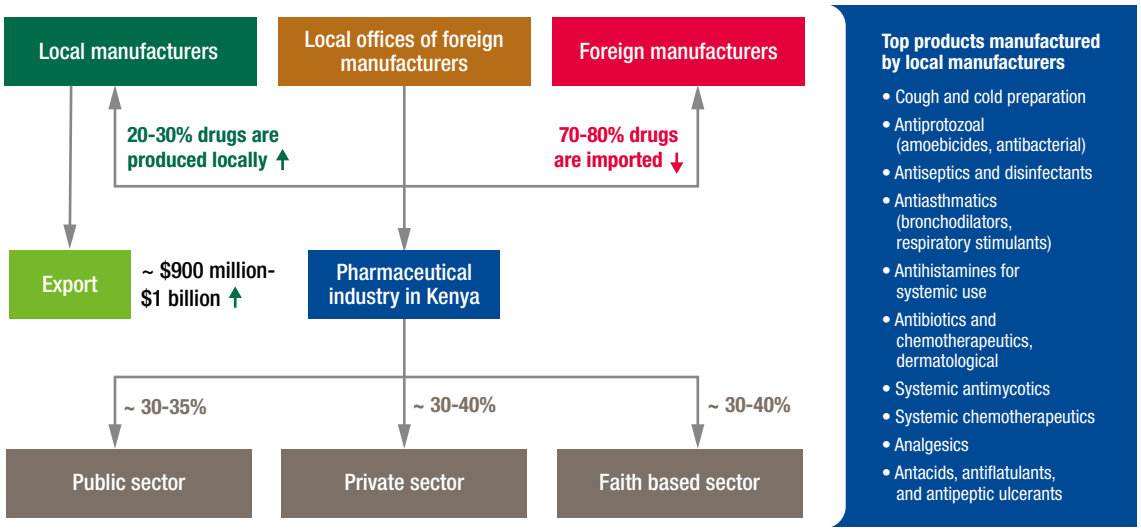
Kenya is also the largest producer of medicines in the Common Market for Eastern and Southern Africa (COMESA) region. Its largest pharmaceutical export markets include Tanzania and Uganda, which are part of East African Community (EAC) to which Kenya belongs. It also exports to other EAC member states, such as Rwanda and Burundi, and other countries in COMESA, such as the Democratic Republic of the Congo, Comoros, Ethiopia, Malawi, Zambia. Outside COMESA, Kenya exports to Mozambique.

The bulk of local production of pharmaceuticals is at the formulation stage of the value chain. There is only one API – pharmaceutical-grade artemisinin (manufactured by East African Botanical Extracts EPZ Limited.) – produced in Kenya but it is exported 100%. 95% of raw materials inputs are imported (estimated cost KES 25 billion annually) (Ministry of Health 2020, 45), implying that even local producers

must thus heavily rely on imported content. The weight of APIs in the value of local formulation of antibiotics ultimately depends on the product and location-specific factors, such related to technology, labour, finance, access to market and investment incentives in place. As a rough indication, a McKinsey report (Conway et al, 2019) sets the incidence of the costs of imported API on manufacturer price at just above 10% for a generic over-the-counter drug produced in sub-Saharan Africa (see also annex 3).[2]

APIs are imported at 0% rate into Kenya. The CET recognizes finished pharmaceuticals as meritorious goods and reduces their duty to 0%. Excipients do attract tariffs, but Kenya has negotiated exemptions for certain excipients. Machines and machine parts needed to manufacture pharmaceuticals are not covered by import duty exemptions and they also attract value-added-tax (VAT).

Figure 1. Broad overview of the Kenya pharmaceutical sector



Source: Kenya Pharmaceutical Diagnostic Report 2020

Similar to elsewhere on the African continent, local manufacturers face a strong competitive challenge from imported products. Imports dominate the Kenyan market, with approximately 70%-80% of the value of all medicines used in Kenya being imported (Kenya Pharmaceutical Diagnostic Report 2020). In 2021, the major source of imports was India – accounting for 42.8% of the total value (although that share was above 50% for 2014-2020 inclusive) (Table 2). India's share is more than 3 times that of the next largest source of imports – United States (14.2%), whose share increased suddenly from only 3.6% in 2020. India plays a prominent role in the global pharmaceutical industry as a producer, and supplier of large volume, of finished generic drugs.

[2] According to another (outdated) reference (Guimier et al., 2004), significance of API in manufacturer's selling price varies massively depending on the drug, reaching up to 40% for some antibiotics. See also Hill et al. (2018).

Table 2. Major source of pharmaceutical formulation imports to Kenya 2021

Source of Imports	2022 imports (US$ thousand)	% of total
World	287,073	100.0
India	263,265	42.8
United States of America	87,273	14.2
Germany	68,557	11.1
United Kingdom	28,873	4.7
France	22,715	3.7
China	18,990	3.1
Italy	16,482	2.7
Pakistan	15,926	2.6
Belgium	11,837	1.9

Source: Data from ITC Trade Map. Product category 3004 "Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, ..."

This picture does not differ when focusing on product categories. India remains the major source of all pharmaceuticals (human and veterinary) registered in Kenya (Table 3). Over half of products registered are from India. The next highest source is Kenya, with 16.6% of all registered products produced by local manufacturers, a relatively high share for the Sub-Saharan Africa.

Table 3. Source of products registered in Kenya

	TOTAL	6.921	% of total
1	INDIA	3,546	51.2
2	KENYA	1,149	16.6
3	BANGLADESH	272	3.9
4	GERMANY	245	3.5
5	PAKISTAN	216	3.1
6	CHINA	184	2.7
7	FRANCE	171	2.5
8	UNITED KINGDOM	100	1.4
9	SWITZERLAND	95	1.4

Source: Data from Intergovernmental Authority on Development: https://mrh.igad.int/production/index_ke (last accessed 09th May 2023).

The Kenyan government has frequently expressed a goal to increase the share of local pharmaceutical production. The Kenya National Drug Policy (1994) included a specific objective "to encourage self-sufficiency through local manufacture of drugs for consumption and export" (1994, 5). The subsequent Kenya National Pharmaceutical Policy 2012 similarly includes an objective to "Encourage local manufacture of essential medicines for self-sufficiency in the domestic market and to promote growth in pharmaceutical exports" (Ministry of Medical Services 2012, 3). Pharmaceuticals is one of the sectors listed under the medium to high technology sectors as a priority alongside labour intensive sectors and advanced manufacturing industries in Kenya's National Industrialization Policy Framework 2012-2030. The Kenya Pharmaceutical Sector Development Strategy, developed by UNIDO in collaboration with various Kenyan governmental stakeholders as well as the Federation of Kenya Pharmaceutical Manufacturers, was released in 2012. The 2020-2025 Strategic Plan of the Pharmacy and Poisons Board includes promotion of local production as a strategic objective.

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However, despite such policy attention, the Ministry of Health's (2020, 21) 'Health products and technologies: Supply chain strategy 2020-2025' has noted that ".... Efforts to revitalize local production of Health Products and Technology (HPT) with a view to improving accessibility, affordability and contributing to economic growth are notable, but have not had significant impact".

2.2. Focus on local production of antibiotics

Antibiotics are among the top products manufactured in Kenya. Yet, local producers cover only a narrow range of all antibiotics registered in Kenya. Specifically, it is possible to identify 189 antibiotics (out of 269 antimicrobial products that include antifungals and antiprotozoals) of different formulations and strengths supplied by 13 local manufacturers (see annex 2), relative to 1,254 antimicrobials registered by exporters and importers. Locally manufactured antibiotics include penicillins such as cloxacillin, amoxicillin, and amoxicillin trihydrate BP.

The three leading antibiotic manufacturers in Kenya are Laboratory & Allied Ltd, Cosmos Limited and Dawa Limited based on 2021 data. Notably, Dawa produces more antibiotics among its products than any other classes of medicines, with more that 50% of its production (number of products) being antibiotics. Formulation of antibiotics used include tablets, capsules, liquids and powder for suspensions.

In 2019, WHO developed a classification of antibiotics "Access, Watch, Reserve" (AWaRe) where antibiotics are classified into different groups to emphasize the importance of their appropriate use.3 A comparison between the locally manufactured antibiotics in Kenya with the AWaRE/WHO lists reveals that most are in the 'Access' group, including 2 non-essential antibiotics; 8 are in 'Watch' group, half of which are non-essential antibiotics under the AWaRe classification. There are no antibiotics under the 'Reserve' group being produced in Kenya. Instead, there are three antibiotics that are in the 'not recommended' group of the WHO list. Not recommended antibiotics have no therapeutics advantages to the already existing antibiotics often they are in the same class.

[3] Access: This group includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while also showing lower resistance potential than antibiotics in the other groups. Watch: This group includes antibiotic classes that have higher resistance potential and includes most of the highest priority agents among the critically important antibiotics. These antibiotics should be prioritized as key targets for stewardship and monitoring programmes. Reserve: This group includes antibiotics that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms. Reserve group antibiotics should be treated as "last resort" options.

Table 4. Classification of locally manufactured antibiotics in Kenya by active ingredient and AWaRe group

Access Group		Watch Group	Not recommended
Amoxicillin	Phenoxymethyl Penicillin	Clarithromycin	1. Ampicillin/ Cloxacillin
Ampicillin	Sulfamethoxazole/ Trimethoprim	Azithromycin	2. Amoxicillin/ Flucloxacillin
Cefalexin	Amoxicillin/ clavulanic Acid	Cefuroxime	3. Amoxicillin/ Flucloxacillin
Chloramphenicol	NON-ESSENTIAL	Ciprofloxacin	
Cloxacillin	Tetracycline	NON-ESSENTIAL	
Doxycycline	Flucloxacillin	Rifampicin	
Metronidazole (oral)		Ofloxacin	
Nitrofurantoin		Norfloxacin	
		Erythromycin	

Source: Compiled by author from interviews

The Kenyan pharmaceutical industry productive capacity is underutilized. For example, in 2019 only 43% average capacity was used for production of beta lactam antibiotics (48% tablets, 28% capsules and 52% liquids).

3. PRICE AND AVAILABILITY OF LOCALLY PRODUCED RELATIVE TO IMPORTED ANTIBIOTICS

One key dimension in the policy discussion around local production of antibiotics – and of any pharmaceutical product in general – is the analysis of the competitive dynamics facing local production relative to imports. This type of analysis is typically very challenging because it requires information on the price and availability of locally manufactured and imported products.

An earlier study by the WHO and Health Action International (Ewen and Okemo 2018) provides some useful insights into the market dynamics of locally-produced relative to imported antibiotics. The study surveyed a total of 31 medicines (both locally produced and imported) – all on Kenya's Essential Medicines List, of which 10 are antibiotics.

The analysis of prices and availability of locally produced relative to imported antibiotics is segmented according to the three main distribution channels – a. Government procurement, b. Public sector and c. Private and other sectors – reflecting different market dynamics.[4]

a. Government procurement prices:

The government procured eight antibiotics in the survey group from local manufacturers and only two were imported (Table 5). Only one antibiotic was procured from both local producers and importers, although these were of different pack sizes. However, when compared to the international reference price, the locally produced product has a lower price ratio (0.28) compared to the imported product (0.35). Moreover, the median MPR for the eight antibiotics procured from local manufacturers was relatively low (0.58), and with the MPR for each smaller than one and thus lower than the international reference price. For the survey as a whole, the median MPR of the locally produced products was 30% lower than the imported products (0.55 compared to 0.78). However, only two antibiotics were imported, making little sample available for meaningful price comparison.

Table 5. Government procurement prices – antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (KSh)	Median MPR	Products (n)	Median unit price (KSh)	Median MPR
Amoxicillin 250mg disp tab				1	7.36	2.29
Amoxicillin 500mg	1	1.77	0.58			
Ciprofloxacin 250mg	1	1.26	0.58			
Ciprofloxacin 500mg						
Cotrimoxazole 240mg/5ml susp.	1	0.32	0.66			
Cotrimoxazole 480mg	1	0.81	0.66			
Doxycyline 100mg	1	0.92	0.68			
Metronidazole 200mg	1	0.31	0.49			
Metronidazole 200mg/5ml susp	1	0.25	0.46			
Silver sulphadiazine 1% cream	1	0.57	0.28	1	0.73	0.35

Source: Ewen and Okemo (2018, 32). All antibiotics products included in the original survey are listed above. Some listed were not procured from either local producers or importers.

[4] Availability is understood as "whether the medicine was in the outlet on the day of data collection" (Ewen and Okemo 2018, 10). Prices for locally produced products are inclusive of all costs to the central store. The original authors adjusted the imported prices, given they were split across Free Carrier (FCA), Free on Board (FOB) and Cost and Freight (CFR), to ensure comparability with locally produced prices. The median price ratio (MPR) is defined as "the ratio of the median price in local currency (Kenyan Shilling, KSh) divided by an international reference price converted to KSh" (Ewen and Okemo 2018, 10). It allows comparison internationally with prices governments could expect to pay. Values greater than 1 are more than the international reference price.

b. *Public sector patient prices:*

Patients then pay for publicly procured medicines (at public sector patient prices) out of pocket at public hospitals and health facilities. For a small number of the products, patient prices could be compared between locally produced and imported antibiotics in the public sector (Table 6). The public sector prices of locally produced antibiotics (median MPR of 1.31 the international reference across nine medicines, some of which have multiple products) were on average slightly cheaper than imported products (median MPR of 1.59 the international reference across 7 medicines). For the six antibiotics where both locally produced and imported products were found, the median MPR was lower for locally produced products (1.52) than for imported products (1.95). However, the number of products was small, especially for the imported category. For the full group of medicines in the original study, patient prices in the public sector were almost identical across locally produced and imported.

Table 6. Patient prices in the public sector - antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (KSh)	Median MPR	Products (n)	Median unit price (KSh)	Median MPR
Amoxicillin 250mg disp tab				13	Free	
				3	2.7	0.84
Amoxicillin 500mg	3	Free		4	Free	
	3	0.20	0.07	6	3.67	1.2
Ciprofloxacin 250mg	9	Free		4	Free	
	6	3.75	1.73	6	5	2.31
Ciprofloxacin 500mg	4	Free				
	1	5	1.31	2	6.07	1.59
Cotrimoxazole 480mg	16	Free				
	14	2	1.63	0		
Cotrimoxazole 240mg/5ml susp.	26	Free				
	5	0.5	1.02	0		
Doxycyline 100mg	11	Free				
	17	5	3.68	2	5	3.68
Metronidazole 200mg	3	Free		9	Free	
	9	1.68	2.69	11	1.67	2.67
Metronidazole 200mg/5ml susp	27	Free				
	3	0.5	0.91	0		
Silver sulphadiazine 1% cream	8	Free		2	Free	
	12	1.2	0.58	5	0.8	0.39

Source: Ewen and Okemo (2018, 32).

Note: All antibiotics products included in the original survey were listed above. Note: n is the number of products found that were free and where patients paid out-of-pocket. An MPR and price in KSh is given for medicines where the patient paid out-of-pocket. Prices in KSh are for a unit (i.e., a tablet or capsule, mL of liquid, gram of cream).

c. *Patient prices in the private and mission sector:*

Prices were available for both locally produced and imported antibiotics for five drugs in the private sector. The prices were higher (Median MPR) for imported products in 3 cases, equal in one, and lower in the final. For 5 drugs in the mission sector with prices available for both imported and locally produced, the prices were higher for 3 of the imported drugs, but lower for the other 2. For all drugs in the study in both

the private and mission sectors, a paired analysis found the median MPR to be slightly higher for imported products than those locally produced.

Table 7. Patient prices in the private sector - antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (KSh)	Median MPR	Products (n)	Median unit price (KSh)	Median MPR
Amoxicillin 250mg disp tab	0			3		
Amoxicillin 500mg	2			32	6	1.96
Ciprofloxacin 250mg	1			1		
Ciprofloxacin 500mg	0			34	10	2.62
Cotrimoxazole 480mg	16	2.5	2.04	5	2	1.63
Cotrimoxazole 240mg/5ml susp.	34	1	2.04	2		
Doxycyline 100mg	17	3	2.21	13	5	3.68
Metronidazole 200mg	17	1	1.6	9	1	1.6
Metronidazole 200mg/5ml susp	33	0.8	1.45	5	6	10.87
Silver sulphadiazine 1% cream	16	4	1.95	17	5.78	2.81

Source: Ewen and Okemo (2018, 36). Note: All antibiotics products included in the original survey are listed above. Note: An MPR and price in KSh is given for medicines with >3 price points. Prices in KSh are for a unit i.e. a tab or cap, mL of liquid, gram of cream etc. Note: Zinc disp tabs were found to be supplied free-of-charge from two pharmacies.

Table 8. Procurement prices in the mission sector – antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (KSh)	Median MPR	Products (n)	Median unit price (KSh)	Median MPR
Amoxicillin 250mg disp tab	0			2		
Amoxicillin 500mg	3			15	6.6	2.15
Ciprofloxacin 250mg	7	6	2.77	4		
Ciprofloxacin 500mg	7	13.5	3.54	11	12	3.15
Cotrimoxazole 480mg	2	free				
	14	5	4.08	3		
Cotrimoxazole 240mg/5ml susp.	4	free				
	9	1	2.04	1		
Doxycyline 100mg	13	10	7.36	8	5	3.68
Metronidazole 200mg	7	2	3.21	10	2.5	4.01
Metronidazole 200mg/5ml susp	1	free				
	14	5	3.26	9	9.44	6.16
Silver sulphadiazine 1% cream	1	free				
	12	2.67	1.3	4	5.7	2.77

Source: Ewen and Okemo (2018, 37-38). Note: All antibiotics products included in the original survey are listed above.

Availability: A major argument in favor of local production relative to imports is the availability of key medicines in the market. In the case of antibiotics, this argument is made even more pressing by AMR considerations. According to the 2018 WHO-HAI study, locally-produced antibiotics are more available than imported products in the public (54% vs. 22%), private (38% vs. 35%) and mission sectors (41% vs. 27%) (Table 9). For all 31 medicines in the study as a whole, locally produced products were more available than imports in the public sector, while availability was very similar in the private and mission sectors.

Table 9. Percentage availability by sector – antibiotics

	Public sector		Private sector		Other sectors	
	Local	Import	Local	Import	Local	Import
Amoxicillin 250mg disp tab	0%	47%	0%	10%	0%	9%
Amoxicillin 500mg	20%	33%	7%	90%	14%	68%
Ciprofloxacin 250mg	47%	33%	3%	3%	23%	14%
Ciprofloxacin 500mg	17%	7%	0%	83%	27%	50%
Cotrimoxazole 240mg/5ml susp.	90%	0%	77%	7%	55%	5%
Cotrimoxazole 480mg	90%	0%	50%	17%	64%	14%
Doxycyline 100mg	90%	7%	57%	40%	59%	36%
Metronidazole 200mg	33%	67%	57%	27%	32%	45%
Metronidazole 200mg/5ml susp	90%	0%	83%	17%	73%	9%
Silver sulphadiazine 1% cream	60%	23%	50%	53%	59%	18%

Source: Ewen and Okemo (2018, 42-43).

Note: Data on all antibiotics products included in the original survey – 10 of the 31 medicines – are included above. Availability is understood as "whether the medicine was in the outlet on the day of data collection" (Ewen and Okemo 2018, 10), assessed as the share of the number of outlets where the medicine is available over all outlets, in the public, private and other sector.

Although data is from 2018, and limited in terms of the limited number of items where direct comparison can be made between imported and locally produced price, some indications of key patterns emerge. The pricing data shows that locally produced antibiotics can be procured by government and sold (to patients) at lower or similar levels to imported medicines in both the public sector and in the private sector. Moreover, greater availability is found for locally produced antibiotics. Thus, current production and supply of the antibiotics currently produced by local manufacturers can be competitive with imports and increase availability.

4. INVESTMENT INCENTIVES LANDSCAPE

Pharmaceuticals production and supply in Kenya is regulated by a number of government agencies (Table 10). The major government ministries with interests in, and activities, related to pharmaceuticals are the Ministries of 'Investments, Trade and Industry' and 'Health', which are comprised of three and two state departments, respectively. The Pharmacy and Poisons Board is mandated under the Pharmacy and Poisons Act (last updated in 2012) that regulates the practice of pharmacy, manufacturing and trade in drugs and poisons. While the PPB is in charge of registration of pharmaceuticals, the National Quality Control Laboratory (NQCL) is responsible for testing and providing quality control of medicines that are imported to or manufactured in Kenya. The Kenya Medical Supplies Authority (KEMSA) coordinates public procurement for the government, while the Kenya Investment Authority is the main government body charged with promoting private sector investment. Annex 3 to this report shows a summary of the policies and laws that relate to the pharmaceutical manufacturing in Kenya.

Table 10. Major government agencies in the pharmaceutical sector

Major government agencies	Description of their role
Ministry of Investments, Trade and Industry	Concerned with promotion and expansion of trade, cooperatives and industrializations via 3 distinctive state departments
Ministry of Health	Body concerned with stewardship and leadership of the health sector, comprised of two state departments - Medical Services; Public Health and Professional Standards
Pharmacy and Poisons Board (PPB)	Regulation of manufacture and trade in drugs, as well as practice of pharmacy. Operating under State Department for Public Health and Professional Standards.
National Quality Control Laboratory (NQCL)	Examination and testing of drugs and medical substances to ensure quality. Operating under State Department for Public Health and Professional Standards.
Kenya Medical Supplies Authority (KEMSA)	Procurement, storage and distribution of drugs for public health programs and national referral hospitals. Operating under State Department for Medical Services.
Kenya Investment Authority (KIA)	Promotion and facilitation of private sector investment, operating under the State Department for Investments Promotion

Source: Authors' elaboration.

Kenya provides some incentives to attract investment and encourage local manufacturing, including in the pharmaceutical industry, both oriented to make the supply-side more attractive to local manufacturers ("production-facilitating") and to make the demand-side more attractive ("market-shaping") (Table 11). However, there is no incentive regime geared towards the local production of antibiotics as a specific class of pharmaceutical molecules, taking into account stewardship requirements and the recommendations of the AMR National Action Plans. The absence of a targeted investment policy for the promotion of local production of antibiotics is not specific of the Kenyan case but it is a common gap across most developing countries. In the context of developed countries however there are examples of national industrial and investment policies aimed at supporting specifically local production of antibiotics – as opposed to pharmaceuticals in general (Box 1). While not immediately replicable in the Kenyan context, and more generally in developing countries, they represent options of more sophisticated and targeted measures to support local production of antibiotics.

Table 11. Incentives for local production of pharmaceutical products in Kenya

Production-facilitating	Market-shaping
i. VAT exemption on finished pharmaceutical products and raw materials (produced or imported)	iv. Price preference of up to 15%
ii. Corporate income tax reduction for first 3-5 years on pharmaceutical greenfield projects	
iii. Export processing zones (EPZs) and special economic zone (SEZs)	

Production-facilitating incentives

i. Finished pharmaceutical products, whether imported or produced locally, are exempted from VAT. The VAT (Amendment) Act 2014 also eliminated VAT on "inputs or raw materials" used in the manufacturing of pharmaceuticals. The list of inputs and raw materials exempted from VAT is developed and approved by the Cabinet Secretary for the Treasury in consultation with the Cabinet Secretary for Health. There remain questions on how often the list will be updated (Wamae, Watu, et al, 2014). Yet, VAT is applied to packaging materials at 17%, raising the cost of medicines to the health institutions and ultimately the patients. VAT can be claimed back if proof can be provided on their sale, delivery to the client, and use in the pharmaceutical manufacturing industry. This, however, takes time to process, with implication of affecting the working capital of industries.

ii. Not only are fiscal incentives granted to VAT but also on income taxation. Namely, any greenfield project in pharmaceutical production benefits from a tax holiday from 3 to 5 years. The determination of the period is made by the government through the application process. (Kenya, 2020).

iii. A major emphasis of Kenya's investment framework to facilitate industrial transformation and diversification under Vision 2030 is the creation of export-processing zones (EPZs) and special economic zones (SEZs) (KIA 2020). Both offer dedicated infrastructure, including with power and water supplies, alongside a range of financial incentives. Already 5 pharmaceutical manufacturers are in EPZ/SEZ. These are Dinlas Pharma, Ivee Aqua EPZ Limited, Revital Healthcare EPZ Limited, B Braun Pharmaceuticals and Square Pharmaceuticals.

The purpose of EPZs is to facilitate exports and they are managed by the Export Processing Zones Authority (EPZA), seeking to concentrate foreign investment in specific areas. There are currently more than 40 gazetted EPZs. A range of incentives are available to companies with > 80% of sales to countries outside the EAC (only new investments in Kenya are allowed; 100% foreign shareholding is not allowed):

- 10 year corporate income tax holiday (followed by a 25% rate for subsequent 10 year)
- 10-year tax holiday on dividends and remittances to non-resident parties
- Permanent exemption from VAT and customs on input
- Permanent exemption from stamp duty payments on legal instrument
- 100% investment deduction, applicable over 20 years, on new investments in EPZ buildings and materials

SEZs allow sale of products locally or to export without restrictions, with a wider range of activities permitted to be carried out than in an EPZ (where investment needs to be manufacturing, as a zone developer or for export-oriented services). There are SEZs in Mombasa, Lamu and Kisumu. The SEZ authority is responsible for all SEZs, including functions of designing, approving, establishing, developing, operating, promoting and regulating. Companies operating in a Special Economic Zones enjoy a 10-year tax holiday, a 15% corporate tax for another 10 years, duty and VAT exemptions, a single license, as well as exemptions from stamp duty and withholding tax (Kenya, 2020).

Market-shaping incentives

Market-shaping incentives are also in place, including through preferential price treatment for local pharmaceutical producers in procurement. The Kenya Public Procurement and Disposal Act, 2015, legislates for the extent of price preference, stating that ""the procuring entity may grant a margin of preference of up to 15 percent in the evaluation of bids to candidates offering goods manufactured, mined, grown, and extracted in Kenya." (Government of Kenya 2020, 49). KEMSA gives this price preference of 15% for locally produced pharmaceuticals (in the mission sector, MEDS gives a 10% preference for such products).

Box 1. Lessons from other countries and international initiatives

Desktop research and discussion during an international expert meeting did not reveal major examples or case studies of recent measures or innovative mechanisms in developing countries to advance local production of antibiotics, including in the context of addressing AMR. However, some notable initiatives in developed countries demonstrate clear targeting of antibiotics production specifically. These initiatives can provide an insight on potential approaches but are very difficult to implement in Kenya and other developing countries contexts given the different regulatory and institutional framework and resources available to the public health systems. Yet, comments from the expert group meeting suggest that the local production of antibiotics and the establishment of their sustainable supply chains necessitates a special consideration, beyond the generic investment regimes for pharmaceutical production.

While high income countries are pursuing initiatives, such as reimbursement policies, aimed at shaping the wider usage of antibiotics (including via prescription, dispensation and consumption), they are also targeting production. Measures which affect producers include (Dzintars Gotham et al , 2020 and Jane Mingjie Lim, et al, 2020):

1. Shaping the pricing of selected antibiotics in order to influence investment patterns. For example, in France minimum prices referenced at or higher than the lowest price in United Kingdom, Germany, Italy, and Spain, are guaranteed for recently developed antibiotics. Other countries provide a more complex pricing system akin to service contracts in which annual revenue is guaranteed for a 'security stock' (an estimated safe reserve amount) or supply under strict obligations of stewardship. Another potential market-shaping mechanism is renegotiation of prices if a company is planning to cease production or commercialization of a certain product with no substitute.
2. Using a framework agreement or contracts between industry and public health agencies to work out the pricing, stewardship, or other terms and establish a long-term relationship.
3. Exemption of revenue generated from a supply of essential antibiotics from fiscal obligations, such as contributions to social security.

The specific example of Sandoz Pharmaceuticals (the generics arm of Novartis) in Austria shows how private sector investment can be shaped by government support. In 2020 there were announcements that Sandoz would close its production site in Austria. Upon government intervention, it was agreed that Sandoz would keep the local production of generic antibiotics for a minimum of 10 years with an investment of 150 million Euro of which 50 million Euro was contributed from public funds. The funding would support process innovations for the production of penicillin preparations and help the company withstanding the global price pressure. In this case, public intervention through a targeted Public-Private Partnership (PPP) was aimed at avoiding risk of concentration of manufacturing in particular countries – an option that may provide cheaper alternative but not secured supply line for life saving medicines. This is a lesson COVID-19 has clearly highlighted to global health systems.

As the Austrian example shows, while local pharma production has not been a priority in Europe for some time, it has now returned on the political agenda, motivated by concerns around increasing medicines shortages, further aggravated by the experience of the COVID-19 pandemic. The European Commission's "Pharmaceutical Strategy for Europe" published in Nov. 2020, mentions it as one policy option to consider.

In parallel to initiatives to incentivize local production of antibiotics at national level, Kenya participates in a number of regional efforts to promote pharmaceutical manufacturing in the East African region, including most notably through a recent collaboration between East African Community and UNCTAD, specifically on local production of antibiotics (box 2).

Box 2. Regional efforts to promote pharmaceutical manufacturing in East Africa

The East African Community (EAC) is among the most integrated regional economic communities in Africa. It consists of the Customs Union, Common Market, Monetary Union, and Political Federation. In addition to overall trade, services, and investment liberalization, EAC is implementing policies and strategies, in the context of vision 2050, that are aimed at promoting local production of medicines including:

1. EAC Industrialization Policy and Strategy (2010-2030) that identifies the pharmaceutical industry as one of the six priority sectors that need to be promoted through collective efforts of the EAC partner states.
2. EAC Pharmaceutical Manufacturing Plan of Action (EACRPMPOA: 2017-2027)- a regional roadmap, which aims to guide the EAC towards evolving into an efficient and effective regional pharmaceutical sector that can supply national, regional and international markets with efficacious and quality medicines.5
3. EAC Medicines and Health Technologies Policy and Strategic Plan (2016-2021) that focuses on promoting domestic pharmaceutical production, Good Manufacturing Practice (GMP) strengthening and incentivizing local industry, skills development, quality assurance (QA) systems and medicines financing.
4. Medicines Regulation Harmonization Guidelines, that was adopted in 2015 providing for similar standards and procedures for marketing authorization of medicines across partner states.

Currently, EAC is debating a Pharmaceutical Bill 2020 that would provide a more permanent and legal mandate for regional cooperation on pharmaceutical sector development.

Further to the work of EAC on the pharmaceutical sector, UNCTAD and EAC started a project to enhance the local production of antibiotics in the region leading to the adoption on 1st April 2023 by the EAC 38th Extra Ordinary Sectoral Council on Trade, Industry, Finance, and Investment (SCITIFI) of:

- Regional Policy Framework for the Promotion of Antibiotics Production and Supply (EAC/ExSCTIFI 38/Decision 5)
- Regional Cooperation Mechanism for Information Exchange and hold multi-sectoral meeting to operationalize the information exchange (EAC/ExSCTIFI 38/Decision 6).

These EAC instruments are the first of their kind on regional cooperation specifically applied to antibiotics

[5] EAC Pharmaceutical Manufacturing Plan of Action: 2017 -2027

5. STAKEHOLDER'S PERCEPTIONS ON ANTIBIOTICS LOCAL PRODUCTION AND INVESTMENT FRAMEWORK

5.1. General view on investment landscape and incentives

Insufficient incentives...

Interview respondents showed great interest on the role of incentives and the means to enhance local production of antibiotics in Kenya. The general feedback was that a boost for local investment in the pharmaceutical sector in Kenya is definitely needed and possible as the industry grows. However, some felt that the investment framework in Kenya is not as conducive compared to other countries in the region, such as Rwanda. The exemptions from income tax, tariffs and land lease rates remain inadequate.

The price preference in public procurement for local manufacturers is deemed small and not significant, and manufacturers have demanded more preferential treatment. However, UNIDO noted complaints by local manufacturers regarding "a lack of implementation of these provisions for preferential treatment" (UNIDO 2010, 7). UNIDO (2010, 9) also noted a reason given for the lack of implementation being the Finance Ministry not providing guidelines for implementation. The Government of Kenya also reported that there were little benefits for local manufacturers from the incentives, including not being given price preference in tender awards even when they fell within a range of 15 percent above that of an importing company (Government of Kenya 2020, 49).

Competitive pressure from imported products...

Local manufacturers reported strong and sometimes unhealthy competition from imported antibiotics. According to Government of Kenya (2020, 50), "The lack of import duty on medicines has helped create an import-driven market". UNIDO referred to there being a "flood of imported pharmaceuticals", due to ease of product registration, lack of pharmaceutical import tariff, little capacity in the PB to do foreign inspections of plants, uneven quality testing of imported drugs, low penalties on import of substandard drugs (UNIDO 2010, 6). The Ministry of Health (2020, 46) states that unregulated medicines, which are estimated at 8% of the market, pose competition for local manufacturing.

There have been calls from the Federation of East African Pharmaceutical Manufacturers (FEAPM) and other groups to update the regions' import duty to factor the value addition cost. According to them, the existing framework does not recognize the cost associated with value addition during local production compared to imported finished formulations. Some of the excipients are not duty exempt and consequently local manufacturers become uncompetitive against imported finished products. The FEAPM has called for the reduction of all charges, including the up to 9.25% of miscellaneous duties charged on pharmaceutical goods and related equipment, to be dropped for all EAC trading partners.[6] Addressing this could lead to additional incentives for local production of medicines including antibiotics. It would lower the costs of machinery and excipients including packaging needed for antibiotic production.

Disconnected from AMR issues…

Overall, manufacturers and other key stakeholders argued that for local manufacturing to be effective and efficient, it must be guided by domestic public health needs and resistance data. Currently, antimicrobial

[6] FEAPM Position Paper. FEAPM, FEAPM Position Paper.

stewardship does not inform, regulate nor guide manufacturing of antibiotics in Kenya. Current manufacturing is in response to market demand. For example, most antibiotic manufacturers in Kenya are not aware of AMR, AWaRe classification and national stewardship policies and agenda for AMR. There is a key gap between country policies, knowledge and practice as expressed by one manufacturer:

> There is not enough data to prove that the AMR burden is indeed a public threat; if there is such data, then it doesn't reach manufacturers. It is for this reason that manufacturing in Kenya is designed and responds to increased client demand. If truly AMR was an existential threat, why is there no drop in demand of majority of antimicrobials that continue to be manufactured.
>
> The knowledge gap extends to wholesalers whose business is driven by sales volume and profits. Pharmaceutical sales representatives are still compensated for high volumes of sales.

Unfit business model...

Stakeholders criticized the current business models of the local pharmaceutical industry that fail to diversify and expand production lines and products. One respondent stated that:

> The majority of the current local pharma manufacturers are family-owned businesses that are satisfied with the status quo, hence do not see the need to engage foreign investors, nor kick in much needed change of harnessing joint efforts to consider quality before demand and profits.

Supply chain vulnerability...

Local manufacturers reported their potential vulnerability to supply chain disruptions as a result of their reliance on importation of active pharmaceutical active ingredients (APIs) and most excipients. Any disruptions in the global supply chain of APIs impacts local production schedules. One respondent highlighted the COVID-19 pandemic's consequence on the antibiotic supply chain as follows:

> Once production is resumed in China and India, they will most likely first cater for their local population and then turn to export markets. Currently, Kenya is experiencing a shortage of Cotrimoxazole due to global API shortage and is affecting a large population of HIV positive patients who need it for their treatment regimen. Other examples include the shortages in the supply of benzathine penicillin an antibiotic used for the treatment of syphilis.

Gap in skills and human resources.

Manufacturers suffer from lack of skilled human resources for the industry. There are only 0.5 trained pharmacists per 10,000 people in Kenya (Ministry of Health, 2015). Additionally, those pharmacists trained in Kenya lack industrial skills, useful for production of specialized products such as antibiotics. There is no comprehensive industrial pharmaceutical curriculum available to students in Kenyan pharmacy schools. This delays the usefulness of domestically trained pharmacists to manufacturers. As a way to build some of this capacity, all pharmaceutical manufacturers are required to contribute to an education fund on a per employee basis, but there is a lack of consensus among contributors on how to use the money to best benefit the sector as a whole.

Red tape and administrative burdens…

One respondent noted that, for example, establishing a company in Kenya requires navigating through numerous government offices and payment of multiple fees. Registration of new pharmaceutical products takes between 2 to 5 years, discouraging pharmaceutical firms from taking initiatives to produce new products.[7]

[7] Medicines can be registered under the fast-track approval process that can take about 90 days in cases of national emergencies or some local products in special circumstances deemed by the PPB.

Other incentives relate to faster registration of locally manufactured drugs. Reimbursement for payment of the VAT on packaging materials can take "years" (Government of Kenya 2020, 64). The World Bank study also noted that local firms face challenges with claiming rebates on VAT from the Kenya Revenue Authority (2019, 122). Tariffs are being paid on imported packaging due to difficulties in claiming refunds and writing off rebates (World Bank 2019, 117).

5.2. Investment-related focus areas

Science, innovation & technology policy:

Respondents stated that Kenya has a long way to go to enable the different stages of drug development from bench to patient. Government's support and commitment throughout the process is important. The government would need to ensure the protection of intellectual property rights; improve the funding of R&D and skills development and improve the interaction between industry and academia. It was recommended that:

I. In order to expand into new areas of antibiotic production apart from investing in equipment it is important to partner with foreign pharmaceutical companies with many years of experience and resources. This will allow for knowledge and technology transfer currently missing in Kenya.

II. Existing and new manufacturing plants must possess the following at a minimum, with the necessary support from relevant policy bodies: i) robust quality management systems; ii) adequate skilled human resource (technical expertise); and iii) new technology and efficient equipment.

III. Strengthening pharmaceutical education especially, in R&D and other disciplines in industrial pharmacy and collaborating with research institutes such as KEMRI and International Livestock Research Institute, among others.

Effective regulation and management of the volume of supply of antibiotics:

The general view from the stakeholders was that appropriate medicines regulations are in place in Kenya. The main hurdle is effective enforcement. It was stated that the mandate of PPB is focused on ensuring that medicines found in the local market meet the set GMP regulations and safety standards. It, however, does not have the mandate to control the overall volume supplied to the market, which in the case of AMR and antibiotics is important for stewardship. The PPB has a role on adherence to good promotional policies and guidelines to control medicines marketing. Effective stewardship measures including optimal documentation on adherence, use of the EML could shape the market. In this way, demand for inferior products would naturally die off. The regulatory system needs to be strengthened (including, but not limited, to closure of all unregulated drug shops) and this should be accompanied by rigorous, all-year round sensitization and awareness creation amongst the public about the importance of proper use of antibiotics. Punitive measures for lack of adherence to stipulated guidelines need to be put in place by regulatory bodies as a way of enforcing adherence to guidelines. Current punitive action is not a sufficient deterrent. Another respondent stated that:

> For the AMR agenda to be a success, government needs to take leadership. Currently, the regulatory authority is hands-off in terms of ensuring control of medicines imports and use, under the protection of existing free trade policy. Therefore, they no longer regard the need for effective medicines as a science to treat people but simply a trade through which the demand is manufacturer driven. The fact that there was a general marked drop in pharma sales during COVID-19 movement restriction months (despite their availability), but has since picked again, is proof of this. A plausible solution is a government-driven/owned intervention in which the "push" aspect is not pegged to commissions.

Delinked Model.

Respondents were introduced to two models of de-linkage that have been proposed to increase access to essential antibiotics while incentivising investment for the production and supply of antibiotics and asked if they can be implemented in Kenya. Current models of revenues rely on volumes of sales for profits and return on investments. Alternative models have been proposed, such as partial and full delinkage where the innovator receives annual payments in addition to the revenues from quantities sold or the innovator does not receive any revenues based on volumes sold but a fixed annual payment[8]. Such models are used in Europe to incentivize R&D, with Sweden, Norway and the UK being examples.

Of the delinkage models presented to them, respondents felt that the UK model is the one that could possibly work in the Kenyan context, where the government commits to buy specific antibiotics from manufacturers, based on data on their effectiveness and effective stewardship at both industrial and hospital/pharmacy levels. The model can be coupled with UHC policy based on a system similar to the UK whereby access to finance from the country's National Health Service by health facilities is determined by the score attained on indicators such as hospital acquired infections, antibiotic use and resistant infection rates. The lower the score, the higher the chance of not being reimbursed by the National Health Service. The system is said to be good for antimicrobial stewardship through reduction of antibiotic use and early conversion of parenteral antibiotics to oral conversion. It is important to note that this model would only work if Kenya had more of its citizens insured, as well as a strong health system that tracks and can report certain key indicators. Unfortunately, less than 20% of the population are insured. The UK model is a reimbursement model based on performance and other key indicators such as the number of hospital acquired infections and readmission rates. These indicators are not generally collected in Kenya. Sweden equally has a partially delinked model which is also unlikely to work in Kenya. There, the government guarantees revenue and sales revenue.

Pooled procurement.

Addressing access challenges to critical and essential antibiotics have led to different strategies and discussions that have included pooled procurement models. These models have included sharing of information, pooling of resources and volumes for procurement to joint manufacturing audits and harmonization of pharmacy laws. Some policies that promote pooled procurement have been in place but have not been actualized by member states due to various reasons. On a smaller scale the Faith-based Organizations from Kenya, Rwanda, Tanzania and Uganda have shown the benefits of pooled procurement, as they procure together once a year. The strategy has improved their stock levels, reduced procurement costs, increased their revenues and increased quality assurance of antibiotics procured through this system. Countries could benefit more through stringent screening methods from the pooled procurement model.

Import regulations and tariffs.

Kenya is member of the WTO and has an economic policy based on free market principles. There is no law that prevents importation of competing products as long as they meet stipulated regulations. In this light, PPB, as the national regulatory agency for medicines, cannot dictate nor place a cap limiting imported brands of different molecules. According to PPB, the responsibility to manage imports and supplies belongs to the Ministry of Health. Yet, despite a major reduction of tariffs, an important factor that needs to be addressed is removing tariffs on all excipients and packaging materials that currently do not fall under the medicines' category.

[8] Årdal C, Johnsen J, Johansen K. Designing a Delinked Incentive for Critical Antibiotics: Lessons from Norway. J Law Med Ethics. 2018 Jun;46(1_suppl):43-49. doi: 10.1177/1073110518782914. PMID: 30146956.

6. SUMMARY OF MAIN FINDINGS AND KEY RECOMMENDATIONS

This report assesses the investment incentives for local production of essential antibiotics in Kenya in light of mitigating AMR. Kenya, like other African countries, has a weak health system faced with a high burden of infectious diseases often requiring antibiotic treatment. Stock-outs of essential medicines including antibiotics unfortunately is common.

The purpose of this advisory report is to (i) examine the current status of the manufacturing of antibiotics in Kenya and the relevant investment framework and (ii) propose recommendations for enhancing it, with particular reference to incentives for promoting investment in local manufacturing.

This study involved policy and literature review, secondary data analysis, and primary data analysis based on field survey and interviews with various stakeholders including government, the private sector and civil society. This section summarizes the main findings and provides key recommendations.

Main findings

a. *Local production landscape:*

1. *Large number of local manufacturers, but few involved in antibiotics production.* 35 local pharmaceutical manufacturers are present in Kenya, with 13 having antibiotics registered. However, their share of supply is only 30% of the overall Kenyan pharmaceutical market and growing below expectations.
2. *Confined to the formulation stage, but some API production present in the country.* Local production has remained confined to the formulation stage and thus dependent on imports of inputs (APIs). Yet, unlike most African countries, a limited local production of API is present, but entirely devoted to exports.
3. *Foreign investment relatively limited, growing recently.* Only one foreign-owned manufacturer was present until 2015. But five such firms have invested in recent years. Four of these are confirmed EPZ investments, pointing to that incentive initiative as a key driver of the upturn in FDI in the sector.
4. *AMR considerations not a critical driver of antibiotics production or consumption patterns.* Instead, market factors appear to be the key shapers of supply.

b. *Locally produced vs. imported antibiotics:*

1. *Pricing of locally produced antibiotics competitive in public sector outlets.* Based on a 2018 survey on a sample of antibiotics, the prices of locally produced antibiotics were found marginally cheaper than imported ones for patients in public sectors outlets and lower than international standards.
2. *Comparable prices between locally-produced and imported antibiotics, in the private and mission sector.* A mixed pattern was found in the private and mission sectors as to which had higher prices for the five antibiotics where data was available for both. In both sectors, the imported products were higher priced for three of the five antibiotics.
3. *Higher availability associated with local production.* Locally-produced antibiotics had higher availability in the outlets surveyed than imported products in the public (54% vs. 22%), private (38% vs. 35%) and mission sectors (41% vs. 27%).

c. *Incentive system:*

1. *A rather standard package of incentives for local pharmaceutical production* comprising both production-facilitating incentives (to make the supply-side more attractive to local manufacturers) and market-shaping incentives (to make the demand-side more attractive):

   - Production-facilitating incentives – including exemptions from VAT for inputs and raw materials into the production of pharmaceuticals, corporate income tax incentives, and a package of incentives for investment in EPZs and SEZs

   - Market-shaping incentives – 15% price preference for local manufacturers in public procurement

2. *But not product specific.* No incentive is designed specifically for antibiotics, to address either production-specific issues or AMR-specific issues. As a result, AMR objectives are not incorporated into the design of the incentive package.
3. *Concerns over effective implementation.* Some incentives, such as SEZs, appear to have leveraged investment. But others (e.g. preferential public procurement, reimbursement of duties on inputs) are not functioning as intended, as raised by the interviewed stakeholders.
4. *Centrality of the SEZs/EPZs, particularly for attracting MNEs/FDI.* The special zones model (either SEZs or EPZs) is at the core of the incentive system. In recent years, it has been in particular highly instrumental to attracting foreign investment.

d. *Stakeholder survey*

1. *Incentives perceived as too mild and implementation weak.* A range of different interviewees recognise the level of incentives has been too small relative to other countries and implementation uneven, pointing to cumbersome processes for firms to avail of some incentives.
2. *Local producers highly exposed to competitive pressure from importers.* Local manufacturers reported strong and sometimes unhealthy competition from imported antibiotics.
3. *Dependence on imports of APIs* and other excipients make supply chain vulnerable.
4. *AMR considerations not a critical factor.* Currently, antibiotics production is market-driven and production incentives are offered for local pharmaceutical manufacturing, but there is no evidence of substantial coordination with health-driven AMR policymaking.
5. *Red tape and administrative inefficiencies weighting heavily on investors.* Red tape and administrative inefficiencies in deploying incentives are reported to be hindering the capacity of companies to fully and timely benefit from the incentive package. The lack of market information and regulatory information is also reported as a criticism.

Key Recommendations

Kenya has a well-established local pharmaceutical manufacturing industry, including a limited production of antibiotics. While an incentives package to support local production (in general, not product-specific) is in place, the impact of the scheme is unclear. The challenge is not to kick-start local antibiotics manufacturing, but rather to improve the functioning of the existing incentives system, pushing some elements and potentially re-assessing others, including with a view to integrate health and investment promotion objectives with cost-benefit considerations.

Based on the main findings of this report, the following ten recommendations serve as a guideline for Kenyan government to improve its incentive system to support local production of antibiotics.

1. ***Focus on partnership with MNEs and integration in global production networks.*** Kenyan local production is prominently managed by domestic firms. MNE contribution is key to a successful promotion of local production. Local pharmaceutical manufacturers, including antibiotics, require several inputs from abroad – including raw material, factors of production, know-how

and technology – which MNEs are well positioned to access. Kenya can build on its large and growing market to attract market-seeking FDI – the most common type of FDI in the context of antibiotics production. Even beyond domestic market, Kenya can leverage ongoing regional integration initiatives to strengthen its competitive position as FDI destination, with the prospect to become a manufacturing hub for the region. In order to do that, Kenya should design investment promotion initiatives and incentives specifically tailored for foreign investors. Recent focus on SEZs and EPZs is an example in this direction. Partnership with MNEs and foreign investors is also highly instrumental to attracting know-how and needed skills for GMP-compliant production.

2. *Review and modernize fiscal incentives*. Fiscal incentives for local production of pharmaceuticals are granted through tax holidays and tax exemptions. These incentives provide tax relief based on earnings and not on new investment. In this regard, they are particularly attractive to mobile FDI. Kenya should consider moving from profit-based incentives to expenditure-based incentives - those that reduce the after-tax cost of capital investment expenditure, including for example investment allowance and accelerated depreciation. This class of incentives is more effective to promote reinvestment and therefore further integration into the local economy.[9] Similarly, it should make an effort to integrate key sustainability and GMP considerations in the incentive system.

   Beyond that, general guidelines for strengthening the overall governance of investment incentives need to apply – as defined by UNCTAD Investment Promotion Framework for Sustainable Development (UNCTAD, 2015). In particular, i. Incentives should be granted on the basis of a set of pre-determined, objective, clear and transparent criteria. ii. Their long-term costs and benefits should be carefully assessed prior to implementation, and they should be periodically reviewed to ensure continued effectiveness in achieving the desired objectives.

3. *Re-assess market shaping incentives (preferential procurement), including on a cost-benefit basis.* A 15% price margin for local producers is present, however, some stakeholders feel it hasn't been properly implemented. As local production is now quite well-established and competitive with imported production, Kenya may consider re-assessing this incentive, both in terms of what is offered (and on a cost-benefit basis, given such a margin commits the government to pay more than the minimum) and how it is implemented. To make these evaluations, further and updated analysis of pricing and availability of locally-produced and imported antibiotics is needed.

4. *Consider refining pharma sector-wide incentive system through product-specific incentives.* Given high risks of infections and AMR, it is critical that pharmaceutical companies, governments and procurers take action to ensure (not only access but) appropriate access to antibiotics. The incentive system can be designed to support this objective. To this end, antibiotics should be considered for product-specific interventions, which could include linking incentives to AMR considerations and following international best practices to prioritise antibiotics (see box 1).

5. *Enhance the SEZ/EPZ model.* The SEZ/EPZ model has been the cornerstone of Kenyan investment promotion strategy, recently proving particularly successful at attracting foreign investment. This model should be further leveraged, enhanced and upgraded, moving towards a new generation of SEZs – sustainable, adaptive and holistic – ultimately better equipped to navigate the future competitive investment landscape. Ongoing mega-trends such as the unfolding of the Fourth Industrial Revolution, the heightened focus on sustainable development and the development of regional value chains will require greater adaptability to a constantly changing reality. Holistic interventions will also make or break attempts to develop SEZs as part of coherent policy packages that create synergies across different policy areas. Moreover, sustainability is expected to play a greater role in defining production patterns and investment location choices. Looking at international best practices can provide a major spin to this process of modernization (UNCTAD, 2021).

[9] A review of fiscal incentives in this direction is also demanded by the ongoing global tax reforms that will make tax holidays and exemptions on FDI largely ineffective. In the same spirit, Kenya should also consider prioritizing fiscal incentives not based on corporate income taxation (not affected by the global tax reform) and non-fiscal incentives (UNCTAD World Investment Report 2022).

6. *Use streamlined regulation to facilitate investment.* Poor implementation of investment incentives, red-tapes and administrative efficiencies feature prominently among the main challenges identified by local manufacturers in a survey undertaken for this report. Trade and investment facilitation initiatives aim precisely to tackle such ground-level obstacles to trade and investment. In their most immediate and pragmatic form, they address three key dimensions: better information, transparent rules and regulations, streamlining of administrative procedures. To achieve these objectives, UNCTAD has created a digital platform that countries are using to make their own digital information portals (which show procedures step by step) and digital single windows (which facilitate fully online procedures). The platform is now successfully and effectively used by over 60 countries. Electronic procedures should be enabled for easy and swift registration of business activities, with support from UNCTAD's e-regulations program.
7. *Develop a collaborative mechanism among local manufacturers for procurement, storage and supply of APIs and other critical inputs.* While Kenya – unlike almost all other African countries – has a minimal local API production, it should be recognized that local manufacturing of pharmaceuticals will be largely dependent on API foreign input at least in the medium term. At the same time, full dependency on import for inputs is a major hurdle, even when incidence of inputs' cost is limited and such that it allows – at least in principle – local production to be potentially competitive. In this context, the government can promote and support the development a collaborative mechanism among the local manufacturers through a joint management team (JMT) and related practices for procurement, storage and supply of APIs and other critical input. This can allow aggregating demand, enabling competitive imports (both in terms of price and quality) and ensuring sustainability of supply. Understandably, manufacturers may want to keep their terms of supply contract for some input secret to maintain a competitive advantage in pricing their final products. Initiating JMT, however, would eventually lead to a better understanding of the needs of each manufacturer. Medicines regulatory agencies could also incentivise collaborative efforts by offering to prioritize the certification and marketing authorization of API procured through JMT.
8. *Continue to pursue regional integration and make sure national and regional policies are aligned and synergetic.* Kenya needs to continue to support deeper integration of the EAC market for pharmaceutical producers, including preferential procurement schemes, pooled procurement and harmonization of medicine regulations. Notably in 2023, following a joint initiative led by UNCTAD and East African Community (EAC), the EAC 38th Extra Ordinary Sectoral Council on Trade, Industry, Finance, and Investment (SCITIFI) adopted the Regional Policy Framework for the Promotion of Antibiotics Production and Supply (EAC/ExSCTIFI 38/Decision 5) and the Regional Cooperation Mechanism for Information Exchange and held multi-sectoral meeting to operationalize the information exchange (EAC/ExSCTIFI 38/Decision 6). These EAC instruments are the first of their kind on reginal cooperation on antibiotics. Kenya is well positioned to play a leading role in their implementation and operationalization. Furthermore, Kenya may target not only EAC countries, but also other larger markets in Africa. Finally, as member of the African Medicines Agency (AMA), Kenya may seek to accelerate further harmonization and cooperation on medicines marketing authorization in Africa, that is instrumental to deeper regional integration.
9. *Enhance information systems regarding production and supply.* Improving data on import, local production and consumption of antibiotics can guide industrial and health policymakers, as well as manufacturers. Timely, readily-available, digitised data is especially important given AMR concerns, and to ensure all stakeholders are suitably informed.
10. *Continue to strengthen governance and coordination between health and investment authorities.* Multiple government agencies are regulating different aspects of the industry. Enhanced coordination is needed to ensure their activities and initiatives can be delivered. This is especially true for antibiotics, with the need to ensure health policymakers interest in AMR and the investment interest in promoting local manufacturing are aligned and synergetic. Such intra-government coordination should also be supported by dialogue with local manufacturers of antibiotics.

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ANNEX I: LIST OF ORGANIZATIONS AND PERSONS INTERVIEWED

1. Pharmacy and Poisons Board (PPB)
2. Kenya Medical Research Institute (KEMRI)
3. Cosmos Limited
4. Kenya Ports Authority
5. Dr. Samuel Aketch Health Services Unit, KEMRI/Wellcome Trust Research Programme
6. Dr. Farida Chakera Chief Pharmacist, The Mombasa Hospital
7. Dr. John Jao- Chief Pharmacist, Kenya Ports Authority
8. Dr. Jayesh Pandit, Pharmacovigilance – Bayer Ltd
9. Dr. Karim Wanga, Pharmacy & Poisons' Board
10. Dr. Linda Hassan, Company Pharmacist, Radborne Clarke
11. Mr. Lawrence Ndibo, Consultant, Marketing & Distribution
12. Dr. Agoro – Nyeri County, Kenya
13. Mr. Lawrence Ndibo – Tiger Brands
14. Dr. Simon Muigai – Lab & Allied
15. Dr. Ajay Patel - Dawa
16. Nairobi University School of Pharmacy
17. Ministry of Health Kenya
18. Mission for Medicines and Supplies
19. University of Cape Town Drug Discovery and Development Program
20. Dr. Michukwa Maini –
21. Federation of Kenya Pharmaceutical Manufacturing (FKPM)
22. Kenya Association of Pharmaceutical Industry (KAPI)
23. Kenya Association of Manufacturers (KAM)
24. Kenya Private Sector Alliance (KEPSA)
25. Kenya Health Federation (KHF)
26. WHO Afro
27. Universal Pharmaceutical Limited
28. Ministry of Health Makueni County
29. Ministry of Health Nyeri County
30. Elys Chemical Industries Ltd
31. Pfizer Corp (Agency)
32. Phillips Pharmaceuticals Limited
33. Regal Pharmaceutical Ltd
34. GSK
35. Biodeal

ANNEX 2: LIST OF ANTIBIOTICS PRODUCED IN KENYA IN ACCORDANCE WITH WHO AWARE CLASSIFICATION AND OTHER LOCALLY PRODUCED ANTIMICROBIALS

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
1	Amoxicillin as trihydrate 250mg per capsule	Moxacil 250mg capsule	Dawa Ltd	Access
2	Amoxicillin as trihydrate 500mg	Moxacil 500mg capsules	Dawa Ltd	Access
3	Amoxicillin 250mg as trihydrate BP	Moximed capsules 250Mg	Medivet Products Ltd (Medivet, hereinafter)	Access
4	Amoxicillin 250mg as trihydrate and clavulanic 62.5mg as potassium clavulanate per 5ml	Labclav dry Suspension(312.5Mg/5Ml)	Laboratory & Allied Ltd	Access
5	Amoxicillin as trihydrate 125mg/5ml	Kemoxyl dry suspension	Laboratory & Allied Ltd	Access
6	Amoxicillin powder 125 mg/5mll	Elymox dry syrup	Elys Chemical Industries Ltd (Elys, hereinafter)	Access
7	Amoxicillin trihydrate 250mg	Kemoxyl 250	Laboratory & Allied Ltd	Access
8	Amoxicillin trihydrate 500mg	Unixil 500mg capsules	Regal Pharmaceuticals Limited (Regal, hereinafter)	Access
9	Amoxicillin trihydrate 500mg	Kemoxyl 500	Laboratory & Allied Ltd	Access
10	Amoxicillin as trihydrate 125mg/5ml	Moxacil powder for oral suspension	Dawa Ltd	Access
11	Amoxycillin as trihydrate 250mg	Unixil 250mg tablets	Regal	Access
12	Amoxycillin as trihydrate125mg	Unixil dry syrup	Regal	Access
13	Amoxycillin 125mg as trihydrate BP	Moximed dry powder for suspension 125mg/5ml	Medivet	Access
14	Amoxycillin 500mg as trihydrate BP	Moximed capsules 500mg	Medivet	Access
15	Amoxycillin dry suspension 250 mg/5 ml	Kemoxyl dry suspension forte	Laboratory & Allied Ltd	Access
16	Amoxycillin trihydrate 500 mg / capsule	Elymox-500 capsule	Elys Chemical Industries Ltd	Access
17	Amoxycillin trihydrate 250 mg / capsule	Elymox capsules	Elys	Access
18	Amoxycillin trihydrate B.P equivalent to amoxycillin 125mg/5ml	Alimox dry syrup	Sphinx Pharmaceuticals Ltd (Sphinx)	Access
19	Flucloxacillin Sodium B.P. equivalent to flucloxacillin 125mg/5ml	Fluxate dry syrup	Sphinx	Access

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
20	Amoxycillin trihydrate B.P. equivalent to amoxycillin 250mg per capsule	Alimox capsules 250mg	Sphinx	Access
21	Ampicillin as trihydrate 125mg /5ml	Ampecin oral suspension	Dawa Ltd	Access
22	Ampicillin 125mg as trihydrate BP	Medibritin dry powder for suspension 125mg/5ml	Medivet	Access
23	Ampicillin 250mg as trihydrate BP	Medibritin capsules 250mg	Medivet	Access
24	Ampicillin 500mg per capsule	Lacillin 500 mg capsules	Laboratory & Allied Ltd	Access
25	Ampicillin 500mg as trihydrate BP	Medibritin capsules 500mg	Medivet	Access
26	Ampicillin as trihydrate 125mg/ 5ml	Lacillin dry suspension	Laboratory & Allied Ltd	Access
27	Ampicillin trihydrate 125mg/ 5 ml	Ampilin syrup 125mg/ 5 ml	Elys	Access
28	Ampicillin trihydrate 250mg	Ampilin capsules	Elys	Access
29	Ampicillin trihydrate 500mg	Ampilin-500 capsules	Elys	Access
30	Cloxacillin sodium B.P. equivalent to cloxacillin 125mg/5m	Cloxam dry syrup	Sphinx	Access
31	Ampicillin trihydrate BP equivalent to 250mg of ampicillin	Lacillin 250mg capsules	Laboratory & Allied Ltd	Access
32	Cefalexin as monohydrate 250mg per capsule	Oracef 250mg capsules	Dawa Ltd	Access
33	Cefalexin (as monohydrate) 500mg per capsule	Oracef 500mg capsules	Dawa Ltd	Access
34	Cefalexin 125mg/5ml	Leocef dry suspension	Laboratory & Allied Ltd	Access
35	Cefalexin 500mg per capsule	Leocef capsules	Laboratory & Allied Ltd	Access
36	Cefalexin as monohydrate 125mg/5ml	Oracef powder for oral suspension	Dawa Ltd	Access
37	Cephalexin 125mg as cephalexin monohydrate BP	Mediceff dry powder for suspension 125mg/5ml	Medivet	Access
38	Cephalexin 500mg as cephalexin monohydrate BP	Mediceff capsules 500mg	Medivet	Access
39	Chloramphenicol as palmitate125mg	Chlorocide suspension	Regal	Access
40	Chloramphenicol as palmitate125mg/5ml	Dawaphenicol suspension	Dawa Ltd	Access
41	Chloramphenicol 125mg as palmitate BP	Mediphenicol suspension	Medivet	Access
42	Chloramphenicol 250mg /capsule	Elycetin capsules	Elys	Access
43	Chloramphenicol 250mg	Oramnicol capsules	Laboratory & Allied Ltd	Access
44	Chloramphenicol B.P. 5%	Biophenicol ear drops	Biodeal Laboratories Ltd (Biodeal)	Access
45	Chloramphenicol BP 5% W/V	Mediphenicol ear drops	Medivet	Access
46	Chloramphenicol Palmitate 250mg	Biophenicol capsules	Biodeal	Access
47	Chloramphenicol Palmitate B.P 125mg/5ml	Biophenicol suspension	Biodeal	Access
48	Clarithromycin Usp	Claricos 250 fil coated tablets	Cosmos Ltd	Watch
49	Clarithromycin Usp 125mg/5ml	Claricos 125 dry powder for suspension	Cosmos Ltd	Watch
50	Cloxacillin (As Sodium) 250mg per capsule	Dawaclox-250 capsules	Dawa Ltd	Access
51	Cloxacillin (As Sodium)125mg per 5ml	Dawaclox powder for oral solution	Dawa Ltd	Access

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
52	Cloxacillin 125mg as Sodium BP	Medibenin dry powder for suspension 125mg/5ml	Medivet	Access
53	Cloxacillin 250mg as Sodium BP	Medibenin capsules 250mg	Medivet	Access
54	Cloxacillin sodium 250mg	Kloxy capsules	Laboratory & Allied Ltd	Access
55	Cloxacillin sodium125 mg/5ml	Kloxy dry syrup	Laboratory & Allied Ltd	Access
56	Doxycycline hyclate BP	Doxyline capsules	Cosmos Ltd	Access
57	Doxycycline 100mg	Biodox capsules	Biodeal	Access
58	Doxycycline hydrochloride BP 100mg	Doxan capsules	Medivet	Access
59	Flucloxacillin as sodium 250mg per capsule	Dawaflox 250mg capsule	Dawa Ltd	Access
60	Flucloxacillin as sodium 500mg per capsule	Dawaflox 500mg capsule	Dawa Ltd	Access
61	Flucloxacillin as sodium125mg per 5ml	Dawa-flox powder for oral solution	Dawa Ltd	Access
62	Flucloxacillin sodium 125 mg/5 ml	Elyflox dry syrup	Elys	Access
63	Flucloxacillin sodium 250 mg / capsule	Elyflox capsules	Elys	Access
64	Flucloxacillin sodium 500mg per capsule	Kloxy-f 500mg capsules	Laboratory & Allied Ltd	Access
65	Flucloxacillin sodium equivalent to flucloxacillin 250mg	Kloxy-f 250mg capsules	Laboratory & Allied Ltd	Access
66	Metronidazole benzoate BP 200mg/5ml	Metrozol suspension	Cosmos Ltd	Access
67	Metronidazole 100mg as metronidazole benzoate BP and diloxanide furoate BP 125mg	Flagimed plus suspension	Medivet	Access
68	Metronidazole 200mg /tablet	Elogyl tablets	Elys	Access
69	Metronidazole 200mg	Megyl-200tablets	Regal	Access
70	Metronidazole 200mg as Benzoyl Metronidazole BP	Eflaron suspension	Dawa Ltd	Access
71	Metronidazole 200mg as Benzoate BP	Flagimed suspension	Medivet	Access
72	Metronidazole 200mg/5ml	Nelzole suspension	Universal Corporation Ltd (Universal)	Access
73	Metronidazole 400mg/tablet	Elogyl- 400 tablets	Elys	Access
74	Metronidazole 400mg	Megyl-400 tablets	Regal	Access
75	Metronidazole benzoate 200 mg/5ml	Tricozole 200mg/5ml suspension	Laboratory & Allied Ltd	Access
76	Metronidazole benzoate 125mg/ 5ml	Tricozole suspension	Laboratory & Allied Ltd	Access
77	Metronidazole benzoate 200mg / 5 ml	Elogyl suspension	Elys	Access
78	Metronidazole benzoate 200mg	Megyl suspension	Regal	Access
79	Metronidazole benzoate 200mg per tablet	Tricozole 200mg tablets	Laboratory & Allied Ltd	Access
80	Metronidazole benzoate 200mg/5 ml	Amebil suspension	Njimia Ltd	Access
81	Metronidazole benzoate 400mg per tablet	Tricozole 400 mg tablets	Laboratory & Allied Ltd	Access
82	Metronidazole benzoate BP equivalent to metronidazole 200mg/5ml	Amebazole suspension	Sphinx	Access
83	Metronidazole benzoyloxylate 200mg/5ml	Trogyl suspension	Biodeal	Access

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
84	Metronidazole benzoyloxylate 200mg/5ml and diloxanide furoate 250mg/5ml	Trogyl plus suspension	Biodeal	Access
85	Metronidazole BP 200mg	Metrozol-200 film coated tablets	Cosmos Ltd	Access
86	Metronidazole BP 200mg per tablet	Eflaron 200mg tablet	Dawa Ltd	Access
87	Metronidazole BP 250mg	Metrozol 250 tablets	Cosmos Ltd	Access
88	Metronidazole BP 400mg	Metrozol 400 tablets	Cosmos Ltd	Access
89	Metronidazole bp 400mg per tablet	Eflaron 400mg tablets	Dawa Ltd	Access
90	Metronidazole Usp 200mg	Trogyl 200mg tablets	Biodeal	Access
91	Metronidazole Usp 400mg	Trogyl 400mg tablets	Biodeal	Access
92	Nitrofurantoin 100mg per tablets	Nifuran tablets	Laboratory & Allied Ltd	Access
93	Nitrofurantoin BP 100 mg	Nitrofurantoin-100 tablets	Elys	Access
94	Nitrofurantoin BP 100mg	Nitrofurantoin tablets bp	Cosmos Ltd	Access
95	Phenoxymethyl penicillin potassium 250mg per tablet	Laepen V tablets	Laboratory & Allied Ltd	Access
96	Phenoxymethyl penicillin potassium BP equivalent to penicillin V	Unipen dry syrup	Regal	Access
97	Phenoxymethyl Penicillin Potassium BP equivalent to Phenoxymethyl Penicillin 250mg	Unipen 250mg tablet	Regal	Access
98	Phenoxymethylpenicillin Potassium BP 250mg/ tablet	Elypen-250 tablets	Elys	Access
99	Sulfamethoxazole BP / trimethoprim BP 240mg	Cosatrim 240 dispersible tablets	Cosmos Ltd	Access
100	Sulfamethoxazole 200mg + trimethoprim 40mg/5ml Susp	Sulfran pediatric suspension	Universal	Access
101	Sulfamethoxazole BP / trimethoprim BP	Cosatrim DS tablets	Cosmos Ltd	Access
102	Sulfamethoxazole BP 100mg + trimethoprim 20mg/tablets	Sulfran Kid dispersible Tablet	Universal	Access
103	Sulfamethoxazole BP and trimethoprim BP	Cosatrim Suspension	Cosmos Ltd	Access
104	Sulfamethoxazole BP and trimethoprim BP 100:20mg	Cosatrim dispersible Tablets	Cosmos Ltd	Access
105	Sulfamethoxazole BP and trimethoprim BP 400:80 mg	Cosatrim tablets	Cosmos Ltd	Access
106	Sulfamethoxazole trimethoprim 200Mg/5Ml 40 mg/5ml	Alprim	Elys	Access
107	Sulfamethoxazole trimethoprim 400mg/ 80mg	Alprim	Elys	Access
108	Sulphamethoxazole 200mg/5ml Trimethoprim 40mg/5ml	Lecotrim suspension	Laboratory & Allied Ltd	Access
109	Sulphamethoxazole 800mg and 160mg trimethoprim/per tablet	Lecotrim forte tablets	Laboratory & Allied Ltd	Access
110	Sulphamethoxazole b.p. + trimethoprim BP 400 mg: 80 mg	Sulfran	Universal	Access
111	Sulphamethoxazole BP. trimethoprim BP.	Sulprim suspension	Sphinx	Access
112	Sulphamethoxazole BP 200mg & trimethoprim bp 40mg/5ml	Trimoxol suspension	Dawa Ltd	Access
113	Sulphamethoxazole BP 200mg and trimethoprim BP /5ml	Septrimed suspension	Medivet	Access

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
114	Sulphamethoxazole BP 800mg + trimethoprim BP 160mg	Sulfran-DS	Universal	Access
115	Sulphamethoxazole trimethoprim 400 mg 80 mg	Co-Tri tablets	Elys	Access
116	Tetracycline 250mg per capsule	Racycline capsules	Laboratory & Allied Ltd	Access
117	Tetracycline Hcl 250mg	Biotet capsules	Biodeal	Access
118	Tetracycline Hcl 3% w / w	Elytetra skin ointment	Elys	Access
119	Tetracycline Hcl BP 3%w/w	Biotet ointment	Biodeal	Access
120	Tetracycline hydrochloride 1% w/w	Racycline eye ointment	Laboratory & Allied Ltd	Access
121	Tetracycline hydrochloride BP 250mg	Probax capsules 250mg	Sphinx	Access
122	Trimethoprim 160mg + sulphamethoxazole 800mg	Biotrim DS tablets	Biodeal	Access
123	Trimethoprim 80 mg sulphamethoxazole 400 mg	Lecotrim tablets	Laboratory & Allied Ltd	Access
124	Trimethoprim 80mg + sulphamethoxazole 400mg	Biotrim tablets	Biodeal	Access
125	Trimethoprim BP 40mg & sulphamethoxazole BP 200mg	Biotrim suspension	Biodeal	Access
126	Trimethorprim 40mg sulphamethoxazole 200mg	Unitrim suspension	Regal	Access
127	Trimethorprim 80Mg Sulphamethoxazole 400Mg	Unitrim tablets	Regal	Access
128	Azithromycin as dihydrate 200mg/5ml on reconstitution.	Azidawa 200mg per 5ml powder for oral suspension	Dawa Ltd	Watch
129	Azithromycin as dihydrate 500mg per tablet	Azidawa 500mg tablets	Dawa Ltd	Watch
130	Azithromycin 200mg/ 5ml	Zerocin dry suspension	Laboratory & Allied Ltd	Watch
131	Azithromycin 500mg per tablet	Zerocin tablets	Laboratory & Allied Ltd	Watch
132	Azithromycin dihydrate BP 200mg/5 ml	Throza Dps	Universal	Watch
133	Azithromycin Dihydrate Usp 200mg/5ml	Zithrox dry powder for suspension	Cosmos Ltd	Watch
134	Azithromycin Dihydrate Usp 250mg	Zithrox 250 film coated tablets	Cosmos Ltd	Watch
135	Azithromycin Dihydrateusp 500mg	Zithrox 500 film coated tablets	Cosmos Ltd	Watch
136	Azithromycin Usp 250mg	Azibru 250 tablets	Brawn Laboratories Ltd (Brawn)	Watch
137	Azithromycin Usp 250mg tablets	Throza-250	Universal	Watch
138	Azithromycin Usp 500mg tablets	Throza	Universal	Watch
139	Cefuroxime Axetil Usp 125mg/5ml	Zolidon 125 dry powder for suspension	Cosmos Ltd	Watch
140	Cefuroxime Axetil Usp 500mg	Zolidon 500 film coated tablets	Cosmos Ltd	Watch
141	Ciprofloxacin 500mg	Ciprodeal 500mg tablets	Biodeal	Watch
142	Ciprofloxacin 500mg	Strox 500mg	Universal	Watch
143	Ciprofloxacin 500mg tinidazole 600mg	Cipro-T	Salama Pharmaceuticals Ltd (Salama)	Watch
144	Ciprofloxacin hydrochloride BP	Ciprocos-500 film coated tablets	Cosmos Ltd	Watch
145	Ciprofloxacin hydrochloride BP 500mg	Ciflo tablets 500mg	Elys	Watch

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
146	Ciprofloxacin hydrochloride BP 250mg	Ciprocos 250 film coated tablets	Cosmos Ltd	Watch
147	Clarithromycin 500mg	Clith-500mg	Universal	Watch
148	Clarithromycin Usp 500mg	Claricos 500 film coated tablets	Cosmos Ltd	Watch
149	Erythromycin 125mg as ethyl succinate BP	Medithrocin dry powder for suspension	Medivet	Watch
150	Erythromycin stearate 125mg/ 5ml	Elocin dry syrup	Elys	Watch
151	Erythromycin stearate BP 250 mg / tablet	Elocin tablets	Elys	Watch
152	Erythromycin asethylsuccinate 125mg	Erythyl dry syrup	Regal	Watch
153	Erythromycin 5ml, ethyl succinate BP ethromycin 125mg	Ethro-125 Dps	Universal	Watch
154	Erythromycin ethyl succinate BP 125mg/5ml	Biotrocin syrup	Biodeal	Watch
155	Erythromycin ethyl succinate BP 125mg/5ml	Erocos Es 125 Dry Powder For Suspension	Cosmos Ltd	Watch
156	Erythromycin stearate 250mg	Ethro-250	Universal	Watch
157	Erythromycin stearate 500mg/tablet	Ethro-500Mg	Universal	Watch
158	Erythromycin Stearate BP 125mg/5ml	Erocos St Dry Powder for Suspension	Cosmos Ltd	Watch
159	Erythromycin stearate BP 250mg	Erocos-250 Film Coated Tablets	Cosmos Ltd	Watch
160	Levofloxacin hemihydrate equivalent to levofloxacin 500mg per tablet	Levoxcin 500Mg Tablets	Dawa Ltd	Watch
161	Norfloxacin 400mg per tablet	Floxinor Tablets	Biodeal	Watch
162	Norfloxacin 400mg per tablet	Norlab Tablets	Laboratory & Allied Ltd	Watch
163	Norfloxacin Usp 400mg	Noflox film coated tablets	Cosmos Ltd	Watch
164	Ofloxacin Usp 200mg	Oflox 200mgfilm coated tablets	Cosmos Ltd	Watch
165	Ofloxacin Usp 400mg	Oflox 400mg film coated tablets	Cosmos Ltd	Watch
166	RifampiciniBP 300mg	Rifacos-300 capsules	Cosmos Ltd	Watch
167	Amoxicillin as trihydrate 250mg and flucloxacillin as sodium 250mg	Kemoxyl Plus F capsules	Laboratory & Allied Ltd	FDC Antibiotic - Not Recommended.
168	Amoxicillin trihydrate BP and flucloxacillin sodium BP 125mg/5 ml	Megamox dry syrup	Elys	FDC Antibiotic - Not Recommended.
169	Amoxicillin trihydrate and flucloxacillin sodium 250mg 250/capsule	Megamox capsules	Elys	FDC Antibiotic - Not Recommended.
170	Amoxycillin 125mg and flucloxacillin sodium125mg	Kemoxyl Plus F suspension	Laboratory & Allied Ltd	FDC Antibiotic - Not Recommended.
171	Amoxycillin 125mg and flucloxacillin 125mg/5ml	Supramox powder	Biodeal	FDC Antibiotic - Not Recommended.
172	Amoxycillin 250mg and flucloxacillin 250mg per capsule	Supramox capsules	Biodeal	FDC Antibiotic - Not Recommended.

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
173	Ampicillin as trihydrate 250mg & cloxacillin as sodium 250mg per capsule	Ampiclo-Dawa 500 capsules	Dawa Ltd	FDC Antibiotic - Not Recommended.
174	Ampicillin as trihydrate125mg and cloxacillin as sodium125mg	Medicloamp dry syrup	Regal	FDC Antibiotic - Not Recommended.
175	Ampicillin 125mg as ampicillin trihydrate BP and cloxacillin 125mg as cloxacillin sodium BP	Cloximed Dry Powder for Suspension 250Mg/5Ml	Medivet	FDC Antibiotic - Not Recommended.
176	Ampicillin 250mg as ampicillin trihydrate BP and cloxacillin 250mg as cloxacillin sodium BP	Cloximed capsules	Medivet	FDC Antibiotic - Not Recommended.
177	Ampicillin 250mg and cloxacillin 250mg	Medicloamp 500 mg capsules	Regal	FDC Antibiotic - Not Recommended.
178	Ampicillin 60mg/0.6ml and cloxacillin 30mg/0.6ml	Ampiclo-dawa neonatal drops	Dawa Ltd	FDC Antibiotic - Not Recommended.
179	Ampicillin trihydrate BP and cloxacillin sodium BP 125mg/5ml	Elyclox dry syrup	Elys	FDC Antibiotic - Not Recommended.
180	Ampicillin trihydrate BP and cloxacillin sodium BP 250mg / capsules	Elyclox capsules	Elys	FDC Antibiotic - Not Recommended.
181	Ampicillin 125mg/5ml and cloxacillin 125mg/5ml	Ampiclo-Dawa powder for oral suspension	Dawa Ltd	FDC Antibiotic - Not Recommended.
182	Flucloxacillin as sodium BP 125mg & amoxycillin as trihydrate BP 125mg/5ml	Moxaforte Powder for Oral Suspension	Dawa Ltd	FDC Antibiotic - Not Recommended.
183	Flucloxacillin as sodium BP 250mg & amoxicillin as trihydrate BP 250mg	Moxaforte 500mg capsules	Dawa Ltd	FDC Antibiotic - Not Recommended.
184	Aminosidine as sulphate 250mg	Unibrol-250mg	Universal	Watch
185	Diloxanide furoate 250mg and metronidazole 200mg	Benagyl - Df tablets	Benmed Pharmaceuticals Ltd (Benmed)	Antibiotic Not on Aware
186	Diloxanide furoate bp 125mg and metronidazole BP 100mg	Benagyl Df suspension	Benmed	Antibiotic Not on Aware
187	Metronidazole 200mg diloxanide furoate 250mg	Tricozole Plus tablets	Laboratory & Allied Ltd	Antibiotic Not on Aware
188	Aminosidine as sulphate 250mg per tablet	Minodine tablets	Dawa Ltd	Other Antimicrobials
189	Aminosidine sulphate	Daboral 250 tablets	Cosmos Ltd	Other Antimicrobials
190	Aminosidine Usp 125mg/5ml	Unibrol syrup	Universal	Other Antimicrobials
191	Amodiaquine 50mg/5ml	Laeoquin suspension	Laboratory & Allied Ltd	Other Antimicrobials
192	Amodiaquine hydrochloride/ artesunate 600:200mg	Amqunate forte tablets combipack	Cosmos Ltd	Other Antimicrobials
193	Artemether 20mg lumefantrine 120mg	Medistan-Al	Regal	Other Antimicrobials

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
194	Artemether and lumefantrine 20:120mg	Lufanate 20/120 tablets	Cosmos Ltd	Other Antimicrobials
195	Artemether and lumefantrine 20:120mg	Lufanate dispersible 20/120 tablets	Cosmos Ltd	Other Antimicrobials
196	Artemether and lumefantrine 20:180:1080mg/60ml120mg	Lufanate dry powder for oral suspension	Cosmos Ltd	Other Antimicrobials
197	Artesunate and amodiaquine dispersible tablets 25/76.5mg	Amqunate P 25/76.5 paediatric dispersiblei tablets	Cosmos Ltd	Other Antimicrobials
198	Artesunate and amodiaquine hydrochloride Usp 50:153mg	Amqunate tablets	Cosmos Ltd	Other Antimicrobials
199	Artesunate and amodiaquine tablets 100:270mg	Amqunate 100/270 tablets	Cosmos Ltd	Other Antimicrobials
200	Artesunate and amodiaquine tablets 50:135mg	Amqunate 50/135mg tablets	Cosmos Ltd	Other Antimicrobials
201	B-artemether 20mg & lumefantrine 120mg	Lum-artem tablets	Dawa Ltd	Other Antimicrobials
202	B-artemether 15mg & lumefantrine 90mg/5ml	Lum-artem powder for oral suspension	Dawa Ltd	Other Antimicrobials
203	Betamethasone as valerate 0.1% w/w clotrimazole 1% W/W	Cloben G cream	Biodeal	Other Antimicrobials
204	Calamine 10mg	Calamine	Syner Chemie Ltd	Other Antimicrobials
205	Clotrimazole 1% W/V	Clomzole ear drops	Biodeal	Other Antimicrobials
206	Clotrimazole 1% W/W & betamethasone 0.1% W/W	Cloben cream	Biodeal	Other Antimicrobials
207	Clotrimazole BP beclometasone dipropionate / gentamicin sulphate 1% w/w / 0.025 % W/W / 0.1 % W/W	Elyclob-G	Elys	Other Antimicrobials
208	Clotrimazole BPc 1%W/W hydrocortisone BP 1% W/W	Unisten Hc cream	Regal	Other Antimicrobials
209	Dihydroartemisin 40mg & piperaquinine phosphate 320mg	Co-Malasinin tablets	Dawa Ltd	Other Antimicrobials
210	Dihydroartemsinin 40mg and piperaquine phosphate 320mg	Duotab tablets	Universal	Other Antimicrobials
211	Diloxanide furoate 500mg per tablet	Diloxate 500mg tablets	Dawa Ltd	Other Antimicrobials
212	Ethambutol hydrochloride and isoniazid tablets 400:150mg	Ethizide film coated tablets	Cosmos Ltd	Other Antimicrobials
213	Ethambutol hydrochloride BP 400mg	Etham 400 film coated tablets	Cosmos Ltd	Other Antimicrobials
214	Griseofulvin 500mg per tablet	Grisolab-500 tablets	Laboratory & Allied Ltd	Other Antimicrobials
215	Hexitane 10mg	Hexitane solution	Syner Chemie Ltd (Syner)	Other Antimicrobials
216	Hexitine 10mg	Povidone	Syner	Other Antimicrobials
217	Lumefantrine 120 mg artemether 20mg	Malarate tablets	Laboratory & Allied Ltd	Other Antimicrobials
218	Lumefantrine 120mg + artemether 20mg	Co-Max tablets	Universal	Other Antimicrobials

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
219	Metronidazole as benzoate 200mg and diloxanide furoate 250mg	Eflaron Plus suspension	Dawa Ltd	Other Antimicrobials
220	Metronidazole 200mg & diloxanide furoate 250mg	Eflaron Plus tablet	Dawa Ltd	Other Antimicrobials
221	Miconazole nitrate 2.0%W/W, clobetasol propionate 0.05%W/W and gentamicin as sulphate 0.1%W/W	Miclocin cream	Dawa Ltd	Other Antimicrobials
222	Nalidixic acid 500mg	Uriseptic tablets	Regal	Other Antimicrobials
223	Neomycin sulphate 5mg, bacitracin zinc 2.5mg and gramicidin d 0.5mg	Neogracin powder	Laboratory & Allied Ltd	Other Antimicrobials
224	Nystatin BP 100,000 Iu	Nycostat pessaries	Cosmos Ltd	Other Antimicrobials
225	Nystatin BP 100,000Iu	Nycostat ointment	Cosmos Ltd	Other Antimicrobials
226	Nystatin 100000 I.U /M	Nycodeal oral suspension	Biodeal	Other Antimicrobials
227	Nystatin 100000 Iu / Ml	Fungistin oral suspension	Elys	Other Antimicrobials
228	Nystatin 100000 Iu/Ml	Dawastin oral suspension	Dawa Ltd	Other Antimicrobials
229	Nystatin 100000 units per tablet	Labstatin tablets	Laboratory & Allied Ltd	Other Antimicrobials
230	Nystatin 500 000 Iu	Nelstat tablets	Universal	Other Antimicrobials
231	Nystatin B.P 100000 Iu	Medistatin oral suspension	Medivet	Other Antimicrobials
232	Nystatin BP 100,000 Iu/Ml	Nycostat oral suspension	Cosmos Ltd	Other Antimicrobials
233	Nystatin BP 100,000Iu	Nycostat lozenges	Cosmos Ltd	Other Antimicrobials
234	Nystatin BP 500,000Iu	Nycostat film coated tablets	Cosmos Ltd	Other Antimicrobials
235	Nystatin Oral Suspension 100000 Units/ ml	Labstatin oral suspension	Laboratory & Allied Ltd	Other Antimicrobials
236	Nystatin Usp 100,000 units	Nelstat pessary	Universal	Other Antimicrobials
237	Nystatin Usp 100.000 units/ml	Nelstat oral drops	Universal	Other Antimicrobials
238	Povidone iodine10% solution	Povidone iodine10% solution	Sphinx	Other Antimicrobials
239	Proguanil hydrochloride BP 100mg	Proguanil tablets BP	Cosmos Ltd	Other Antimicrobials
240	Pyrimethamine 12.5mg and sulfadoxine 250mg per 5ml	Falcigo suspension	Biodeal	Other Antimicrobials
241	Pyrimethamine 25mg	Xoprim tablets	Cosmos Ltd	Other Antimicrobials
242	Pyrimethamine 25mg and sulphadoxine 500mg per tablet	Falcigo tablets	Biodeal	Other Antimicrobials
243	Quinine as dihydrochloride BP 50mg/5ml	Topquine mixture	Dawa Ltd	Other Antimicrobials

	International non-proprietary name of API: Strength per dosage	Product name/brand	Manufacturer	Classification
244	Quinine bisulphate 50mg per 5ml	Quinine mixture	Laboratory & Allied Ltd	Other Antimicrobials
245	Quinine bisulphate BP 50mg	Quinine mixture	Medivet	Other Antimicrobials
246	Quinine dihydrochloride 200mg/ml	Topquine paediatric drops	Dawa Ltd	Other Antimicrobials
247	Quinine dihydrochloride BP 50mg/5ml	Quinamor mixture	Sphinx	Other Antimicrobials
248	Quinine Hcl BP eq. To 100mg quinine base	Curaquin syrup	Regal	Other Antimicrobials
249	Quinine sulphate 300mg per tablet	Quinine tablets	Laboratory & Allied Ltd	Other Antimicrobials
250	Quinine sulphate 300mg	Quinine sulphate	Universal	Other Antimicrobials
251	Quinine sulphate 300mg	Quinidil tablets	Biodeal	Other Antimicrobials
252	Scabsol 10mg	Scabsol	Syner	Other Antimicrobials
253	Secnidazole 500mg	Unigentyl 500mg tablets	Universal	Other Antimicrobials
254	Secnidazole 500mg	Labgentil tablets	Laboratory & Allied Ltd	Other Antimicrobials
255	Secnidazole 1gm per tablet	Dawasec 1gm tablet	Dawa Ltd	Other Antimicrobials
256	Sulfadoxine 500mg and pyrimethamine 25 mg per tablet	Malodar tablets	Laboratory & Allied Ltd	Other Antimicrobials
257	Sulfadoxine Usp And pyrimethamine Usp 500: 25Mg	Falcidin Sp-antimalarial Tablets	Cosmos Ltd	Other Antimicrobials
258	Sulfamethopyrazine 500Mg pyrimethamine 25mg	Laefin tablets	Laboratory & Allied Ltd	Other Antimicrobials
259	Sulphadoxine BP 500mg & pyrimethamine BP 25mg	Fanlar tablets	Dawa Ltd	Other Antimicrobials
260	Sulphadoxine BP pyrimethamine BP 25 mg/tablet	Orodar tablets	Elys	Other Antimicrobials
261	Sulphamethoxypyrazine 500mg and pyrimethamine 25mg	Malafin tablet	Universal	Other Antimicrobials
262	Sulphamethoxypyrazine pyrimethamine 500mg 25mg / tablet	Ekelfin tablets	Elys	Other Antimicrobials
263	Tinidazole 500mg/tablet	Tidazol tablets	Elys	Other Antimicrobials
264	Tinidazole 500mg	Tizole-500 tablets	Biodeal	Other Antimicrobials
265	Tinidazole 500mg per tablet	Tynazole tablets	Laboratory & Allied Ltd	Other Antimicrobials
266	Tinidazole BP 500mg	Tinycos film coated tablets	Cosmos Ltd	Other Antimicrobials

ANNEX 3: KEY MESSAGES FROM PAPER "BUSINESS CASE FOR LOCAL PHARMACEUTICAL PRODUCTION IN AFRICA, WITH FOCUS ON ANTIBIOTICS"

The relevant business model for local production of pharmaceuticals in Africa, including in antibiotics, is commoditized and generally confined to a. "**Mixed model**" with localization of the formulation stage and imports of APIs; b. Manufacturing of off-patent drug with **limited R&D component** and value added; c. **High volume, low margin** production, where **economies of scale** play a key role.

Local production can be in principle competitive with the (currently dominant) "full import" model, leading to a **reduction of costs of more than 10%**, according to a McKinsey study*. This reduction is the result of the lower incidence of import costs – applied only to inputs (APIs) in the mixed model as opposed to the entire manufacturing cost in the full import model. **Incidence of API on total manufacturing cost is just above 10 per cent** of the total manufacturing costs. In this context, the relative higher cost of producing in Africa would be more than compensated by savings in import costs, **provided that scale and utilization are held constant** across the two models.

Notwithstanding business fundamentals, realistically, the context of early-industrializing African countries can be hardly comparable with that of established global exporters (e.g. India and China) in terms of achievable scale and utilization. For this reason, **local production in Africa is likely to require some degree of policy support, at least in the initial phase.** The nature and size of the government support depends **on (public) cost-benefit considerations around 1. Impact; 2. Feasibility; and 3. Public resources.**

- In terms of **impact**, the **value proposition for local production is triple: health** (increased access to essential medicine), **strategic** (national health sovereignty and security of minimal supply) and **economic** (contribution to economic growth). While strategic and economic impact can be relatively limited and uncertain, especially in the short to medium term, **health considerations are paramount for** certain categories of essential medicines, including in particular in **antibiotics** where lack of appropriate access can have significant negative effects both on spread of infectious diseases and antimicrobial resistance.
- **Feasibility** is primarily driven by **volume production and economies of scale**. The **integration in global value chain and the presence of MNEs** also play an important role, as well as **other enablers** – such as on the production side: presence of infrastructure, availability of skills; on the market side: procurement model (public, private, donor, …), regional integration. Depending on the size of their domestic market and the level of development of the pharmaceutical industry, African countries can widely differ in their feasibility profiles.
- When value at stake in terms of impact is relevant, governments can support feasibility by providing a r**ange of incentives**. Each incentive is associated with a different degree of intervention and different requirements in terms of financial resources. Broadly, most used incentives to support local production in Africa are of two types: **market-shaping incentives** aimed at making the demand side more attractive to local producers (e.g preferential procurement, reserved lists, …); and **production-facilitating incentives** aimed at making the supply side more attractive (e.g. fiscal incentives, capacity building programs, …).

In general, **African countries with non-existent or nascent pharma industries** – the majority in sub-Saharan Africa – will face significant feasibility constraints and will need to employ significant resources

to kick-start the industry, including **market-shaping incentives** (typically quite costly) **for a prolonged period**. These countries may face significant costs and risks in pursuing local production and should carefully ponder available alternatives to secure access before resorting to local production. At the opposite extreme, where **industry is already developed and market size is appealing, the potential for development of local production is high**, risks are limited and financial resources are confined to standard investment promotion incentives for a limited period of time – if at all needed.

* Conway, M., Holt, T., Sabow, A. and Sun, I. (2019). Should sub-Saharan Africa make its own drugs? McKinsey Report. Public Sector Practice. January. https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs#/ (Exhibit 3)