UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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

An Advisory Report

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NOTES

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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."

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.

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 Uganda can do to foster a conducive investment environment for local production of antibiotics.

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 Uganda, 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 (V) to this Report, for the benefit of interested Ugandan 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	Anti-Microbial Resistance
NAP	Anti-Microbial Resistance National Action Plan
API	Active Pharmaceutical Ingredient
AWaRe	Access, Watch, Reserve
BUBU	Buy Uganda, Build Uganda
cGMP	Current Good Manufacturing Practice
EAC	East African Community
FDI	Foreign Direct Investment
HEPS	Coalition of Health Promotion and Social Development
HSDP	Health Sector Development Plan
IFPMA	International Federation of Pharmaceutical Manufacturers Association
MNE	Multinational enterprise
MoH	Ministry of Health
NDA	National Drug Authority
NDP	National Development Plan
NIP	National Industrial Policy
NMS	National Medical Stores
NPSSP	National Pharmaceutical Sector Strategic Plan
PPP	Public Private Partnership
R&D	Research and Development
SDG	Sustainable Development Goals
TB	Tuberculosis
UHC	Universal Health Coverage
UNCTAD	United Nations Conference on Trade and Development
VAT	Value-Added-Tax
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this advisory report is to (i) examine the current state of antibiotics manufacturing in Uganda 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 key insights into the trends and issues of local production of antibiotics in Uganda.

This study finds that:

- Local production of antibiotics is present in Uganda but still at an early stage of industrial development, covering about 10% of the market, corresponding to an estimated amount below $10 million.
- Sector-wide pharma incentives are in place, including production facilitating incentives (e.g., no customs duties on inputs) and market-shaping incentives (e.g., public procurement preferences).
- No targeted incentives are designed for antibiotics – as a result, AMR objectives are not specifically addressed by the incentive system.
- Regional-integration initiatives for the promotion of local production of pharmaceuticals in general, and antibiotics in particular, are taking off, improving the prospects for local production and supply.

Based on these insights, this Report provides nine policy recommendations for improving the investment framework for local production of antibiotics, with a particular (but not exclusive) focus on investment incentives.

Notwithstanding the specific recommendations provided in this Report for the antibiotics Ugandan 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. Carefully assess the economic viability of local production, based on benefits, costs and risks – and in comparison with available alternatives.
2. Emphasize the regional approach to reduce costs.
3. Focus on attracting MNEs and FDI promotion.
4. Refine the pharmaceutical-sector-wide incentive system through product-specific incentives.
5. Develop a collaborative mechanism among local manufacturers for procurement, storage and supply of APIs and other critical inputs.
6. Link incentives to Good Manufacturing Practice (GMP) compliance needs.
7. Use streamlined regulation to facilitate investment
8. Enhance information systems regarding production and supply.
9. 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 potential interventions to improve local 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). Uganda stated support for local pharmaceutical production for a number of years, including in its National Drug Policy 2002 and National Medicines Policy 2015.

This report approaches the issue of local pharmaceutical production in Uganda 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 forecasted that more than 10 million people will die because of AMR in 2050 if appropriate interventions are not implemented (O'Neill J., 2016).

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, 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.

While AMR is an issue of global concern, studies show that Uganda has a high burden of AMR (Kajumbula et al. 2018). The country has an "Anti-Microbial Resistance National Action Plan (2018-2023)" and related programmes to address the problem. Uganda has developed its own five-year "Antimicrobial Resistance National Action Plan (NAP), 2018-23, which is integrated into the overall "One Health Strategic Plan" [1] of Uganda. The country's National Action Plan for Health Security (2019-2023) also identifies strategies to strengthen the country's capacity to prevent, detect and respond to public health threats, including improved awareness on AMR.

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

[1] Uganda, 2018. Uganda One Health Strategic Plan 2018-2022.

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 wwithout 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 Ugandan government has expressed a goal to increase the share of local production. Expanding pharmaceutical manufacturing is recognised as a priority for the Uganda government in the National Drug Policy 2002 and the National Medicines Policy 2015. The 2015 National Medicines Policy states a policy objective "To promote the development and growth of domestic production of pharmaceutical products of assured quality, safety and efficacy" (2015, 23). The stated justification for such support is the potential for serving public health as well as economic and industrial development benefits and promoting self-sufficiency (National Medicines Policy 2015, 23). Promoting local production of pharmaceuticals and other health products is one of the strategic objectives of the Ministry of Health's (2021) National Pharmaceutical Services Strategic Plan 2020/21-2024/25.

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. Within East African Community, to which Uganda belongs, a regional pharmaceutical bill is under consideration to push for a coordinated policy response for the development of the sector in the region (see also box 2).

The purpose of this study is to examine the current situation and the investment framework for the manufacturing and supply of antibiotics in Uganda. The study of this therapeutic category can inform the opportunities and challenges facing wider initiatives concerning local pharmaceutical production in Uganda. 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 Uganda and other countries.

Extensive semi-structured interviews were conducted targeting key informants in the pharmaceutical sector. These include Ministry of Health, Ministry of Trade, Industry and Cooperatives, National Drug Authority, National Medical Stores, industry associations and health related professional bodies and academia. A full list of the 17 organizations interviewed is presented in Annex I. Secondary data concerning policy framework, procurement, supply and current manufacturing capacity for antibiotics was extensively collected.

The draft report was submitted to an international expert review meeting convened virtually by UNCTAD on 17 May 2021, and the feedback was incorporated into the report with the support of an international expert. Part of the recommendations in this report were discussed and debated in a multi-stakeholder workshop held virtually on 21 July 2021 and then finalised before being presented to the government.

A number of challenges were encountered during the preparation of this advisory report. One critical challenge was the difficulty to get access to all the relevant data. There is no central repository for all data on antibiotics supply (imports, local production and distribution), instead data were spread across several institutions. Multiple visits and requests to relevant organizations were required.

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 Uganda, 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 Ugandan stakeholders, a pre-view excerpt of the key findings of the study is added as annex (V) to this Report.

The remaining part of this report is organized as follows. The next section provides brief background on socio-economic trends of Uganda. Section 2 assesses the pharmaceutical industry landscape, while section 3 dives into the local production of antibiotics. Section 4 illustrates investment incentives currently in place to support local production in Uganda. The last section summarizes the main findings and provides some policy recommendation.

1. SOCIO-ECONOMIC CONTEXT

Uganda is an East African country with a population of about 46 million people, the majority of whom live in rural areas. According to the World Bank, in 2021 the GDP of Uganda was estimated at USD 40.5 billion (current US$) and the GDP per capita (current US$) was estimated at USD 885. Although GDP growth in Uganda has been fast in the last three decades – most years above 4% - the country is low-income, and continues to have considerable poverty, despite emphasis on and progress against eradicating poverty. The majority of the population still depend on subsistence agriculture – around 70% in 2020.
Uganda's Vision 2040, launched in 2010, aims for the country to become a middle-income county within 30 years. A series of five-year National Development Plans have been issued to guide the country on this trajectory, with key themes so far including socio-economic transformation (NDP I 2010/11-2014/15), strengthening competitiveness (NDP II 2015/16-2019/20) and sustainable industrialization (NDP III 2020/21-2024/25). Commercialization of agriculture, and expansion of value capture from such activities, are major priorities through the series of NDPs.

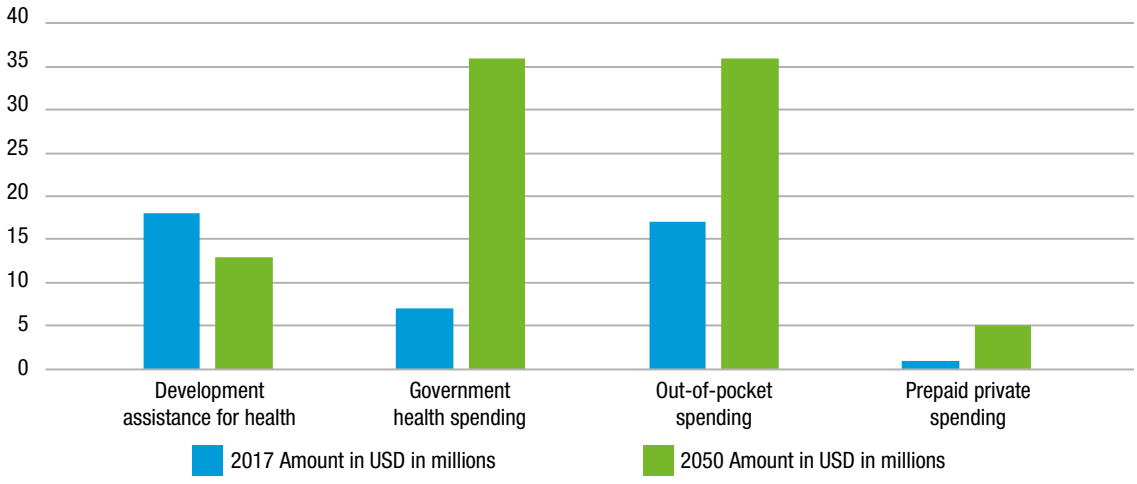
The 2020 National Industrial Policy (NIP) succeeds the first National Industrial Policy of 2008. The 2020 NIP emphasises resource-led industrialization through primary commodity and mineral product value chains. As a member of the East African Community (EAC), Uganda is also part of various regional initiatives and plans. These include the EAC Industrialization Policy 2012-2032 and associated Strategy.

Uganda's development strategy for the manufacturing sector emphasises import substitution. The Buy Uganda Build Uganda (BUBU) Policy was launched in 2014, aiming to promote consumption and use of locally manufactured goods and services (which conform to standards). It emphasises both public procurement and private sector activity and an implementation strategy was launched in 2017. The National Planning Authority has developed an Import Substitution Action Plan (2020/21-2024/25).

A major emphasis of the government policy was to increase access to medicines. Much of the supply of medicines comes from donors, who provide more than 70% of the public sector funding for essential medicines and health supplies in Uganda. In 2021, the Ministry of Health launched a 10-Year Roadmap for Government of Uganda's Health Supply Chain Self-Reliance 2021/2022 – 2031/2032. Increasing the range and scale of locally manufactured products is a goal of NDP III, with a target to "reduce value of imported health commodities from USD 285.6 million to USD 200 million" (Ministry of Health NPSSP 2021, 48).

In 2017 the spend on health per person was USD 1 for prepaid private spending, USD 17 from out-of-pocket spending, USD 7 from Government health spending, and USD 18 from development assistance spending. The spending by the government is expected to significantly expand by 2050 (figure 1).

Figure 1. Health expenditure in Uganda in 2019



Source: Institute for Health Metrics and Evaluation (2017)

2. THE UGANDAN PHARMACEUTICAL INDUSTRY

The domestic pharmaceutical market of Uganda is estimated at USD 340 million as of 2018 (Fitch 2019). As a benchmark, this corresponds to about 40% and a third of the market size of Ethiopia and Kenya respectively.

The National Medical Stores (NMS) are the largest public procurer of medicines in the country and responsible for distribution of drugs to all government institutions around the country. Private not for profit facilities are also prominent, with 70% of that supply through the Uganda Catholic Medical Bureau (UCMB), Uganda Protestant Medical Bureau (UPMB), Uganda Orthodox Medical Bureau (UOMB) and Uganda Muslim Medical Bureau (UMMB) (Ministry of Health NPSSP 2021, 35).

Export values in 2017 were reported at USD 15 million representing a significant rise from USD 3.07 million in 2009, but still very limited. The main exports destinations for local manufacturers are Eswatini, Rwanda, Zambia, Democratic Republic of Congo and Southern Sudan. Local distribution of pharmaceutical products is managed by about 55 local pharmaceutical distributors, and of these 10 pharmaceutical distributors control approximately 85% of the market.

Local manufacturers are estimated to supply less than 20% of the value of products in the market (NPSSP 2020/21-2024/25). The National Drug Authority states that there are 43 licensed pharmaceutical manufacturers in the country (https://www.nda.or.ug/licensed-outlets-statistics/), however only 4 companies are listed as GMP-compliant facilities, of which three are majority foreign-owned (Table 1).

Table 1. List of GMP-compliant facilities in Uganda

Company	Ownership	Founded	Employees	Other
Abacus Parenterals Ltd.	Foreign (75% Indian, 25% Kenyan)	2006 (production 2009)	Over 300	Domestic 44%, Exports 56% (2017); Exports to 8 African countries (2017)
Cipla Quality Chemicals Ltd.	Majority-owned by Indian company Cipla	2006	350 Permanent	Exports to 13 African countries, 2 in South-East Asia
Kampala Pharmaceutical Industries (1996) Ltd.	Part of Aga Khan Development Network	1996		
Rene Industries Ltd.	Locally-owned	1998	500	Exports to Rwanda, Burundi, South Sudan and Democratic Republic of Congo.

Source: National Drug Authority, sourced from: https://www.nda.or.ug/gmp-compliant-facilities/): Data as per 03rd April 2023.

As with other countries in Africa, local production of pharmaceuticals is all at the formulation stage of the value chain. All active pharmaceutical ingredients (API) are imported implying that even local producers must thus 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 as 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 V).[2]

[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).

A Ministry of Health (2021, 32) report notes capacity utilization rates for different formulations as creams and ointments (33%), liquid formulations (36%), ORS (43%), tablets (64%) and capsules (73%) (National Pharmaceutical Services Strategic Plan 2020/21-2024/25).

Similar to elsewhere on the African continent, local manufacturers also face a strong competitive challenge from imported products. Imports dominate the Ugandan market, with imported medicines representing more than 80% of the market share (NPSSP 2020/21-2024/25). In 2021, the major source of imports was India – accounting for 62% of the total value. India's share is almost 10 times that of the next largest source of imports – Kenya (6.6%), while only 5.5% were sourced from China. India plays a prominent role in the global pharmaceutical industry as a producer, and supplier in large volume, of finished generic drugs (Table 2).

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

Source of Imports	2021 imports (US$ thousand)	% of total
World	287.073	100.0
India	177.627	61.9
Kenya	19.041	6.6
China	14.690	5.1
Switzerland	11.990	4.2
Belgium	6.232	2.2
France	6.006	2.1
Germany	5.930	2.1

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 Uganda (Table 3). 51.6% of products registered are from India, with the next highest source, Kenya, at 6.6%. Only 3.9% or 179 of all 4,540 products are from Uganda.

The Ugandan government has expressed a goal to increase the share of local production. Expanding pharmaceutical manufacturing is recognised as a priority for the Uganda government in the National Drug Policy 2002 and the National Medicines Policy 2015. The 2015 National Medicines Policy states a policy objective "To promote the development and growth of domestic production of pharmaceutical products of assured quality, safety and efficacy" (2015, 23). The stated justification for such support is the potential for serving public health as well as economic and industrial development benefits and promoting self-sufficiency (National Medicines Policy 2015, 23). Promoting local production of pharmaceuticals and other health products is one of the strategic objectives of the Ministry of Health's (2021) National Pharmaceutical Services Strategic Plan 2020/21-2024/25.

Table 3. Source of pharmaceutical products registered in Uganda

	TOTAL	4.540	% of total
1	India	2.341	51.6
2	Kenya	301	6.6
3	China	235	5.2
4	Uganda	179	3.9
5	Germany	175	3.9
6	Egypt	124	2.7
7	Belgium	99	2.2
8	United Kingdom	94	2.1
9	France	90	2.0

Source: Data from Intergovernmental Authority on Development: https://mrh.igad.int/production/index_ug (last accessed 28th April 2023)

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. Within East African Community, to which Uganda belongs, a regional pharmaceutical bill is under consideration to push for a coordinated policy response for the development of the sector in the region (see also box 2).

3. LOCAL PRODUCTION OF ANTIBIOTICS

3.1. Market insights

The supply of antibiotics in Uganda is led by government procurement through the NMS and the private sector. NMS procures medicines through both international and domestic tenders. In addition, there are occasional donations of specific medicines to institutions such as the Uganda Cancer Institute and the Uganda Heart Institute. However, most donations are channelled through NMS for distribution throughout the country.

The health conditions in Uganda contribute to demand for antibiotics. In 2019, half of the top 10 causes of deaths in Uganda (neonatal disorders, malaria, HIV/AIDS, lower respiratory infections, TB, stroke, diarrheal diseases, ischemic health disease, congenital heart defects, and sexually transmitted infections) are those that require treatment with antibiotics.[3]

Precise figures on the size and patterns of antibiotic market in Uganda are extremely difficult to find due to the absence of organized, accessible and granular data. This study has assembled available data, particularly from the NDA database, to provide some policy relevant insights in the Ugandan market of antibiotics.

First indicative evidence is given by the source of antibiotics registered in Uganda. Although there are over 800 different brands of antibiotics on the National Drug Authority (NDA) registry, only 46 (6%) are manufactured in Uganda. The top 10 countries exporting antibiotics to Uganda contribute to 88% of the antibiotic brands registered in Uganda (table 4). The most imported antibiotics were amoxicillin, co-trimoxazole, ciprofloxacin, amoxicillin/clavulanic acid.

Table 4. Source of antibiotics registered in Uganda

Manufacturing Country	No. of Brands Registered	% of Total
India	460	57
Kenya	55	7
Uganda	46	6
Egypt	41	5
China	33	4
Cyprus	32	4
Pakistan, Jordan	19	2
UK	16	2
RSA, France	11	1

Source: Information obtained from the NDA and compiled by the author.

Data on imports can also be loosely retrieved from NDA, which approves every proforma invoice prior to products being imported. NDA data for 2019 hints at a total value for antibiotics imports at $57 million of which penicillin antibiotics were a huge component. The most imported antibiotics were amoxicillin, co-trimoxazole, ciprofloxacin, amoxicillin/clavulanic acid. Top exporting country to Uganda was India, with a share of around 60% in Ugandan imports of antibiotics (see also Bjerke, 2022).

Local manufacturers also provided some data on antibiotic production and sales over the 3-year period 2017-2019 as summarised Table 5. There are only 2 local manufacturers of antibiotics in Uganda, and

[3] http://www.healthdata.org/uganda

the total value of antibiotics produced during 2019 was $6.7 million, in face of an imported value of $57 million – corresponding then to just 10% of local production. The top product manufactured locally was amoxicillin, worth approximately $ 3 million. Only generic antibiotics are manufactured locally and are in the Access and Watch categories. None are from the Reserve category.

Table 5. Value of antibiotics produced in Uganda, million US$

Antibiotic Type	2017 Value	2018 Value	2019 Value
Beta Lactam Penicillin	3,6	3,4	3,4
Non-Penicillin	2,2	3,0	3,3
Total Antibiotics	5,8	6,4	6,7

Source: information obtained from local manufacturers and compiled by the author. The full list is available under Annex III.

The production capacity utilization for antibiotics has remained stable between 50% and 70% between 2017-2019 for most of the formulations (Table 6). The increase in the installed capacity of capsules in 2019 was due to one of the manufacturers upgrading to an automatic filling machine primarily to improve the product quality but also to increase capacity. There is significant unused capacity available which indirectly translates to an increase in the cost of production. The data also suggests that over the last 3 years there has not been any significant volume growth in the market for locally manufactured antibiotics. Penicillin antibiotics are the most common antibiotics produced locally. No new/modern classes of antibiotics are locally manufactured. Compared to the utilization rates for the industry as a whole noted by Ministry of Health (2021), those for antibiotics are lower for tablets (56% vs. 64% overall), capsules (69% vs. 73% overall), but higher for liquids (55.6% vs. 36%).

Table 6. Capacity utilization by antibiotic formulation

Antibiotic Formulation	% Capacity Utilization in 2017	% Capacity Utilization in 2018	% Capacity Utilization in 2019	% Average Capacity Utilization 2017-19
Tablet	55%	52%	60%	56%
Capsule	74%	68%	65%	69%
PFOS	19%	20%	18%	19%
Syrup	60%	52%	55%	56%
Topical	40%	40%	60%	46%
Liquid Oral	60%	52%	55%	55.66%

Source: information obtained from local manufacturers and compiled by the author.

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.[4] A comparison between the available antibiotics in Uganda with the AWaRE/WHO lists reveals that most common antibiotics available in Uganda, either from local manufacturers or imports, are from the penicillin

[4] 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.

beta-lactam group, such as amoxicillin and ampicillin ("Access"). Very few of the "Reserve" antibiotics are procured by the government through NMS. However, several antibiotics not recommended for use by the WHO, due to a lack of efficacy data, are routinely used in the private sector, such as fixed dose combinations of ampicillin and cloxacillin (Ampiclox). In addition, a number of antibiotics on the "Watch" list such as ciprofloxacin, erythromycin and ceftriaxone are routinely used in both the private and public health sectors.

3.2. Key challenges of local antibiotics production (stakeholders' view)

A wide variety of stakeholders were interviewed to capture their views on the supply, availability and local production of antibiotics in Uganda. The main outcomes can be broadly summarised in four categories; business model for production and supply of antibiotics, data and information management, collaborations and linkages, and health systems approach to AMR.

On the business model for production and supply of antibiotics, stakeholders highlighted the challenge of low profit margins on antibiotics and how, from a portfolio management perspective, the local manufacturers find it difficult to include them in their expansion plans, especially for newer classes of antibiotics such as cephalosporins. The concerns amongst the public about the quality of generics and locally manufactured products also pose another challenge on the business model for local production of antibiotics.

The second aspect is data and information management systems. There is the perception among stakeholders that many of the commonly used antibiotics have the highest levels of resistance, such as amoxicillin (Access Group) and ciprofloxacin (Watch Group). There is some data available to support this perception, however it is not extensive because there appears to be insufficient monitoring and surveillance of fake or sub-standard products in the market. The stakeholders reported that there is an urgent need to capture all antibiotic usage data in a central repository that could be used to shape public health policy. NDA is in the process of finalising the National Drug Authority Management Information System to capture all the pertinent data.

The third category of challenge concerns collaborations and linkages between local manufacturers and policy makers. Stakeholders asserted that local manufacturers have not been engaged in discussions with the relevant Ministries on antibiotic policy development and any effort to promote local production of antibiotics.

Finally, stakeholders identified challenges arising from the proper health system and regulation. The perception among stakeholders interviewed is that that health regulations, clinical guidelines and prescription policy are not regularly followed, especially in rural health facilities.

4. INVESTMENT INCENTIVES LANDSCAPE FOR LOCAL ANTIBIOTICS MANUFACTURING

Uganda's National Medicines Policy of 2015 has identified the need to improve medicines use, pharmaceutical information systems, increasing public financing for essential medicines, strengthening NDA, and to proactively engage the private sector to identify areas in which they can contribute to achieving the policy goal. [5] Uganda's current National Pharmaceutical Sector Strategic Plan 2020/21-2024/25 is developed with a view to:

- Increase the share of locally manufactured health commodities broadly, including personal protective equipment, blood products, medical oxygen and traditional and complementary medicines;
- Develop pharmaceutical service that maximises health outcomes; and
- Ensure governance, government leadership and stewardship; and proactive multisectoral engagement for the promotion of the pharmaceutical sector.

There are other broad economic initiatives that can assist the development of the pharmaceutical sector in general in Uganda. Currently, Uganda is experiencing a boom in infrastructure development to facilitate the development of the oil and gas sector. This has resulted in building of major roads linking the main towns and building a new airport. In the energy sector, two new hydroelectric power projects are about to be completed that are expected to ensure sufficient supply of electricity for the country, including its industries. The health sector has also received additional funding to improve health services provided by hospital and clinics especially in the rural areas.

At a broad industrial level, Uganda is currently implementing Buy Uganda - Build Uganda policy (BUBU) (2014) that aims at promoting consumption of locally manufactured goods and services; promoting use and conformity to standards to guarantee quality goods and services; and building capacity to of local suppliers of goods and services. The goal was that within five years local content of goods and services in Uganda should grow to 50% and half of all local products should conform to national standards. For this purpose, the policy proposed to allocate 20% of all government procurement by value to local products and services, and 50% of shelf space in supermarkets to be populated by local products. BUBU is premised on existing policies that support and encourage the consumption of locally produced goods and services. The BUBU targets all products, including pharmaceutical products, such as antibiotics. Although BUBU has ambitious targets, so far beyond the oil and gas sector, the policy has not been translated into law.

In Uganda, general investment incentives include:

- *Income tax and tariff free imports of capital goods:* Government incentives around income tax vary according to the business sectors. The greatest incentives are offered to the agricultural sector. For the pharmaceutical sector, a greenfield investment would benefit from a 10-year tax holiday, tariff free import of capital goods, API and other pharmaceutical input and packaging material.
- Policy on land: In principle, the government offers free land to investors particularly in the manufacturing sector. Several industrial parks have been established in Uganda to attract investors for green field projects.

Pharmaceuticals production and supply in Uganda is regulated by a number of government agencies (Table 6). The *Ministry of Trade, Industry and Cooperatives and the Ministry of Health* both have key interests in, and activities related to the sector. Within the Ministry of Health, the Department of Pharmaceuticals and

[5] Ministry of Health, Uganda, 2015. National Medicines policy. Available at https://www.who.int/medicines/areas/coordination/NationalMedicinesPolicy2015.pdf

Natural Medicines was upgraded from a Division of Pharmacy, during the period of NPSSP 2015/16 – 2019/20. Operating within the Ministry of Finance, Planning and Economic Development which sets the strategic direction of the country, *The Uganda Investment Authority* seeks to attract FDI to the country and improve services for investors. A new investment code (in 2019, replacing the 1991 version), strengthened the UIA, making it a one-stop centre for investors (Calabrese et al. 2009, 11). From a regulatory side, the *National Drug Authority (NDA)* governs activities related to product evaluation and registration, import and export control, licensing and inspection of pharmaceutical establishments, post-marketing surveillance and pharmacovigilance. The *National Medical Stores (NMS)* are responsible for purchasing and distributing pharmaceuticals and other health products for the government. Annex IV provides a list and brief description of the health policies and measures of Uganda.

Table 6. Major government agencies in the pharmaceutical sector

Major government agencies	Description of their role
Ministry of Trade, Industry and Cooperatives (MTIC)	Concerned with promotion and expansion of trade, cooperatives and industrializations
Ministry of Finance, Planning and Economic Development (MoFPED)	Economic policy making, overseeing public expenditure and national planning
Ministry of Health (MoH)	Body concerned with stewardship and leadership of the health sector
Department of Pharmaceuticals and Natural Medicines (DP&NM)	Within the Ministry of Health, guides implementation of the National Medicine Policy and coordinates national pharmaceutical services
National Drug Authority (NDA)	Regulation of drugs – including registration, licensing, inspections
Uganda Investment Authority (UIA)	Promotion and facilitation of private sector investment, operating under the MoFPED
National Medical Stores (NMS)	Responsible for procurement, storage and distribution of pharmaceuticals and health products to public health facilities

Source: Authors' elaboration.

Uganda provides various 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 7). However, there are currently no government incentives specifically designed to promote local manufacturing of essential or modern antibiotics. Incentives offered to manufacturers are not linked to any particular medicine.

Table 7. Incentives for local production of pharmaceutical products in Uganda

	Incentive	Potential impact
Production-facilitating		
	Zero duties on imports of raw and packaging materials	Positive impact on the cost of production
	VAT on all pharmaceutical inputs is recoverable	Positive impact on the cost of production (however, government taking long to re-imburse the VAT can create cash flow issues)
	Income tax benefits / tax holidays	Encourages new investment
	Industrial parks	Favours industrial clustering and synergies; provides integrated infrastructures and services
Market-shaping		
	Price preference of 15% in government tenders[6]	Increase competitiveness of local manufacturing in comparison to imports.
	List of products that NMS will procure first from local manufacturers	Encourages local manufacturers to increase capacity for certain product lines
	Issue of "domestic only" tenders	Assist to level the playing field when there are products benefiting from export subsidies or subject to dumping practices.
	Supply through a 3-year framework contract with predetermined price and quantity	Allows local manufacturers to be more efficient at inventory and cash flow planning leading to potentially lower production costs
	NDA verification fee of 12% on a short list of products (37) applied to all imports[7]	Allows local manufacturers to be competitive versus imported products

Source: Authors' compilation based on different sources.

Yet, although none of the incentives listed in Table 7 are specifically for antibiotics, several antibiotics benefit because they are included in the drugs lists that receive preferential treatment. The absence of a targeted investment policy for the promotion of local production of antibiotics is not specific of the Ugandan 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 Ugandan context, and more generally in developing countries, they hint at options of more sophisticated and targeted measures to support local production of antibiotics.

Production-facilitating incentives.

In Uganda, pharmaceutical raw and packaging materials are totally exempt from any taxes/duties, including VAT. If VAT is applied, it is always recoverable (Ministry of Health 2021 NPSSS 2021, 32). There is no consistent application of the tariff and VAT exemptions on importation of spare parts of manufacturing equipment, due to the decision-making process that is left up to the individual inspector to determine whether the importation is eligible for the exemption. It is not always clear which codes should apply to

[6] PPDA, 2013. Amendment to the PPDA Law on Preference and Reservation Schemes. https://www.ppda.go.ug/wp-content/uploads/2017/12/Preference-and-Reservation-Schemes.pdf

[7] NDA, 2017. Special Notice on date Commencement of 12 percent Verification Fees on the list of selected medicines, 13 July 2017

which spares parts. There is a need to simplify the way taxes are applied to pharmaceutical spares. As mentioned above, a greenfield investment in pharmaceuticals can benefit from a 10-year tax holiday.[8]

Industrial parks will be a key mechanism aimed at accelerating Uganda's industrialization (UIA 2021). These parks aim to provide integrated infrastructure and services (e.g., land, electricity, water, waste disposal and management, ICT, roads etc.). The government is aiming to make 22 industrial and business parks available across Uganda, with work on 10 already commissioned at the start of the current decade (Ministry of Trade 2020, 12). Ugandan media reported in 2022 that the UIA and Ministry of Health are planning to create a 500 acre fully serviced pharmaceutical industrial park in Nakasongala (Monitor 2022). On 4th May 2022, the Ugandan Ministry of Health issued a press release stating plans by UK based companies to establish a Pharmaceutical industrial Park in Nakasongola District".

Market-shaping incentives.

Preferences and support for local pharmaceutical production are available through the public procurement system, under the Public Procurement and Disposal of Assets Amendment Act, 2013. The Act provides for the application of preference and reservation schemes for locally produced products under public procurement. NMS has implemented the Act by providing price preferences of 15%, restricting bids only to local manufacturers, and providing priority to local manufacturers before procuring from international suppliers and proving for a framework agreement. The price preference policy of 15% was noted to be introduced in 2012 (Brhlikova et al. 2020). It is, however, lower than the 25% price preference margin for locally manufactured pharmaceutical products offered in some other countries, such as Ethiopia and Brazil.

NMS primarily procure essential medicines under framework contracts, that cover a period of 3 years, specifying a minimum quantity per annum and a fixed price for each product. This allows local manufacturers to be more efficient at inventory and cash flow planning leading to potentially lower production costs. NMS would procure the specific products exclusively from that local manufacturer unless the manufacturer is unable to supply according to the agreed plan.

Over the years, NMS has been increasingly more supportive to local manufacturers. For many products that are not part of the framework contracts, NMS will first ask if local manufacturers are able to fulfil their requirement in terms of volumes, delivery times and price, among others. If the products can be supplied locally then NMS will not approach foreign companies. This has generally benefited local manufacturers, except where manufacturers are unable to comply with urgent requests due to lag time to import raw materials.

Notably, NMS issues tenders restricted to domestic suppliers on a 2 to 3 years cycle for products that are manufactured locally in Uganda (not including producers in East African Community). NMS issues such restricted tenders when they have confidence that the products can be supplied in the quantities needed and at competitive prices. Products are awarded to local companies based on a combination of factors such as prices, delivery history and product quality. Occasionally, NMS will put out an emergency tender for a specific product that is also restricted for local manufacturers.

Another major market-shaping initiative for local pharmaceutical production by the Ugandan government is the increase from August 01st 2017 in import verification fees from 2% to 12% on 37 selected medicines that are locally manufactured (Ministry of Health 2017). The stated aim noted was "to discourage importation of locally manufactured drugs, and also support the growth of our economy" (Ministry of Health 2017). The 37 medicines were selected after an assessment of manufacturing capacity. A recent study examining

[8] For example, one of Uganda's leading pharmaceutical manufacturers, APDL, benefited from a 10 year tax holiday ending in 2019 (https://www.unido.org/sites/default/files/files/2018-03/Abacus%20Parenteral%20Drugs%20Ltd.%2C%20Uganda_Company%20Presnetation%2001032018%20Bonn.pdf).

the impact of the policy has found that local production capacity of the selected medicines increased by 8.2% from 2017 to 2020, and that all producers also had an increase in the number of employees – with an average increase of 42% (Rajab et al., 2023).

In parallel to initiatives to incentivize local production of antibiotics at national level, Uganda 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 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 Uganda 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):

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.

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.

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.

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.[9]
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.

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

5. CONCLUSIONS

The purpose of this advisory report is to (i) examine the status of the manufacturing of antibiotics in Uganda 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. Local production of antibiotics at the early stage of development, covering about 10% of the market size. Market size for pharmaceutical products overall – at $340 million, including both locally produced products and imported ones – is quite small, at 40% and one third of that of Ethiopia and Kenya respectively. Within that, antibiotics is however a substantial segment, covering about 20% of the total market.
2. Confined to the formulation stage. Local production has remained confined to the formulation stage and is thus dependent on imports of inputs, especially APIs.
3. With GMP-compliance issues. Only 4 companies are listed by the NDA as meeting quality standard, less than 10% of the stated 43 licensed pharmaceutical manufacturers in the country. Of these four GMP-compliant facilities, three are majority foreign-owned.
4. Capacity utilization in line with the industry, yet with major margins of improvement. Capacity utilization is generally between 50% and 70%, in line with the rest of industry, highlighting significant margins of improvement.
5. AMR considerations are not a critical driver of antibiotics consumption patterns. Local demand is key in both private and public markets, it does not appear to have been shaped by AMR consideration.

b. *Investment landscape*

1. Sector-wide incentives for local pharmaceutical production are in place. These include production facilitating measures - no customs duties on raw materials and packaging, VAT recoverable VAT, 10-years tax holidays on greenfield projects and current rolling-out of industrial parks. Market-shaping measures are also taking place through public procurement (price preference for local producers, some tenders only for local manufacturers) and increased import-verification fee on selected list of products that are locally-produced.
2. But not product-specific. No incentive is designed specifically for antibiotics, to address either production-specific issues or AMR-specific issues. This is particularly relevant as Uganda is currently implementing its “Antimicrobial Resistance National Action Plan, 2018-2023.” The plan focuses on combating AMR through antibiotics stewardship; however, it does not directly link this strategy with local production of antibiotics to ensure uninterrupted supply of antimicrobial products. As a result, AMR objectives are not incorporated into the design of the incentive package.
3. Information system not supportive. A major challenge encountered in this study was the lack of complete and consistent data on the local markets for antibiotics. In this context it is extremely difficult to design consistent, targeted and product-specific incentives, based on solid cost benefit analysis and public health considerations.

4. Wider regional efforts taking off. In parallel to initiative to incentivize local production of antibiotics at national level, Uganda participates in a number of regional efforts to promote pharmaceutical manufacturing in the East African region. Most notably, a recent jointly coordinated UNCTAD-EAC project has led to the adoption of measures specifically targeting local production of antibiotics, the first of their kind in the context of regional cooperation in Africa.

Key Recommendations

Uganda already has some elements of a pharmaceutical incentives package that has facilitated the emergence of a small number of local manufacturers compliant with GMP. However, a more coordinated and consistent set of actions and implementation to support local production of antibiotics is required. Improved information is also required in order to inform such policies, including cost-benefit considerations.

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

1. ***Carefully assess viability of local production, based on benefits, costs and risks – and in comparison with available alternatives.*** As a low-income country with relatively small market and pharmaceutical industry still at the early stage of development, Uganda will face significant feasibility constraints to scale local production of antibiotics, heavily relying on volumes and economies of scale (see annex V). The government will likely need to employ substantial incentive schemes to support the industry, including costly market-shaping incentives and potentially for a long period of time. In this context, there are significant costs and risks associated to pursuing local production and available alternatives should be seriously considered and assessed against local production. While support for local production has been advocated across various government policy documents, an overall coherent strategy supported by fact-based cost-benefit analysis is lacking. The development of a Uganda pharmaceutical manufacturing plan can be instrumental to this objective, as noted as an action by the Ministry of Health for its National Pharmaceutical Services Strategic Plan 2020/21 – 2024/25.

1. ***Emphasize the regional approach to reduce costs.*** Regional integration is especially important for Uganda to reduce costs, given its small market size. While in the initial stage it may result in higher benefits for countries with relatively stronger manufacturing capacity, in the longer term properly designed regional integration will help to build regional value chains, facilitate specialization and business to business linkages, with benefits for all participant countries. Antibiotics could present an opportunity to initiate this process through a specific therapeutic category with particularly critical public health implications. Uganda can take the lead for deeper integration of the EAC market for pharmaceutical producers, including preferential procurement schemes, pooled procurement and harmonization of medicine regulations. The adoption of 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 (EAC/ExSCTIFI 38/Decision 6) are steps in this direction.

2. ***Focus on attracting MNEs and FDI promotion.*** MNE contribution is key to a successful promotion of pharmaceutical local production. Local pharmaceutical manufacturers, including of antibiotics, require several inputs from abroad – including raw material, factors of production, know-how and technology – which MNEs are well positioned to access. MNEs are already present in Ugandan pharmaceutical manufacturing. Three of the four GMP-compliant facilities as listed by NDA are majority foreign-owned. However, to scale local production stronger integration in global production network is needed. Government policies aimed at boosting local production of antibiotics should have FDI promotion as a priority. It should also be recognised that in a context where market-seeking motivations are less relevant than for larger countries, generous and targeted incentives and business responsibility considerations would play a major role for attracting MNEs. Prospects of market expansion through regional integration may also be a driver for MNE investment decisions.

3. ***Refine pharmaceuticals-sector wide incentive system through product-specific incentives.*** Although existing support has largely been sector-wide, HIV/AIDS and malaria have occupied considerable attention given their burden and the government has been a key buyer of local production of such drugs. Antibiotics could 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).

   Uganda for example can consider to further strengthen incentive packages for local pharmaceutical manufacturers to promote production of specific essential antibiotics within the stewardship framework. This can be done via implementing specific framework agreements which will promote the selection of strategically essential antibiotics and simultaneously limit their supplies in accordance with the national AMR priorities. Options for consideration in the framework contracts include: guaranteed volume off-takes at an agreed price for new investment schemes or expansion of existing production of antibiotics; restricted imports of specific products covered by the contract that can be cost-efficiently manufactured locally; advance payments to local manufacturers of contract value to enable efficient cash flow, reduce cost of finance and improve ex-factory price of antibiotics; agreement with donors to ensure their donations are procured from local manufacturers that meets the regulatory standards, or at least avoid unregulated supply that disrupt the market for local producers; reduce the level of income tax derived from revenue from sale of specific antibiotics by local manufacturers and distributors; strengthening of the price preference margin for essential antibiotics produced in Uganda to ensure the continued production and uninterrupted supply of the products.

4. ***Develop a collaborative mechanism among local manufacturers for procurement, storage and supply of APIs and other critical inputs***. It should be recognized API production at a local scale is an unviable option in the short-medium term, given the current status of development of the global and domestic industry and technologies available. 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 competitive. Limitations related to availability and sustainability of imported inputs are particularly acute when volumes are relatively small such as in the Ugandan market. In this context, the government can promote and support the development of 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.

5. ***Link incentives to Good Manufacturing Practice (GMP) compliance needs.*** Despite some local manufacturers reaching the standard, GMP compliance needs further attention to ensure all local manufacturers attain the appropriate quality levels in order to meet the aim of quality local production. The NDA requires resourcing (people, finance) for enforcement of GMP standards[10], while manufacturers need training and resourcing. This has been frequently noted in various previous reports regarding local manufacturing. It is a goal which is especially important for health-reasons and strengthening regulation to ensure adherence to local manufacturers to GMP is a strategic objective of Government of Uganda's Antimicrobial Resistance National Action Plan 2018-2023. GMP-related skills can be promoted by attracting know-how transfer from foreign investors, by hiring foreign consultants and by exploiting existing technologies.

[10] https://www.nda.or.ug/nda/files/downloads/Strategic%20Plan_July2016-June2021_NDA_Uganda.pdf

6. ***Use streamlined regulation to facilitate investment.*** For low-income countries such as Uganda, with limited spending capacities, facilitation measures are often a cost-effective way to maximize the investment impact. Trade and investment facilitation initiatives aim to tackle ground-level obstacles to investment. They primarily address three dimensions: better information, transparent rules and regulations, streamlining of administrative procedures – all of them have emerged as priority issues in the diagnostic of local pharmaceutical industry undertaken in this report. 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. ***Enhance information systems regarding production and supply.*** Assessing the supply and consumption of antibiotics in Uganda is very challenging due to the absence of organized and accessible data for medicines including antibiotics. Uganda is implementing an initiative to develop a National Drug Authority Management Information System. This source needs to provide comprehensive and accessible data on medicines supply and consumption. This is especially important for antibiotics, given AMR concerns and the need to guide both investors and policymakers regarding which products need more or less investment. Related to this dimension, the elaboration of a pricing and availability study of locally-produced and imported drugs in Uganda, including of antibiotics, would be very helpful. Such studies have previously been conducted by the WHO and Health Action International for Ethiopia, Kenya and Tanzania, for example, and can help inform assessment of the business case for local production.
8. ***Continue to strengthen governance and coordination between health and investment authorities.*** Multiple government agencies have interests in the sector, but their under-resourcing contributes to lack of coherence across different bodies. Enhanced coordination is needed to ensure their activities and initiatives can be delivered. In particular, synergy between health and industrial/investment authorities is common to successful promotion of local pharmaceutical production elsewhere. While UNIDO's assessment over a decade ago (UNIDO, 2010) called for more intra-government coordination, the issue is still relevant. The National Industrial Policy (2020, 26), for example, noted that its successful implementation requires involvement of the Ministry of Health as a partner institution for strengthening capacity amongst local producers to meet WHO-GMP and WHO prequalification quality standards, alongside promoting local content in procurement. Such intra-government coordination should also be supplemented by dialogue with local manufacturers of antibiotics.

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ANNEX I: LIST OF ORGANIZATIONS/ STAKEHOLDERS INTERVIEWED.

1. Ministry of Health

2. Ministry of Trade, Industry and Cooperatives

3. Makerere University School of Health Sciences

4. Makerere University, Dept of Microbiology

5. National Drug Authority (NDA)

6. National Medical Stores (NMS)

7. World Health Organization (WHO) office, Uganda

8. Infectious Disease Institute

9. Fleming Fund Uganda

10. Uganda Pharmaceutical Manufacturers Association

11. Uganda National Health Consumers Organization (UNHCO)

12. Coalition for Health Promotion and Social Development (HEPS)

13. Pharmaceutical wholesalers/importers

14. Uganda Healthcare Federation (UHF) – private physicians

15. Pharmaceutical Society of Uganda (PSU)

16. Aga Khan University Clinics management

17. Women in Pharmacy

ANNEX II: LIST OF ANTIBIOTICS PROCURED BY NMS IN 2019.

DESCRIPTION	PACK SIZE	THERAPEUTIC GROUPING	SOURCE	ANNUAL QTY [FY2020/21]
REGULAR ORDER ITEMS				
RH(RIFAMPICIN 75MG+ISONIAZID50MG) 84TABLETS	84	ANTI-TB MEDICINES	TPT	8,175
RH(RIFAMPICIN150MG+ISONIAZID75MG) 28TABLETS	24	ANTI-TB MEDICINES	NMS + TPT	13,830
RHZ(RIFAMPICIN 75MG+INH 50MG+PYRAZ 150MG)	84	ANTI-TB MEDICINES	TPT	7,312
RHZE(RIF150MG+INH75MG+PZA400MG+ ETHAMB275MG)28TABS	24	ANTI-TB MEDICINES	NMS + TPT	8,027
BETAMETHASONE SODIUM PHOSPHATE 0.1% EYE DROPS 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	67,502
BETAMETHASONE+NEOMYCIN 0.1%+0.5% EYE DROPS 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	65,682
CHLORAMPHENICOL 0.5% EYE DROPS 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	194,432
CHLORAMPHENICOL 1% EYE OINTMENT 3G	1	EYE/EAR/NOSE MEDICINE	NMS	26,838
CHLORAMPHENICOL 5% EAR DROPS 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	65,765
CIPROFLOXACIN 0.3% EYE DROPS 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	7,405
GENTAMYCINE 0.30% EYE/EAR DROP 10ML	1	EYE/EAR/NOSE MEDICINE	NMS	201,427
TETRACYCLINE 1% EYE OINTMENT 3.5G TUBE	1	EYE/EAR/NOSE MEDICINE	NMS	679,620
TOBRAMYCIN EYE DROPS 0.3%, 5ML DROPPER BOTTLE	1	EYE/EAR/NOSE MEDICINE	NMS	1,342
TOBRAMYCIN+DEXAMETHASONE EYE DROPS; 0.3%+0.1%, 5ML DROPPER BOTTLE	1	EYE/EAR/NOSE MEDICINE	NMS	4,196
AMOXICILLIN 250MG CAPSULE	1000	ORAL PREPARATIONS	NMS	237,853
AMOXICILLIN DISPERSABLE TABLETS 250MG	100	ORAL PREPARATIONS	NMS	230,588
AMPICILLIN/CLOXACILLIN 250MG/250MG CAPSULES	100	ORAL PREPARATIONS	NMS	26,200
AZITHROMYCIN TABS 500MG	3	ORAL PREPARATIONS	NMS	23,362
CEFUROXIME TABLETS 500MG	100	ORAL PREPARATIONS	NMS	1,865
CHLORAMPHENICOL 250 MG CAPSULE	1000	ORAL PREPARATIONS	NMS	268
CIPROFLOXACIN 500MG TABLET	100	ORAL PREPARATIONS	NMS	180,436
CLOXACILLIN 250MG CAPSULES	100	ORAL PREPARATIONS	NMS	15,701
DOXYCYCLINE CAPSULES	100	ORAL PREPARATIONS	NMS	155,915
ERYTHROMYCIN 125MG/5ML 100ML BOTTLE	1	ORAL PREPARATIONS	NMS	16,479
ERYTHROMYCIN STEARATE 250MG TABLET	1000	ORAL PREPARATIONS	NMS	8,232
METRONIDAZOLE 200MG TABLET	1000	ORAL PREPARATIONS	NMS	148,595
METRONIDAZOLE SUSPENSION 200MG/5ML 100ML BOTTLE	1	ORAL PREPARATIONS	NMS	16,181

DESCRIPTION	PACK SIZE	THERAPEUTIC GROUPING	SOURCE	ANNUAL QTY [FY2020/21]
REGULAR ORDER ITEMS				
AMPICILLIN 500MG POWDER FOR RECONSTITUTION IV/IM/ INFUSION	100	PARENTERALS	NMS	15,726
AMPICILLINE/CLOXACILINE 250MG/250MG INJECTION	100	PARENTERALS	NMS	6,240
CEFOTAXIME SODIUM POWDER FOR INJECTION 1GM VIAL	1	PARENTERALS	NMS	10,190
CEFTRIAXONE SODIUM 1G POWDER FOR INJ.VIAL	1	PARENTERALS	NMS	2,195,047
CHLORAMPHENICOL SODIUM SUCCINATE 1G INJECTION	50	PARENTERALS	NMS	2,763
CIPROFLOXACIN IV 200MG/100ML VIAL	1	PARENTERALS	NMS	31,950
CLOXACILLIN 500MG INJ (PFR) IV/IM	50	PARENTERALS	NMS	2,596
ENOXAPARIN 40MG/0.4ML,0.4ML VOL,PRE-FILLED SYRING	2	PARENTERALS	NMS	2,314
ENOXAPARIN 80MG/0.8ML,1ML SYRINGE	1	PARENTERALS	NMS	1,648
IMIPENEM + CILASTATIN 500MG INJ	1	PARENTERALS	NMS	566
METRONIDAZOLE 500MG/100ML INFUSION	1	PARENTERALS	NMS	881,644
PENICILLIN, BENZATHINE BENZYL 2.4MU/1.44G AMPOULE	10	PARENTERALS	NMS	16,116
PENICILLIN, PROCAINE 3MU+ BENZYL 1MU AMPOULE	10	PARENTERALS	NMS	11,896
PENICILLIN. BENZYL 1MU/600MG INJ (PFR) IM	10	PARENTERALS	NMS	113,106
PIPERACILLIN -TAZOBACTAM 4.5G INJ	1	PARENTERALS	NMS	8,084
CLOTRIMAZOLE 1% TOPICAL CREAM 20G	1	TOPICAL PREPARATIONS	NMS	302,326
MICONAZOLE 2% CREAM ,20G TUBE	1	TOPICAL PREPARATIONS	NMS	8,212
MICONAZOLE 2% ORAL GEL 20G TUBES	1	TOPICAL PREPARATIONS	NMS	3,302
ETHAMBUTOL HCL 100MG	100	ANTI-TB MEDICINES	TPT	6,903
ISONIAZID 300MG 28TABS	24	ANTI-TB MEDICINES	NMS + TPT	2,774
MOXIFLOXACIN 400MG TABLETS	5	ANTI-TB MEDICINES	NMS	24
RIFAPENTINE 150MG	24	ANTI-TB MEDICINES	NMS + TPT	3,000
AMOXICILLIN/CLAVULANIC ACID TAB 375MG	10	ORAL PREPARATIONS	NMS	191
CEFIXIME 200 TABLET	120	ORAL PREPARATIONS	TPT+NMS	2,484
CEFIXIME CAPSULES 400MG	100	ORAL PREPARATIONS	NMS	60
CEFIXIME CAPSULES 400MG	100	ORAL PREPARATIONS	NMS	60
CLARITHROMYCIN SR 500MG TABS	100	ORAL PREPARATIONS	NMS	7
CLINDAMYCIN HCL CAPSULES 150 MG	100	ORAL PREPARATIONS	NMS	20
AMIKACIN SULPHATE 250MG/ML INJ, 2ML	1	PARENTERALS	NMS	9,960
FLUCLOXACILLIN/AMOXYCILLIN 500MG/500MG INJECTION	1	PARENTERALS	NMS	1,800
GENTAMYCIN 80MG/2ML INJ IV/IM	100	PARENTERALS	NMS	16,238
METRONIDAZOLE 500MG PESSARIES	14	PESSARIES/ SUPPOSITORIES	NMS	24
AMOXICILLIN CLAVULANATE 1.2G INJECTION	1	UHI SPECIALIST MEDICINES	NMS	460
AMOXICILLIN CLAVULANATE 156MG/5ML SYRUP	1	UHI SPECIALIST MEDICINES	NMS	200

DESCRIPTION	PACK SIZE	THERAPEUTIC GROUPING	SOURCE	ANNUAL QTY [FY2020/21]
REGULAR ORDER ITEMS				
AMOXICILLIN CLAVULANATE 625MG TABLET	14	UHI SPECIALIST MEDICINES	NMS	240
AMOXICILLINE+FLUCLOXACILLINE CAPSULES 250MG/250MG	16	UHI SPECIALIST MEDICINES	NMS	50
CEFUROXIME INJ. 1.5GM	1	UHI SPECIALIST MEDICINES	NMS	200
CEFUROXIME INJ. 750MG	1	UHI SPECIALIST MEDICINES	NMS	300
CEFUROXIME SYRUP 125MG/5ML	1	UHI SPECIALIST MEDICINES	NMS	200
MEFENAMIC ACID TABS 500MG	100	UHI SPECIALIST MEDICINES	NMS	50

ANNEX III: LIST OF ANTIBIOTICS MANUFACTURED LOCALLY IN UGANDA 2017-2019

Generic Name of Anti-microbial	Formulation	Strength	Pack Size	Production Volume (packs) in 2017	Price per Pack (UGX)	Sales Value (UGX) in 2017	Production Volume (packs) in 2018	Price per Pack (UGX)	Sales Value (UGX) in 2018	Production Volume (packs) in 2019	Price per Pack (UGX)	Sales Value (UGX) in 2019
Amoxicillin trihydrate	Capsules	250 mg	10x10's	209,858	4,223	886,230,334	379,565	5,610	2,129,359,650	682,801	5,056	3,452,241,856
Amoxicillin trihydrate	PFOS	125 mg /5ml	100 ml	195,000	1,150	224,250,000	240,000	1,100	264,000,000	195,000	1,200	234,000,000
Amoxicillin trihydrate	Dispersible tablet	125mg	20 Blister	57,359	592	33,934,000	5,059	3,759	19,015,300	3,500	2,586	9,050,000
Amoxicillin trihydrate	Dispersible tablet	125mg	30 Blister	10,000	139	1,388,000	39,441	139	5,482,300	-	-	-
Amoxicillin trihydrate	Dispersible tablet	125mg	100 Blister	43,378	6,076	263,579,300	65,699	4,845	318,288,000	80,570	5,057	407,452,000
Amoxicillin trihydrate	Dispersible tablet	250mg	10 Blister	51,500	1,113	57,332,000	8,111	9,283	75,293,500	3,225	9,283	29,934,300
Amoxicillin trihydrate	Dispersible tablet	250mg	20 Blister	25,165	3,343	84,115,000	17,934	6,186	110,936,000	2,400	25,571	61,369,600
Amoxicillin trihydrate	Dispersible tablet	250mg	100 Blister	28,542	6,230	177,827,000	30,022	6,692	200,901,000	58,766	7,784	457,448,200
Amoxicillin trihydrate	Dispersible tablet	250mg	100 Blister	16,923	13,455	227,698,965	13,533	13,455	182,093,000	2,423	13,455	32,599,000
Amoxicillin trihydrate (UG)	Capsule	250mg	1000's	149,769	39,876	5,972,240,000	100,422	17,751	1,782,560,000	15,241	92,354	1,407,560,000
Ampicillin trihydrate	Capsules	250 mg	10x10's	802,807	4,210	3,379,817,470	141,157	6,661	940,246,777	87,949	6,096	536,137,104
Ampicillin trihydrate	PFOS	125mg /5ml	100 ml	21,125	1,200	25,350,000	60,000	1,200	72,000,000	15000	1,300	19,500,000
Ampicillin trihydrate + cloxacillin sodium	Capsules	250 mg	10x10's	147,287	9,223	1,358,428,001	180,000	13,378	2,408,040,000	270,000	13,675	3,692,250,000
Ampicillin trihydrate + cloxacillin sodium	PFOS	125 mg /5ml	100 ml	210,000	1,900	399,000,000	180,000	2,000	360,000,000	225,000	2,300	517,500,000
Cloxacillin sodium	Capsules	250 mg	10x10's	52,309	5,156	269,705,204	91,478	5,519	504,867,082	58,178	6,500	378,157,000
Cloxacillin sodium	PFOS	125 mg /5ml	100 ml	31,500	1,200	37800000	15,000	1,200	18,000,000	5000	1,250	6,250,000

Generic Name of Anti-microbial	Formulation	Strength	Pack Size	Production Volume (packs) in 2017	Price per Pack (UGX)	Sales Value (UGX) in 2017	Production Volume (packs) in 2018	Price per Pack (UGX)	Sales Value (UGX) in 2018	Production Volume (packs) in 2019	Price per Pack (UGX)	Sales Value (UGX) in 2019
Azithromycin	Tablet	500 mg	1x3's	45,000	1,200	54,000,000	150,000	1,200	180,000,000	350,000	1,500	525,000,000
Chloramphenicol	Capsules	250mg	10x10's	110,000	10,000	1,100,000,000	110,000	10,000	1,100,000,000	150,000	11,500	1,725,000,000
Ciprofloxacin hydrochloride	Tablet	500mg	100 Blister	209,413	379	79,465,000	-	-	-	-	-	-
Doxycycline	Capsules	100 mg	10x10's	209,977	3,731	783,424,187	179,864	4,200	755,428,800	305,602	5,701	1,742,237,002
Doxycycline (UG)	Capsule	100mg	100 Blister	120,450	3,561	428,981,000	76,142	3,500	266,497,000	86,077	4,972	427,955,000
Erythromycin estolate	Suspension	125mg /5ml	100 ml	240000	2,000	480,000,000	205000	2,000	410,000,000	195000	2,300	448,500,000
Erythromycin stearate	Tablet	250 mg	10x10's	120,000	8,500	1,020,000,000	282,000	8,500	2,397,000,000	252,000	9,000	2,268,000,000
Metronidazole	Suspension	200 mg /5ml	100 ML	35000	750	26,250,000	15000	800	12,000,000	30000	1,500	45,000,000
Phenoxymethylpenicillin	Tablet	250mg	10x10's	15,000	5,000	75,000,000	480,000	5,000	2,400,000,000	100,000	5,500	550,000,000
Sulphamethoxazole + trimethoprim	Tablet	400mg +80mg	10x10's	752,894	3,500	2,635,129,000	1,015,060	3,700	3,755,722,000	934,143	3,800	3,549,743,400
Sulphamethoxazole + trimethoprim	Tablet	800mg +160mg	10x10's	4,641	7,500	34,807,500	93,089	7,800	726,094,200	25,725	9,300	239,242,500
Sulphamethoxazole + trimethoprim	Tablet	100mg +20mg	10x10's	3,000	800	2,400,000	80,000	900	72,000,000	130,000	1,000	130,000,000
Sulphamethoxazole + trimethoprim	Suspension	200mg +40mg /5 ml	60 ml	133,333	700	93,333,333	100000	750	75,000,000	283,333	800	226,666,667
Sulphamethoxazole + trimethoprim	Tablet	960mg	1000's	5	20,800	104,000	-	-	-	-	-	-
Tetracycline	Capsules	250mg	10x10's	60,000	6,000	360,000,000	50,000	6,200	310,000,000	90,000	6,500	585,000,000
Total - UGX						20,571,589,294			21,850,824,609			23,703,793,629
Total US$						5,559,889.00			5,905,628.27			6,406,430.71

ANNEX IV: LIST OF KEY POLICIES ON AMR AND PHARMACEUTICAL PRODUCTION IN UGANDA

Policy Name and Date/Validity	Issued By	Purpose	Content	Relevance to AMR and Antibiotics Production
One Health Strategic Plan (2018-2022)	Multi-sectoral[11]	To build resilient, sustainable systems that are able to prevent, detect and respond to zoonotic diseases and address AMR and biosecurity. Goal to reduce the burden of zoonoses and AMR by 50% by 2022	Strategic objectives and implementation including plans for preparedness and response to zoonotic diseases, AMR and biosecurity	Incorporates the AMR national plan and the AMR surveillance plan
National Medicines Policy (2015)	MoH	Accelerate movement towards Universal Health Coverage (UHC)	Focus on improving medicines use, improving pharmaceutical information systems, increasing public financing for essential medicines and strengthening NDA, among others.	Recognises the problem that antibiotics are easily available without a prescription
National Pharmaceutical Sector Strategic Plan III (2015-2020)	MoH	Support the implementation of the National Medicines Policy	Road map for investment and interventions to improve access to essential medicines.	Section on Appropriate Medicines Use, including AMR
Health Financing Policy (2015-2020)	MoH	Facilitate the attainment of UHC and achieve the health-related SDG's	Focus on resource mobilisation, steering investment in the right direction, aligning resources and creating efficiency gains in health	No specific mention of therapeutics
National Action Plan for Health Security (2019-2023)	MoH	Strengthen health security capacity	Strategies to strengthen country's capacity to prevent, detect and respond to public health threats.	Increase political engagement and advocacy to improve AMR programs
National Drugs Policy and Authority Act (2006)	MoH	Establishes the NDA	Provides for the mandate to ensure the availability of essential, efficacious, and cost-effective drugs for both human and animal health.	Provides for improved regulation of antimicrobial use and distribution
Pharmacy and Drugs Act (1971)	MoH	Governs the pharmacy profession	Regulations on trade and use of drugs and poisons. Defines the specifications for premises used as a pharmacy, chemist, or drug store. Sets qualifications for pharmacist, chemist, druggist, as pertains to pharmacy practice	Advocates for appropriate use of antimicrobials under the supervision of qualified health professionals and describes the standard of inventory and stock records.

[11] It includes the MoH, the Ministry of Agriculture, Animal Industries and Fisheries and Uganda Wildlife Authority

Policy Name and Date/Validity	Issued By	Purpose	Content	Relevance to AMR and Antibiotics Production
Public Procurement and Disposal of Public Assets ACT (2003) & Regulations (2014)	Ministry of Finance	To establish an autonomous authority; to formulate policies and regulate practices in respect of public procurement and disposal activities and other connected matters	Describes the Authority's structure, objectives, role and responsibilities, powers, governance, funding etc. Preference for locally manufactured goods, contractors and consultants. Defines "local"	No specific mention of AMR
Buy Uganda, Build Uganda Policy (BUBU) (2014)	Ministry of Trade Industry and Cooperatives	Support private sector growth and reduce poverty	Situation analysis of priority sectors (food and milk, shoes, books, etc) identified. Five years targets set. Guiding principles established; public private partnership (PPP), quality, branding, etc incorporated.	No specific mention but support for procuring locally manufactured medicines
AMR specific plans				
Anti-Microbial Resistance National Action Plan (2018-2023)	MoH	To address the threat of AMR through a multi-stakeholder approach. This is line with the Global Action Plan adopted by WHO members in 2015	Clearly laid out goals and strategies including an implementation, surveillance and plan	Includes 18 objectives and activity plan including funding requirements. Focus on surveillance
National Guidelines on Anti-Microbial Consumption and Surveillance in Human Health 2019, draft)	MoH	To generate evidence needed to identify trends in anti-microbial consumption and use.	Detailed guidelines on data management, analysis and reporting for AM consumption and use. Sets out priorities and key areas to focus on. Governance structure in place.	Very specific for anti-microbials, including data collection tools, lists of products, etc,
National Guidelines on Anti-Microbial Consumption and Surveillance in Animal Health (2020, draft)	Ministry of Agriculture Animal Industries and Fisheries	Similar to human health policy as above	Similar to human health policy as above	Similar to human health policy as above

Source: Author's own compilation)

ANNEX V: 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*[12]. 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 range 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-

[12] 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)

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.