UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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

An Advisory Report

UNITED NATIONS
UNCTAD

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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

An Advisory Report

UNITED NATIONS
UNCTAD
Geneva, 2023

UNCTAD/TCS/DIAE/INF/2023/6

NOTES

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

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

Public health policies and measures to mitigate antimicrobial resistance per se are within the remits of the World Health Organization 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 ctive pharmaceutical ongredients, 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 Ethiopia 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 Ethiopia, general aspects of the framework developed in the paper have contributed to inform and shape the discussion and recommendations presented in this Report. A pre-view excerpt of the paper is added as Annex (3) to this Report, for the benefit of interested Ethiopian stakeholders.

CONTENTS

ACKNOWLEDGEMENTS

This Advisory Report was prepared as part of the UNCTAD project, "Investment incentives for local production of essential antibiotics in East Africa", under the overall supervision of James Zhan, Director of the Division on Investment and Enterprise (DIAE). The UNCTAD report team was led by Bruno Casella (UNCTAD DIAE) and included Ermias Tekeste Biadgleng (UNCTAD DIAE). At UNCTAD, during various stages of preparation, the report team benefited from comments and inputs from Joerg Weber and Richard Bolwijn, while Christoph Spennemann provided guidance in the early stages of the preparation of the report. Any errors are the responsibility of the report team.

I. UNCTAD recognizes with appreciation the extensive contributions provided to the report team by Rory Horner (University of Manchester) and Mulu Gebreeyesus (Policy Studies Institute, Ethiopia).

II. 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.

III. UNCTAD gratefully acknowledges the support from and valuable contributions to the report of Heran Gebra, Director, Ethiopia Drug Administration, Messay Woldemaria, Director, Pharmaceutical Industry Development, Armauer Hansen Research Institute (AHRI), Ethiopia , Food Beverage and Pharmaceutical Development Institute, Wendosen Shewarega Sitotaw, AMR prevention and Containment officer Pharmaceutical and Medical Equipment Directorate, Ministry of Health, and Geoffrey Banda, Co-Director, the Innogen Institute, University of Edinburgh. Maarten van der Heijden, Technical Officer, Antimicrobial Resistance Division of the World Health Organization provided valuable comments on the draft study of the report.

EXECUTIVE SUMMARY

The purpose of this advisory report is to (i) examine the current state of antibiotics manufacturing in Ethiopia 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 appropriate 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 critical that pharmaceutical companies, governments and procurers take action to ensure (not only access but) appropriate access to antibiotics and antifungals. Local production – the focus of this study – is one possible way to achieve this objective.

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

- Antibiotics is a key segment for pharmaceutical local production in Ethiopia, with a market share of locally produced antibiotics of around 50%, significantly higher than that of other pharmaceutical products. Foreign investment plays a prominent role in local production.
- While more expensive than imported products for public procurement, locally-produced antibiotics are lower-priced in the private market, and they are generally more available in public and private sector facilities.
- Generous sector-wide pharma incentives are in place, including production facilitating incentives (notably a dedicated pharmaceutical park and targeted fiscal incentives) and market shaping incentives (public procurement preferences). Yet, no specific incentives are designed for antibiotics.
- According to local producers, competitive challenges from imported antibiotics and forex shortages are the two main factors undermining new investment plans. Red tapes and administrative burdens are also weighing heavily on investors.

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

Notwithstanding the specific recommendations provided in this Report for the antibiotics Ethiopian industry, general guidelines for strengthening the overall governance of incentives also apply – as defined by UNCTAD Investment Promotion Framework for Sustainable Development (UNCTAD, 2015). In particular,

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

2. *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. Leverage multinationals' presence and contribution.
2. Review fiscal incentives, with a view to move from profit-based (e.g. tax holidays) to expenditure-based (e.g. accelerated depreciation).
3. Re-assess market shaping incentives (e.g. preferential procurement) on a cost-benefit basis.
4. Consider refining pharma sector-wide incentive system through product-specific incentives.
5. Link incentives to Good Manufacturing Practice (GMP) compliance needs.
6. Use streamlined regulation to facilitate investment.
7. Develop a collaborative mechanism among local manufacturers for procurement, storage and supply of APIs and other critical inputs.
8. Emphasize the regional approach to reduce costs and expand market.
9. Make sure broad trade, investment and industrial policies are coherent and conducive.
10. Continue to strengthen governance and coordination between health and investment authorities.

ABBREVIATIONS

AMR	Antimicrobial resistance
API	Active pharmaceutical ingredient
AWaRe	Access, Watch, Reserve
EEML-2020	Ethiopian Essential Medicine List – 2020
EFDA	Ethiopian Food and Drug Authority
EFMHACA	Ethiopian Food, Medicine and Health Care Administration and Control
EHIA	Ethiopian Health Insurance Agency
EIC	Ethiopian Investment Commission
EPHI	Ethiopian Public Health Institute
EPSA	Ethiopian Pharmaceuticals Supply Agency
FBPIDI	Food Beverage and Pharmaceutical Industry Development Institute
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
HSTP	Health Sector Transformation Plan
R&D	Research and Development
UNCTAD	United Nations Conference for Trade and Development
WHO	World Health Organization

INTRODUCTION

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

Local pharmaceutical production is a priority development policy issue at national, regional and continental levels in Africa. Such initiatives involve, with different levels of emphasis, three main aims: improving access to medicines (i.e. public health), national health sovereignty/security of supply (i.e. strategic) and growth, jobs, trade balance (i.e. economic development) (African Development Bank 2022, 4). Ethiopia has supported local pharmaceutical production for a number of years, notably through implementing a "National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025)" (Ethiopia, 2015).

This report approaches the issue of local pharmaceutical production in Ethiopia 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).

To contain 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, 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.

While AMR is an issue of global concern, initiatives have been taken at various national levels to address the problem. Ethiopia has a "Strategy for the Prevention and Containment of Antimicrobial Resistance", 2015-2020, and related programmes. However, despite the recent interventions, studies show that AMR continues to be a major concern and it is increasing in Ethiopia.[1]

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

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

[1] For example, a meta-analysis undertaken in 2018 on over 3,300 clinical samples from six clinical sites reported alarming levels of resistance among Gram negative bacteria (WHO, 2018).

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

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

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

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

(ii) Regulatory agencies.

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

(iv) Pharmaceutical companies and

(v) Donor agencies and civil society.

After delays due to COVID-19, the project started in July 2020. In total, 22 organizations, including six manufacturers were interviewed. The survey was administered through phone and face-to-face interviews depending on availability. In addition to the interviews, the study involved extensive collection and analysis of empirical data on local production of antibiotics and the associated relevant investment policy framework.

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. Finally, a generous collaboration of the then FBPIDI (Food and Beverages and Pharmaceuticals Industry Development Institute) helped to generate the relevant data under the institute's control. [2]

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 World Health Organisation and civil society organisations concerned with public health.

As an additional deliverable to the project, the project team coordinated by UNCTAD is preparing a paper, developing 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 Ethiopia, some general aspects of the framework presented in the paper have been informing and shaping the material presented here. To the timely benefits of the

[2] The Pharmaceutical Industry directorate is currently moved to be a department of the Armauer Hansen Research Institute (AHRI).

interested Ethiopian stakeholders, an excerpt of the key findings of the study is added as Annex (3) to this Report.

The remaining part of this report is organized as follows. The next section provides brief background on socio-economic trends of Ethiopia. Section 2 assesses the pharmaceutical industry landscape, with a particular focus on local production of antibiotics. Section 3 makes a comparison between locally produced and imported antibiotics in Ethiopia in terms of the two key dimensions of price and availability. Section 4 illustrates investment incentives currently in place to support local production in Ethiopia. Section 5 reports the results from interviews with Ethiopian stakeholders regarding their perceptions on antibiotics local production and on the investment environment. The last section summarizes the main findings and provides some policy recommendations.

1. SOCIO-ECONOMIC CONTEXT

With 120 million people (2021), Ethiopia is the second most populous country in Africa.[3] The country has experienced tremendous economic growth after implementation of successive economic development policies since mid-2000s. According to the International Monetary Fund, in 2020 the size of the Ethiopian economy reached USD95.5 billion at nominal GDP, or USD 272.02 billion at GDP purchasing power parity.[4] This translates to only USD 974 nominal GDP per capita, or 2,772, GDP purchasing power parity per capita.[5] Ethiopia has also registered major progress on poverty reduction, access to education and health services and in many other social indicators. However, it remains among the low-income countries and among the globally lowest-ranked countries in terms of human development[6] with complex socio-economic challenges, including high unemployment, macroeconomic imbalances and human development challenges on several fronts.

Ethiopia implemented two phases of its 2010-2020 Growth and Transformation Plan (GTP). Following an earlier emphasis on poverty reduction, GTP I and II focused on economic growth and the structural transformation of the economy. As well as supporting higher-value activities in agro-industries, particular emphasis has been placed on encouraging manufacturing through facilitating the private sector and attracting foreign investment. This has resulted in a massive increase of FDI inflows to Ethiopia from an annual average of USD300 million in the period 2000-2010 to USD2.300 million in the following decade 2010-2020, placing Ethiopia as the fourth largest FDI recipient in Africa in 2022 with record inflows at USD4.260 million (World Investment Report 2022)

Ethiopia has also recently developed a 10-year perspective plan (2021-30) that considers private sector development, productivity, and competitiveness among its pillars and includes manufacturing with a focus on agro-processing, human capital development, innovation and technology, infrastructure, energy, and logistics among its priority areas.[7] The national plan includes health-related goals to achieve universal health coverage, to protect society from health emergencies and disasters, and to build the health response system, among others.

Ethiopia is currently undertaking several economic reforms centred on liberalisation, privatizations and financial sector reform, including options to address foreign exchange shortages – an issue that is seen by local producers as highly critical for the future prospects of local pharmaceutical manufacturing as emerging by the survey undertaken in this study (section 5).

3 World Bank World Development Indicators.
4 IMF, World Economic Outlook Database, October 2020».
5 Ibid.
6 UNDP, Human Development Report, 2020.
7 FDRE/PDC (2020). "Ethiopia 2030: The Pathway to Prosperity - Ten Years Perspective Development Plan (2021 – 2030)". Unpublished.

At USD 860 million, pharmaceutical sales account for 32% of Ethiopia's USD $2.7 billion health expenditure in the same year. Ethiopia's per capita expenditure on health (USD 24) is far below the sub-Saharan Africa (SSA) average, estimated at USD 80. Domestic private health expenditure accounts for about 52% of total current health expenditure while the remaining is external (encompassing all financial inflows into the national health system from external sources). About one-third of the current health expenditure is out-of-pocket expenditure. Ethiopia is almost equal to the SSA average in both these measures.

Table 1. Ethiopia health spending: an overview

	2000	2005	2010	2015	2016	2017	2018	2019
Health spending (USD billion)	0.4	0.5	1.5	2.5	2.8	2.7	2.6	2.7
Current health expenditure (% of GDP) SSA average	4.4	4.1	5.5	3.9	3.9	3.5	3.19	3.1
	5.1	5.4	5.2	5.1	5.1	5.1	..	..
Current health expenditure per capita (current US$)SSA average	5.4	6.6	16.7	24.9	26.7	25.3	23.5	24
	32	55.8	83.7	86.1	79.4	83.8	..	..
Domestic private health expenditure (% of current health expenditure)SSA average	42.5	35.6	48.3	54.6	51.5	52.9	..	..
	59.9	57	51.6	52.2	52.9	52.7	..	..
Out-of-pocket expenditure (% of current health expenditure)SSA average	36	31.3	42.3	35.6	33.7	34.4	..	..
	32	34.1	33.3	35.8	36.4	35.5	..	..
Pharmaceutical sales (US$ billion)							0.84	0.86
Pharmaceutical sales (% of GDP)							1.04	0.98
Pharmaceutical sales (% of health expenditure)							32.7	31.7

Source: World Development Indicators data base, while the source of information for the years 2018 and 2019 is Fitch Solutions (2020).

2. THE ETHIOPIAN PHARMACEUTICAL INDUSTRY: FOCUS ON LOCAL PRODUCTION OF ANTIBIOTICS

2.1. Pharmaceutical industry landscape

According to Fitch Solutions (2020), Ethiopia's pharmaceutical market was valued at USD 855 million in 2019. This translated to just USD 8 per capita and 1.0% of the country's GDP, which is almost a third of its total healthcare spend. Generic medicines hold the dominant share of the market given the low purchasing power of the population. Moreover, public procurement is a key part of the market too, with purchasing by the Ethiopian Pharmaceuticals Supply Agency, estimated to account for 70% of the market volume. Future growth in the market is expected from the expanding middle class, subsequent lifestyle changes and the disease profile shift towards non-communicable diseases.

Local pharmaceutical production is estimated to supply about 20% of the value of products in the market. Currently, local pharmaceutical manufacturing in Ethiopia comprises of eleven companies producing generic human medicines (see Table 2). Another 11 companies are involved in producing veterinary drugs and medical supplies, as well as packaging activities. Only about half (six out of the eleven) of the manufacturers of human medicines are good manufacturing practice (GMP) certified by the Ethiopian Food and Drug Authority (EFDA). This shows lack of competitiveness of some of the local producers in terms of quality compared to imports. Local producers have a relatively limited product portfolio. It is estimated that local producers supply only 90 of the 380 products on the national essential medicines list. As a result, local producers can supply no more than 20% of the local market and the majority of medicines are imported (UNCTAD, 2020; Fitch Solutions, 2020).

Ethiopia has already attracted notable foreign investment in the sector – while three companies are locally owned, the remaining ones are foreign owned or joint ventures with varying foreign shares. In fact, five out of eight are joint ventures, which is not common in Ethiopian industries. The foreign investors involved in these projects are mainly from countries in the Global South including China, India, Sudan, and United Arab Emirates.

Local production of pharmaceuticals is all at the formulation stage of the value chain, with no active pharmaceutical ingredients (API) production in the country, implying that even local producers must thus rely on imported content. The weight of APIs compared to the value of local formulation of antibiotics ultimately depends on the product and location factors, such as labour, finance, access to market and investment incentives in host country. As a rough indication, a McKinsey report (Conway et al, 2019) sets the incidence of the costs of imported API on manufacturer price at just above 10% for a generic over-the-counter drug produced in sub-Saharan Africa (see also annex 3).[8]

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

Table 2. List of currently operational medicine manufacturers in Ethiopia

	Name of Factory	Location	Establishment year G.C	Employment (2019)	GMP certification	Ownership Type	Type of Products
1	Ethiopian Pharmaceutical Manufacturing	Addis Ababa		943	No	Private (local)	Human Drugs
2	East African Pharmaceuticals	Addis Ababa		151	Yes	Joint Venture (British-Sudan)	Human & Veterinary Drugs
3	Addis Pharmaceutical Factory Sh.co	Adigrat, Tigray	1997	917	Yes	Joint Venture	Human Drugs
4	Pharmacure	Addis Ababa	1998	102	No	Fully foreign (Saudi Arabia)	IV fluids
5	Sino Ethiop Associate Africa PLC	Gelan, Oromia	2001	108	Yes	Joint venture (Ethio-Chinese)	Empty Gelatine Capsule
6	Cadila Pharmaceuticals (Ethiopia)	Addis Ababa	2011	219	Yes	Joint venture (Ethio-India)	Human Drugs
7	Faws Pharmaceuticals	Addis Ababa	2012	45	No	Private (local)	Human drugs
8	Medisol Pharmaceuticals	Addis Ababa	2012	70	No	Private (local)	IV fluids
9	Julphar Pharmaceuticals	Addis Ababa	2013	104	Yes	Joint venture (Ethio-UAE)	Human Drugs
10	Sansheng Pharmaceutical	Addis Ababa	2018	371	Yes	Fully foreign (China)	Human Drugs
11	Human well Pharmaceutical	HagerieMariam, Amhara	2018	487	?	Fully foreign (China)	Human Drugs

Source: FBPIDI

Local producers operate below their capacity and have low productivity levels due to among other reasons deficient infrastructure, outdated machinery and equipment, inadequate staffing levels and qualifications, and difficulties with raw material procurement.

Local manufacturers face a strong competitive challenge from imported products, which comprise more than 80% of the value of pharmaceuticals consumed in the country. Table 3 below indicates sources of Ethiopia pharmaceutical products. In 2021, the major source of imports was India – accounting for 38.3% of the total value, followed by the United States (19.1%) and China (11.7%). While these figures are by value, the volume share of India and China is expected to be higher given they supply lower-cost generic drugs, while more expensive products (including under patent) are generally imported from the United States and Europe. Both India and China play major roles in the global generics industry, having advantages of economies of scale and the presence of capabilities across the full range of the pharmaceutical value chain.

Table 3. Major source of pharmaceutical formulation imports to Ethiopia 2021

Source of Imports	2021 imports (US$ thousand)	% of total
World	502,435	100.0
India	192,216	38.3
United States of America	96,028	19.1
China	58,991	11.7
Italy	33,873	6.7
Switzerland	26,262	5.2
France	15,564	3.1
Germany	12,445	2.5
Cyprus	11,425	2.3
Turkey	7,466	1.5

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

The Ethiopian government has clearly expressed a goal to increase the share of local production. Expanding pharmaceutical manufacturing is recognised as a priority for the Ethiopian government in successive national plans since 2010.[9] Both Growth and Transformation Plans I ((2010/11-2014/15) and II (2015/16-2019/20) and the subsequent Ten Years Development Plan 2021-2030 emphasise the importance of local production in substituting for imported products and in supplying export markets.

Based on the Health Sector Transformation Plan (HSTP I), the government prepared a ten-year (2015-2025) detailed National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (Ethiopia, 2015). Driven by a goal of combining the objectives of industrial development policy (moving up the value chain, economic growth) and health policy (access to good quality medicines) (WHO Government of Ethiopia (2015, 1), this strategy sets out the following seven strategic objectives with the aim of transforming the pharmaceutical sector in Ethiopia:

- Improve access to medicines through quality local production – implement the GMP Roadmap.
- Strengthen the national medicine regulatory system.
- Create incentives designed to move companies along the value chain.
- Develop human resources through relevant education and training.
- Encourage cluster development and production of active pharmaceutical ingredients (APIs).
- Create a research and development platform.
- Attract foreign direct investment in the pharmaceutical sector.

[9] The earlier National Health Policy (1993) and National Drug Policy (1993) emphasised the importance of promoting local production, although a more concentrated set of activities has taken place since 2010.

2.2. Trends and patterns in local production of antibiotics

In 2019, about 30 antibiotics (disregarding the different formulations) were in use in Ethiopiaa. Of these 11 (nearly one-third) are locally produced suggesting a relatively narrow range of local antibiotics production. Table 4 provides the list of the major antibiotics products consumed in Ethiopia and their value in USD for the year 2019 (Annex 1 shows the extended list of antibiotics - including the different formulations consumed in Ethiopia over three years (2017-19) and the quantities). The selected antibiotics products in Table 4 account for about 97% of the total value of antibiotics consumption.

In antibiotics the share of local production – covering about half of the total value of consumption – is significantly higher than for the pharmaceutical industry overall, at about 20%. This share has not significantly changed in the last 3 years. Antibiotics are thus a key category of drugs for local producers.

Table 4 also lists the antibiotic products by Access, Watch, Reserve (AWaRe) classification. The AWaRe classification was introduced by the WHO as a tool to support antibiotic stewardship and their optimal use. The classification reflects the level of susceptibility of the products to resistance and the corresponding need to monitor their use.[10] Prescription and consumption of 'Watch' group antibiotics need to be tailored to specific group of infections compared to those under 'Access.' 'Reserve' group antibiotics should be prescribed only when all alternatives have failed or are not suitable. Ethiopia has adopted its own Ethiopian Essential Medicine List – 2020 (EEML). The EEML consists of 16 products under Access, 10 products under Watch and 7 products under Reserve.

Table 4. Antibiotics consumption in 2019 by product and Access, Watch, Reserve (AWaRe) classification

	Antibiotics Products	Local production in USD million	Import value in USD million	Total consumption	import share (%) of total consumption	AWaRe classification
1	Amoxicillin	12.76	18.02	30.78	59	Access
2	Cloxacillin	12.79	3.89	16.68	23	Access
3	Ampicillin	4.87	4.77	9.64	49	Access
4	Sulphamethoxazole + Trimethoprim	4.49	2.46	6.95	35	Access
5	Ceftriaxone	0	3.27	3.27	100	Watch
6	Gentamycin	1.82	0.8	2.62	31	Access
7	Ciprofloxacin	2.24	0.16	2.4	7	Watch
8	Doxycycline	1.61	0.41	2.02	20	Access
9	Amoxicilline/Clavulanic	0	1.9	1.9	100	Access
10	Norfloxacin	0.94	0.66	1.6	41	Access
11	Cephalexin	0	1.16	1.16	100	Access
12	Erythromycine	0.18	0.58	0.76	76	Watch (WHO)
13	Tetracycline	0	0.21	0.21	100	Access (WHO)
14	Chloramphenico	0	0.1	0.1	100	Access (WHO)
15	Ciprofloxacine (aslactate)	0	0.04	0.04	100	Watch
16	Benzanthine Penicillin 1.2 MIU	0.01	0.02	0.03	67	Access
17	Cefotaxime sodium	0	0.02	0.02	100	Watch
18	Ampicillin sodium	0	0.14	0.14	100	Watch

[10] WHO (2021). AWaRe classification: WHO access, watch, reserve, classification of antibiotics for evaluation and monitoring of use, 2022. Available at https://www.who.int/publications/i/item/2021-aware-classification.

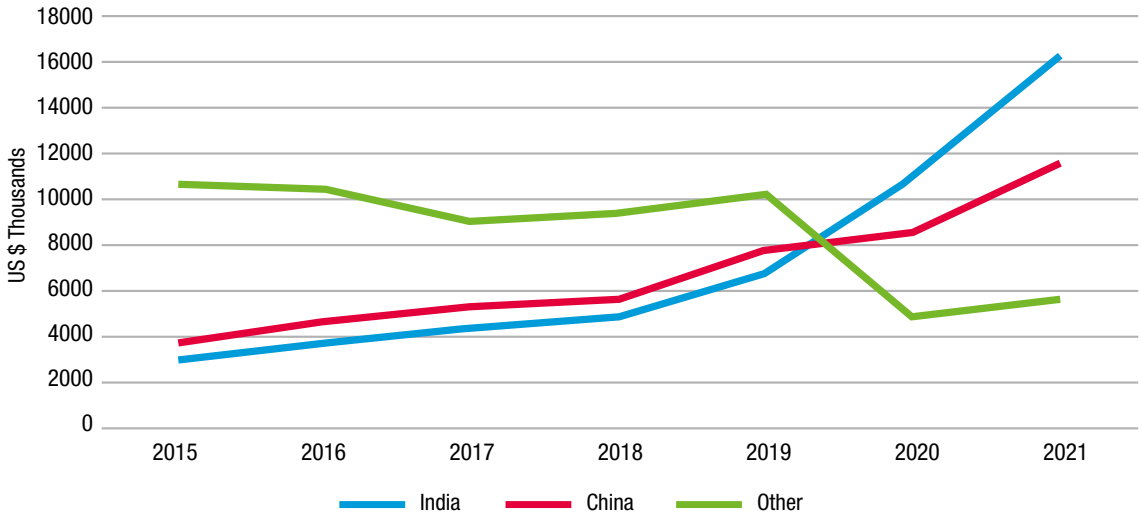
	Antibiotics Products	Local production in USD million	Import value in USD million	Total consumption	import share (%) of total consumption	AWaRe classification
19	Azithromycin	0	0.04	0.04	100	Access
20	Clarithromycin	0	0.87	0.87	100	Access
21	Metronidazole	0.30	0.61	0.91	67	Access
22	Penicillin G Sodium crystalline	0	0.02	0.02	100	Access
23	Other antibiotics	0.01	2.83	2.84	100	
	Total sum	**42.02**	**42.99**	**85.01**	**51**	
	Other products' share (%)	0.02	6.58	3.34		
	Sum of Access list prod.	39.59	35.95	75.54		
	share of Access (%)	94.2	83.6	88.9		
	Sum of Watch list prod.	2.42	4.21	6.63		
	share of Watch (%)	5.8	9.8	7.8		

Source: FBPIDI data but authors compilation. Note that WHO in bracket represents products that are absent in the EEML-2020 but present in the WHO list.

In total, 14 out of 16 antibiotics on the EEML-2020's Access list, 5 out of 10 antibiotics that are on the Watch list and 0 out of 7 antibiotics that are on the Reserve list are consumed in the local market in substantial manner. Additional 2 "Access' and 1 'Watch' products, which are not listed in EEML-2020 but are listed in the WHO classification, are found in the local market. Under Table 4, the "other antibiotics" category that account for no more than 3% of overall antibiotics consumption consists of 1 product under Access list (Cefazoline), 5 under the Watch list (Ceftazidime, Cefepime, Cefuroxime, Clindamycin, Cefixime), and 3 under the Reserve list (Ceftazidime, Meropenem, Piperacillin + Tazobactam).

Of the half of the total consumption imported from other countries, 48.4% were from India, while China's share was 34.6%, showing that supply of antibiotics is highly concentrated in only two countries covering almost 85% of total imports. Furthermore, the shares of both India and China are both on an upward trajectory, within the overall rising total import volume – from a five-year average of US$17.49 million in 2015 to US$33.9 million in 2021.

Figure 1. Source of antibiotics imports to Ethiopia 2015-2021 (5 year moving average)



Notes: Data drawn from ITC TradeMap. Antibiotics imports classified as 300410 "Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, and 300420 "Medicaments containing antibiotics, put up in measured doses". Both are in doses/packing. See also Bjerke (2022) for use of similar data. 5-year averages are calculated i.e. the 2021 figure is the average across 2017-21, in order to smooth out data variations.

In the Ethiopian pharmaceutical sector, seven out of eleven companies are producing antibiotics. Table 5 provides sales values and the numbers of antibiotic products produced by each company. The average number of antibiotic products by company is four. The number of products each company produces has not changed over the years 2017-2019.

The market is expanding. In 2017, total annual sale of antibiotics of all manufacturers was USD 26.01 million, which increased to USD 31.57 in 2019, a 20% increase.[11] The oldest pharmaceutical company, EPHARM, alone accounts for about 60.5% of industry annual sales, followed by Addis Pharmaceutical Factory accounting for about 27.5%. This suggests the concentration of local production of antibiotics in few firms. Yet, two new firms entered the industry in 2018.

Table 5. Antibiotic manufacturers' annual sales value, number of products and capacity utilization rates (2017-19)

	2017	2018	2019	Three years average (2017-19)				
Enterprise name	**Annual antibiotics sales (USD million)**			**# of antibiotics products produced**	**Share of antibiotics production over all medicines (%)**	**Capacity utilization for antibiotics products (%)**	**Capacity utilization for non-antibiotics products (%)**	**Overall Capacity utilization (%)**
1. Ethiopian Pharmac. Manufacturing (EPHARM)	16.46	17.42	19.1	8	50	58	30	44
2. Addis Pharmac. Factory	7.72	8.01	8.75	11	56	64	37	50.5
3. East Africa Pharmac.	1.45	1.38	1.44	2	50	47	23	35
4. Sansheng Pharmac.		0.65	1.07	3	65	40	20.6	33.3
5. Human well Pharmac.		0.66	0.85	3	50	52	29.1	40.5
6. Cadila pharmac. Ethiopia	0.24	0.19	0.22	2	50	45	32.6	28.8
7. Julphar pharmac. Ethiopia	0.14	0.13	0.15	1	56	61	26.1	45.5
Average	3.7	4.1	4.5	4	56	52.4	23.1	39.6
Total	26.01	28.45	31.57					

Source: FBPIDI and own calculations

Across the seven companies producing antibiotics, the average share of antibiotics production in overall companies' production is above 50%. The three years average capacity utilization of all these companies is about 40%. The average capacity utilization for antibiotics at 52.4% is significantly higher than for non-antibiotics (23.1%), likely due to higher local demand for the former.

[11] Note that the sales value in terms of USD is calculated at an annual average rate of Birr/USD for the respective years (29.2Birr/USD in 2019, 27.7Birr/US in 2018, and 24Birr/USD in 2017).

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

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

An earlier study by the World Health Organisation and Health Action International (Ewen et al. 2016) provides some useful insights into the market dynamics of locally-produced relative to imported antibiotics. The study surveyed a total of 25 medicines (both locally produced and imported) – 6 from a WHO/HAI global list and 19 of national importance.[12] Interestingly, of these, 10 products appear in the list of major antibiotics consumed in Ethiopia in Table 3 (which accounts for 97% of all antibiotics consumed in Ethiopia in 2019).

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

a. **Government procurement prices:** Government procurement involves the government purchasing medicines from manufacturers through the Pharmaceutical Fund and Supply Agency (PFSA) for subsequent distribution to public hospitals and health facilities. For six of the antibiotics, the government procured both locally produced and imported products. In all cases, the median procurement price was higher for locally produced than imported products (Table 6) – and generally substantially higher, with the exception of two products only. As a result, on average locally produced antibiotics are 45% more expensive than imported ones for public procurement.

Analysis of the procurement volumes alongside comparison of prices shows that the Ethiopian government could have made significant savings from sourcing their demand from importers instead of local producers. For the six antibiotics where the government procured both, if the government had only procured the imported product, total savings for 2013 are estimated at $3.36 million or 62.83 million Birr (see Annex 2) - which corresponds to around 23% of total government expenditure of $14.67 million for procurement of those key antibiotics products.

Similar findings on government procurement prices were found for the wider set of 25 medicines (including non-antibiotics products) in the study, with locally produced products on average 45% higher priced than the imported products. Given the 25% local preference granted by the government in public procurement (section 4), the authors thus noted that “Even after taking into consideration any additional costs of importing products, it appears that the government was paying in excess of its 25% local preference for some products” (Ewen et al. 2016, 10).

[12] All medicines were included on Ethiopia’s Essential Medicines List, except one (ciprofloxacin 500 mg). Patient prices and availability were assessed in public sector (34 medicine outlets), the private sector (30 retail pharmacies) and the other sector (17 outlets across municipality pharmacies, facilities of the Red Cross, Family Guidance Association and NGOs) in six areas of the country. Availability is understood as “whether the medicine was in the outlet on the day of data collection” (Ewen et al. 2016, 7). Public sector procurement prices are drawn from 2013 tender data from the Pharmaceutical Fund and Supply Agency (since 2019 the Ethiopian Pharmaceuticals Supply Agency). Prices for locally produced products are inclusive of all costs to the central store. The original authors adjusted the imported prices, given they were split across Free Carrier (FCA), Free on Board (FOB) and Cost and Freight (CFR), to ensure comparability with locally produced prices. The median price ratio (MPR) is defined as “the ratio of the price in local currency (Birr) divided by an international reference price converted to Birr” (Ewen et al. 2016, 7). It allows comparison internationally with prices governments could expect to pay. Values greater than 1 are more than the international reference price.

Table 6. Government procurement prices - antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (Birr)	Median MPR	Products (n)	Median unit price (Birr)	Median MPR
Amoxicillin 250mg	2	0.33	0.99	1	0.26	0.79
Amoxicillin 500mg	2	0.68	1.16	1	0.46	0.79
Benzathine penicillin 2.4MIU inj	0			0		
Ciprofloxacin 500mg	5	0.7	0.99	1	0.51	0.72
Chloramphenicol 250mg	1	0.45	1.27	0		
Doxycyline 100mg	4	0.35	1.32	1	0.31	1.31
Erthromycin 250mg	1	1.14	1.6	1	0.49	0.69
Metronidazole 250mg	3	0.2	1.76	0		
Sulfamethoxazole+Trimethoprim 400mg+80mg	4	0.25	1.2	1	0.22	1.05
Tetracycline 250mg	1	0.28	1.13	0		

Source: Ewen et al. (2016, 32). Notes: Products which appear in Table 4 (i.e. in top 97% of antibiotics market in Ethiopia) were extracted above. The median price ratio (MPR) is defined as "the ratio of the price in local currency (Birr) divided by an international reference price converted to Birr" (Ewen et al. 2016, 7). It allows comparison internationally with prices governments could expect to pay. Values greater than 1 are more than the international reference price.

b. **Public sector patient prices:** Patients then pay for publicly procured medicines (at public sector patient prices) out of pocket at public hospitals and health facilities. Patient prices in the public sector were also lower for imported than locally produced for 3 of the 4 products for which data was available (Table 7). For the study more widely, public sector patient prices (median MPR) were 17% higher than procurement prices (median MPR) for locally produced products, but 53% more for imported products, so on average the price difference patients faced was not as great as that for government procurement.

Table 7. Patient prices in the public sector - Antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (Birr)	Median MPR	Products (n)	Median unit price (Birr)	Median MPR
Amoxicillin 250mg	30	0.45	1.35	0		
Amoxicillin 500mg	28	0.85	1.45	1		
Benzathine penicillin 2.4MIU inj	19	5.6	0.92	0		
Ciprofloxacin 500mg	27	0.91	1.28	15	0.8	1.13
Chloramphenicol 250mg	28	0.37	1.05	0		
Doxycyline 100mg	19	0.39	1.46	17	0.4	1.49
Erthromycin 250mg	12	1.45	2.05	20	0.79	1.12
Metronidazole 250mg	37	0.26	2.24	3		
Sulfamethoxazole+Trimethoprim 400mg+80mg	17	0.33	1.56	14	0.26	1.24
Tetracycline 250mg	13*	0.21	0.83	0		

Source: Ewen et al. (2016, 33). Note: Data extracted just for antibiotics products which were both locally produced and imported. * one additional product was found free-of-charge in an outlet. The median price ratio (MPR) is defined as "the ratio of the price in local currency (Birr) divided by an international reference price converted to Birr" (Ewen et al. 2016, 7). It allows comparison internationally with prices governments could expect to pay. Values greater than 1 are more than the international reference price.

c. **Patient prices in the private and other sectors:** With such government procurement accounting for 70% of consumption, the remaining 30% of the Ethiopian market is comprised of sales in private retail pharmacies and in the other sector (municipality pharmacies, as well as health facilities of NGOs and organisations such as Red Cross and Family Guidance Association (FGA). Unlike in public procurement and public sector, in the private sector, locally produced products are cheaper (often substantially) than imported ones (Table 8). For the 6 antibiotics for which data is available on locally produced and imported products, the prices (as measured by median MPR; see note to table 6) of imported products are between 2.87 times higher (for Amoxicillin 500 mg) to almost 28 times higher (for Metronidazole 250mg). In the other sector (including municipality pharmacies, Red Cross, NGOs), for four of the six products with data, the locally produced antibiotics were available at lower prices than those imported. The pattern for antibiotics mirrors the results of the full set of products in the study, with patient prices higher for imported than locally-produced products in both the private and other sector. The apparent consumer willingness to pay higher prices for imported products, as seen in the private sector in Ethiopia, may reflect a perception that imports are of higher quality.

Table 8. Patient prices in the private sector - antibiotics

	Locally produced products			Imported products		
	Products (n)	Median unit price (Birr)	Median MPR	Products (n)	Median unit price (Birr)	Median MPR
Amoxicillin 250mg	21	0.5	1.5	4	4.45	13.35
Amoxicillin 500mg	28	1	1.71	33	2.88	4.91
Benzathine penicillin 2.4MIU inj	21	7	1.15	0		
Ciprofloxacin 500mg	14	1	1.41	79	2.4	3.39
Chloramphenicol 250mg	21	0.6	1.69	0		
Doxycyline 100mg	22	0.5	1.85	41	1.84	6.82
Erthromycin 250mg	6	1.73	2.44	2		
Metronidazole 250mg	31	0.3	2.63	6	8.4	73.56
Sulfamethoxazole+Trimethoprim 400mg+80mg	28	0.3	1.42	16	2.54	12.02
Tetracycline 250mg	18	0.4	1.61	0		

Source: Ewen et al. (2016, 34). Note: Products which appear in Table 4 (i.e. in top 97% of antibiotics market in Ethiopia) were extracted above. The median price ratio (MPR) is defined as "the ratio of the price in local currency (Birr) divided by an international reference price converted to Birr" (Ewen et al. 2016, 7). It allows comparison internationally with prices governments could expect to pay. Values greater than 1 are more than the international reference price.

Availability: A major argument in favour of local production relative to imports is the availability of key medicines in the market. In the case of antibiotics, this argument is made even more pressing by AMR considerations. Indeed, according to the WHO-HAI 2016 study, locally-produced antibiotics are more available than imported products in both the public sector and private sector (Table 9). For 5 of the 6 products which the government procures both from local producers and imports, the former was more available than the latter. Similarly, for 7 of the 8 antibiotics in the private sector which were locally-produced and imported, the former was more available. In the other sector, there was an equal split between antibiotics where local was more available and those where imports were more present.

Table 9 - Percentage availability by sector – antibiotics

	Public sector		Private sector		Other sectors	
	Local	Import	Local	Import	Local	Import
Amoxicillin 250mg	76%	0%	70%	13%	65%	0%
Amoxicillin 500mg	79%	3%	80%	53%	82%	65%
Benzathine penicillin 2.4MIU inj	56%	0%	70%	0%	88%	0%
Ciprofloxacin 500mg	71%	44%	40%	90%	47%	76%
Chloramphenicol 250mg	79%	0%	63%	0%	82%	0%
Doxycyline 100mg	56%	50%	73%	60%	47%	59%
Erthromycin 250mg	35%	47%	20%	7%	65%	24%
Metronidazole 250mg	91%	9%	87%	20%	94%	24%
Sulfamethoxazole+Trimethoprim 400mg+80mg	50%	41%	83%	30%	41%	71%
Tetracycline 250mg	38%	0%	60%	0%	53%	0%

Source: Ewen et al. (2016, 34). Note: Products which appear in Table 4 (i.e. in top 97% of antibiotics market in Ethiopia) were extracted above. Availability is understood as "whether the medicine was in the outlet on the day of data collection" (WHO-HAI 2016, 7), assessed as the share of the number of outlets where the medicine is available over all outlets, in the public, private and other sector.

While the data in this section is from 2013, a pattern is identifiable of locally-produced antibiotics being procured by the government at a significant cost premium. Cost may be only one factor affecting procurement decisions, with preference for local production often justified by needs of security of supply. Cost premiums may also be tolerated for some time as local production develops. The data also demonstrates that locally produced products are more price-competitive than imports in terms of patient prices and also more available. Manufacturing costs are also only part of final patient costs, however, with mark-ups and branding effects also influencing final costs to patients across different sectors. Although detailed price component data is usually inaccessible, such aspects and their potential to raise prices needs to be factored into any market assessment.

4. INVESTMENT INCENTIVES LANDSCAPE

Pharmaceuticals production and supply in Ethiopia is regulated by a number of government agencies (Table 10). The Ministry of Industry and the Ministry of Health both have key interests in, and activities related to the sector. The Ethiopian Investment Commission seeks to attract FDI to the country and improve services for investors. From a regulatory side, the Ethiopian Food and Drug Authority (EFDA) governs activities related to product evaluation and registration, import and export control, licensing and inspection of pharmaceutical establishments, among others. It has also aided local producers to reach GMP requirements (UNCTAD 2017, 15). The Ethiopian Pharmaceuticals Supply Agency (EPSA) is a public procurement agency responsible for purchasing pharmaceuticals, medical supplies, and equipment throughout Ethiopia.[13] It controls and supplies a sizable part of the market and handles the storage and distribution of donated products. The Pharmaceutical Industry Development Directorate at the Armauer Hansen Research Institute (AHRI) provides all-round support to the industry, accelerate technology transfer, achieve transformation & enable the industry to be competitive at international level.

Table 10: Major government agencies in the pharmaceutical sector

Major government agencies	Description of their role
Federal Ministry of Industry	A national policy making and coordinating body tasked with promoting and expanding the development of industry.
Federal Ministry of Health	A national policy making and coordinating body responsible for promoting health and wellbeing.
Ministry of Trade and Regional Integration	A national policy making body on trade and responsible for facilitating trade, including customs administration and clearance, transit and logistics.
Ethiopian Investment Commission	EIC is a facilitating organ for investors in registration and licensing, investment aftercare services, providing investment incentives, and fast-tracking investment partnerships including joint ventures.
Ethiopian Food and Drug Administration	EFDA is responsible for drug registration, inspection, and surveillance, licensing of manufacturers and importers, control of entry/exit of pharmaceuticals, quality control, and pharmacovigilance services.
Ethiopian Pharmaceuticals Supply Agency	EPSA is a public body established to supply medical goods to all public health facilities and private institutions in Ethiopia having sourcing, warehousing, and distribution of health commodities as its core activities.
Pharmaceutical Industry Development.	Currently located within the Armauer Hansen Research Institute (AHRI). It provides all-round support to the development needs of the industry.
Ethiopian Health Insurance Agency (EHIA)	EHIA was established as an autonomous federal government organ through Regulation No. 191/2010 with the objective of implementing health insurance system in the country.

Source: Authors' elaboration.

Ethiopia provides various incentives to attract investment and facilitate production in priority sectors, including in the pharmaceutical industry.

One of the major incentive schemes is the availability of subsidized loans of up to 70% for new investment projects and up to 60% for upgrading existing plant, equipment and machinery. These loans are advanced

[13] Ethiopian Pharmaceuticals Supply Agency, 2021. About Us - Ethiopian Pharmaceuticals Supply Agency - EPSA

by the Development Bank of Ethiopia. Moreover, manufacturers are exempted from customs duty on importing all granted capital goods and spare parts at up to 15% of the total value of imported investment capital goods. In addition, firms that export at least 60% of their products are provided additional incentives such as duty drawback on imported inputs, voucher, bonded warehouse, and export credit guarantee schemes and two years additional income tax exemption.

In a move to attract investors specifically to the pharmaceutical industry, the government established a state-of-the-art specialized pharmaceutical industrial park namely Kilinto Industrial Park. Built by Chinese construction company Tiesiju Civil Engineering Group Co. Ltd. (US$204 million cost), and financed by the World Bank, the park has 270 hectares of land on the edge of Addis Ababa. It opened in 2019. The park aims to meet the infrastructure requirements for pharmaceuticals (Kassahun 2018), including:

- Power availability and reliability
- Water supply – different grades of water purity depending on the product
- Waste management – pollution prevention, reduction and/or treatment related to air, liquid and solid waste
- Warehousing – organised and with good storage conditions
- Others- transport and potential one-stop shop (e.g. customs, environmental, EFMHACA, and other government clearances)

As per the Investment Board Decision of 15 June 2017, income tax exemptions have been granted to the pharmaceutical sector in the parks depending on the segment of the value chain, location of the park and export performance.[14]

- Investment in APIs: 12-14 years;
- Investment in final formulation: 10-12 years; and
- Investment in Pharmaceutical packaging: 7-8 years.

A 2019 media report[15] noted that the EIC had issued licenses to six companies to set up factories in the park – Domina Pharma Plc, Eva Pharma PLC, Intrade.co.uk Ethiopian branch, Africure Pharmaceuticals, Global Pharma, Dagim Dereje Pharmaceuticals (Tilahun 2019). The park has subsequently attracted the first standalone Indian investment (Cadila Pharmaceuticals and Kilitch Estro had entered through joint ventures) in the country (Ethiopian Monitor 2022) by Glocare Pharma in 2022 (Ethiopian Monitor 2022).

[14] Source: EIC at http://www.investethiopia.gov.et/index.php/investment-process/incentive-package.html
[15] https://www.capitalethiopia.com/2019/12/30/six-drug-factories-to-start-operation-at-kilinto-park/

Box. 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 Ethiopia and other developing countries contexts given the different regulatory and institutional framework and resources available to the public health systems. Yet, comments from the expert group meeting suggest that the local production of antibiotics and the establishment of their sustainable supply chains necessitates a special consideration, beyond the generic investment regimes for pharmaceutical production.

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

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

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

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

Various market-shaping initiatives to support local production are also in place. In particular, public procurement rules for pharma provide powerful incentives with a 25 per cent price preference for local producers and a prepayment of 30 per cent of the tender value to local manufacturers that are awarded a supply contract with Ethiopian Pharmaceutical Supply Agency (EPSA) (WHO-GoE 2015, 3). A list of pharmaceuticals and medical supplies produced in the country has been used to guide procurement (Gebre-Marian 2016, 71). Tenders for local manufacturers only are offered for products where two or more domestic manufacturers are producing in sufficient quantity (Kassahun 2018, 16).

One important limitation of this investment framework is that the incentives provided to the pharmaceutical sector are generic in nature. There is no specific incentive scheme targeting antibiotics products. Current

investments including FDI to Ethiopia focus on simple technology and easy to produce medicines. More sophisticated and specialized types of products, such as biologics, some classes of antibiotics, antivirals require significant investment and targeted incentives. The absence of a targeted investment policy for the promotion of local production of antibiotics is not specific of the Ethiopian 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). While not immediately replicable in the Ethiopian context, or more generally in developing countries, they represent options of more sophisticated and targeted measures to support local production of antibiotics.

5. STAKEHOLDERS' PERCEPTIONS ON ANTIBIOTICS LOCAL PRODUCTION AND INVESTMENT FRAMEWORK

In addition to secondary analysis of available information and data, primary data was collected through field survey and key informant Interviews. Relevant stakeholders included importers and antibiotic manufacturers, government agencies, civil society and international organizations and public hospitals. Table 11 shows the list of interviewed organizations and enterprises. In total representatives of 22 organizations, including six manufacturers, were interviewed. The survey was administered through phone and face-to-face interviews depending on availability and suitability for respondents over the months of September – October 2020.

Table 11: List of organizations and antibiotic manufacturers interviewed

Manufacturers (antibiotics)	Government organizations
Addis Pharmaceutical Factory	Federal Ministry of Health
East African Pharmaceuticals PLC	Ethiopian Public Health Institute (EPHI)
Julphar Pharmaceuticals PLC	Food Beverage and Pharmaceutical Industry Development Institute (FBPIDI)
Cadila Pharmaceuticals (Ethiopia) PLC	Ethiopian Food and Drug Administration (EFDA)
Ethiopian Pharmaceutical Manufacturing (EPHARM)	Ethiopian Pharmaceuticals Supply Agency (EPSA)
Sansheng Pharmaceuticals Plc	Ethiopian Investment Commission (EIC)

Civil society and international organizations	Referral public hospitals
Pharmaceutical Association	Black Lion Hospital (AA)
Ethiopian Medical Laboratory Association (EMLA)	Ayder Hospital (Mekelle)
WHO Ethiopia	Paulos Hospital (AA)
USAID (The Medicines, Technologies, and Pharmaceutical Services (MTaPS) program)	Adama Hospital (Adama)
UNICEF	
Medicine importers and wholesalers association	

Source: authors

Different questionnaires were prepared for each category of respondent. From the manufacturers we sought to collect information on type of antibiotics produced, production capacity and utilization, challenges faced and their perception on market demand, investment incentives, and combating AMR. The questions for government agencies, civil societies and hospitals on the other hand, focused on perceptions of supporting local production of antibiotics and combating AMR, antibiotics supply, regulations and effectiveness, AMR surveillance and the impact of Covid-19.

The discussion of survey results is organized in the subsequent two sub-sections as follows; the first part (section 4.1) discusses the survey results with the six antibiotic manufacturers, while the second part (section 4.2) summarizes the survey results with government agencies, civil society, NGOs and international organizations.

5.1. Local producers' perceptions

The Ethiopian pharmaceutical industry comprises of eleven medicine producers, of which seven are currently producing antibiotics. Six of the seven antibiotic producers were interviewed (Table 11).

The state of local production and reasons for low-capacity utilization

One characteristic of the pharmaceutical industry is that producers operate at lower than their installed capacity and hence they have low productivity. There are different estimates from different sources regarding capacity utilization. The data obtained from FBPIDI (Table 5) shows that the three years (2017-2019) average capacity utilization of the seven antibiotic producers was about 40% across all products, but at more than 50% for antibiotics alone.

Local producers are operating at the formulation stage of the pharmaceutical value chain, but are reliant on imported raw materials, as well as machinery and skilled personnel from abroad. The respondents from local manufacturers reported that, given low purchase volumes, they can only access the raw materials from countries such as India and China at expensive prices. At the same time, such countries sell export finished products to Ethiopia at low prices, discouraging local producers from competing in the market. Firms also face difficulty in accessing machinery parts and are constrained by a lack of skilled labour. As one of the respondents indicated:

> *"it is hard to find spare part as our machines are out-dated since technology advancement in the rest of the world has dropped the production of old machine spare parts since they will not be profitable. Not only spare parts but also we lack professionals and we always beg for professionals to come and maintain and service our machines from Egypt, Italy, Germany and we wait for them to come." [Respondent C]*

For all imported requirements of raw materials, spare parts and skilled personnel, timely access to foreign exchange is needed. However, the respondents frequently noted forex to be a critical obstacle leading to capacity underutilization. As one of the respondents indicated:

> *"Forex is not only needed for the raw materials of production but it is also needed to buy expert services and spare parts for the production machines. Forex is also needed for the calibration of the production environment and products. Either we have to send sample products abroad or we have to bring qualified people from abroad that we have to pay them in forex. So forex is the most important factor of efficiency." [Respondent A]*

Another respondent (Respondent C) reported that there is high demand for antibiotics such as Amoxicillin and Penicillin, but shortage of forex is constraining ability to meet that demand.

The procedure to access forex is also very lengthy and cumbersome for the manufacturers, especially given the scale of requirements for importing raw materials. The following quote from Respondent C is illustrative of the challenges reported:

> *"Regarding the forex, we have to go to the bank with two proforma invoices at a time and we have to wait for six months to get response to the proforma invoices that we took to the bank seeking for forex. It is after we get a response for these proforma invoices that we can apply for another proforma invoice again, that might take six months or more. However, if we see the actual production of the very basic antibiotics and penicillin there are enormous ingredients to be used as an input. Leave alone antibiotics, the very basic paracetamol syrup needs 34 ingredients to be used. None of these 34 ingredients is obtained locally and we must import them. Not only importing them but also, it is impossible to get all these 34 ingredients from a single supplier or a single country, but you get them from different countries and multiple suppliers. Each of these 34 items have their own HS codes that are given by the customs office. For example, we may get two ingredients from China from the overall 34 ingredients, and in China, there are two companies that are giving us each item, so we need to have two proforma invoice for these two companies. So, to produce paracetamol*

> *syrup, how many proforma invoices should I have to ask? Then, it is going to be worse when we come to antibiotics."*

The shortage of foreign currency for the importation of raw materials for pharmaceutical production has been a longstanding problem. The National Bank of Ethiopia (NBE) has put in place a system for retaining foreign exchange earnings in a dollar account by exporters for reuse to import raw materials. However, most of the pharmaceutical companies in Ethiopia are local market oriented so they cannot use this option. Although theoretically manufacturers are given priority in the forex allocation, the pharmaceutical companies supplying only the local market have to compete for hard currency with other manufacturers and essential supply importers.

Investment prospects

The firms were asked about their past and present investment efforts as well as intentions for new plants and expansion of existing ones for antibiotic products.

One firm [Respondent C] reported that it has made significant expansion investment (USD 90 million) in recent years with the aim of increasing its share in the local market and eventually exporting. Another firm [Respondent A] received 15,000 square meters of land for expansion with the aim of establishing production of injectable antibiotics in Ethiopia using technology transfer from the parent company outside Ethiopia. The other firms confirmed that they have plans for expansion investment.

The driving factor for firms' decision to expand is growing local demand, the need to enter into new antibiotic product lines, and replace obsolete machinery. For example, one of the respondents indicated that there is high demand in the local market for injectable antibiotics. The requirement for GMP in the government procurement procedures is another driving factor for expansion investment.

One expansion plan has recently been publicly announced. In February 2023, Pharmacure Plc (part of Ethiopia's MIDROC Investment Group), declared it had signed a deal (with India-based Elomatic-Pharmalab Consulting & Engineering Pvt. Ltd.) for a new manufacturing plant for penicillin products in Addis Ababa (https://ethiopianmonitor.com/2023/02/10/midroc-to-build-penicillin-pharmaceuticals-manufacturing-plant/).

However, despite such plans, many firms also noted factors which are bringing some caution to such plans – pointing to day-to-day operational challenges, including around forex.

Respondent F reported that;

> *"We have a good plan to expand, but day to day the obstacles are too much that we became unable to produce what we planned initially leave alone expansion."*

Another respondent [Respondent E] mentioned;

> *"Yes, we have a plan to produce more. The main factor that is making us decide to produce more new antibiotics is the demand for antibiotics. There is a huge demand for antibiotics. … But the problem we are having in forex is still making us think twice on the issue of producing new items as it requires more raw materials than what we are producing now."*

Others reported that the significant capital investment and time required have also hindered implementation of expansion plans.

The investment framework and adequacy of investment incentives and support

The survey assessed the firms' perceptions on the current investment framework including investment incentives and overall business environment. The respondents indicated that they are receiving different types of incentives from the government which include:

a. Procurement incentive to local producers of 25% preferential price over imports.
b. An industrial park designated for the pharmaceutical sector.
c. Cheaper loans through the Development Bank of Ethiopia.
d. Income tax holidays.
e. Free tax and tariff on imports of inputs from abroad.
f. Support in tests of quality products.

The government's investment policy, along with access to the Ethiopian market, were key factors in encouraging Julphar UAE's investment, according to the company's country director (Gebre-Mariam et al. (2016, 76)).

Yet, as expected, investors push for more support and share the perception that the government has not gone far enough. From their perspective, for example, the general tax holidays available are insufficient given the time and nature of investment in pharmaceuticals, and approvals before sales can commence. Along the same line, businesses have not benefited from the incentive mainly because the period of holiday starts not from the day of production but from the approval of construction. Respondents suggest that the government needs to extend the tax holiday.

Among the major perceived challenges the sector is facing, there are shortages of skilled manpower. Hence, several firms are forced to spend scarce forex to bring in expatriates. The government may support the business by providing skilled labour to the industry. To address this concern the government has introduced exemption of personal income tax for expats for those located at the Kilinto industrial park. One firm argued that this incentive needs to be extended to other firms outside the industrial park.

Some respondents argue that the present tax incentives and institutional setup even favour importers. For example, although the country pursues an import substituting strategy to support the local production of pharmaceutical products, they perceive priority is given to importers in the allocation of forex while the manufacturers are regarded as a secondary priority.

The actual deployment of the incentives is also a cause of frustration. The respondents argued that often the incentives are not applied on the ground due to lack of coordination and inefficiency of the government bureaucracy. The civil servants are not well trained and motivated leading to the poor implementation of the incentives. For example, at the customs there are not enough people that understand the pharmaceutical sector.

Some firms indicated that the government could do more to provide coherent and continuous communication to relevant stakeholders of market information regarding finished goods and raw materials both in the local market and the international market. Similarly, there should be a coordinated marketing strategy connecting the manufacturers and the medical practitioners. Medical professionals should be fully informed on the existing supply situations and aware of what is and what is not available from local manufacturers.

All the firms noted waste infrastructure to be an area where there is a critical shortage of suitable facilities, and where the government could facilitate production. The recently built facility in Adama is not yet functional. Consequently, they are forced to wait in the queue for long periods. Some even say that they are not allowed to build their own disposing system. One firm [Respondent A] claimed that for this reason it is now forced to rent a store to keep more than 60 tonnes of waste products. Another firm [Respondent C] suggested that constructing disposable facilities could create an opportunity to attract

FDI. Suitable waste management was also noted to be especially important for antibiotics production, where contamination could contribute to AMR.

5.2. Overall stakeholders' perceptions on local production of antibiotics

There is strong support for local production amongst the interviewees from government agencies, particularly health related. Such backing was justified on the basis of the health benefits of antibiotics e.g. in terms of reduced falsified and substandard antibiotics and increased access. The majority of the study participants have positive perception of the quality of locally produced antibiotics provided they follow the Good Manufacturing Practice. Generally, government officials working in the health sector, as well as focal persons in four tertiary hospitals, believe local antibiotics are reliable, while nevertheless reporting a lack of variety.

When asked about the level of engagement to support local production of antibiotics (and the pharmaceutical sector at large), government officials agreed that the pharmaceutical sector has been given sufficient attention. The original creation of FBPIDI and the subsequent relocation of its Pharmaceutical Industry Development Directorate to Armauer Hansen Research Institute (AHRI), the design of different sub-sector strategies, and the establishment of the specialized pharmaceutical industrial park on the outskirts of Addis Ababa were brought up as evidence of government commitments. Moreover, the Ethiopian Investment Commission (EIC) has recently initiated the formulation of a pharmaceutical investment promotion strategy. Other stakeholders such as the Ministry of Health, EFDA, EPSA, and FBPIDI have been engaged in the formulation of the investment promotion strategy. For example, EFDA had pushed for safety issues to be given sufficient attention in the new investment framework and for the incorporation of Good Manufacturing Practice (GMP) as a requirement in the investment and production process.

With regard to the adequacy of current incentives towards local producers, the respondents indicated that the government has provided various incentives to promote investment in the pharmaceutical sector, in addition to incentives given to all priority sectors.

EPSA engages in market-shaping to support local production and indicated plans to buy 50% of the demand from local production in the near future. Local pharmaceutical producers have 25% preference price compared to international suppliers. The agency advances 30% cash payment to local producers, unlike for international producers and suppliers. However, the utilization rate of the advance payment support and incentive scheme was reported to be low.

Procurement of antibiotics is based on consumption rather than on the national AWaRe (access, watch and reserve) classification, according to multiple informants. Understanding of the AWaRe classification of antibiotics amongst actors such as EPSA, hospitals, doctors and the lower level of health officers, was reported to be limited to non-existent. Several hospitals still order their medicines using the standard list request instead of the new AWaRe classification.

CONCLUSIONS

The purpose of this advisory report is to (i) examine the current status of the manufacturing of antibiotics in Ethiopia 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. Not a nascent industry. Local production of antibiotics is relatively well developed in Ethiopia, covering over half of total consumption. At 51%, its share of the domestic market is more than three times higher than the share of local production in the Ethiopian pharmaceutical consumption as a whole (at less than 20%).
2. But not growing and limited to the formulation stage. Yet, in the three years prior to the study, local producers did not manage to further increase their share in antibiotic market relative to importers. Additionally, none of the local manufacturers managed to integrate vertically and upgrade; local production has remained confined to the formulation stage and thus dependent on imports of inputs (APIs).
3. Integrated in global production. Five out of seven companies locally producing antibiotics have some foreign ownership – four are joint ventures between domestic and foreign owners and one is fully foreign owned. Joint-ventures with multinationals from developing countries are more common than those with multinationals from developed countries.
4. With above-average capacity utilization, still with major margins of improvement. At 52%, the capacity utilization for locally produced antibiotics products is more than twice the Ethiopian average for non-antibiotics, at 23%; but still with major margin of improvement both in utilization and quality standards. Only 6 of the 11 currently operational medicine manufacturers in the country were confirmed to have GMP certification.

b. *Locally produced vs. imported antibiotics*

1. Imported products cheaper in public procurement. Imported products tend to be more competitive in public procurement and in the public sector – while some antibiotics were only sourced from local producers, for the six products which were procured from both local producers and importers, where the median unit price of imported antibiotics is on average 26.8% lower than locally produced, a gap that even exceeds the 25% price preference granted to local producers. This results in additional annual spending of over US $3 million, or 29.7%, on the total cost of procurement of those six antibiotics products.
2. But not more competitive across all channels. Unlike in public procurement and in the public sector, in the private market and in the other sectors (including municipality pharmacies and Red Cross), prices of locally produced antibiotics are mostly more competitive than imported ones – for example in the private sector, the price of imported antibiotics is on average almost 6 times higher (median of median MPR 9.42 vs. 1.61 for locally produced).
3. Higher availability associated with local production. Availability of locally produced antibiotics is generally higher than imported ones across the public, private and other markets. Of all the

antibiotics products surveyed across public, private and other sector outlets, locally produced products had 2.5 times (on average present in 65% of outlets) the percentage availability of imported products (26%).

c. *Incentive system*

1. Generous sector-wide Pharma incentives are in place. Pharmaceutical local production benefits from a generous and structured incentive package, with strong underlying policy coordination, including different stakeholders and tackling different dimensions of local production.

   - Production facilitating incentives; e.g. a dedicated park for pharmaceuticals, income tax holidays)

   - Market shaping incentives; e.g. 25 per cent price preference for local producers in public procurement – higher than in many other African countries (for example Kenya and Tanzania both have 15%), exclusive tenders for local manufacturers.

2. Geared towards international production. Incentive system acknowledges and promotes MNEs involvement by supporting joint ventures between foreign and national players in local production. FDI promotion is an integral part of the policy strategy to support local production, for example through the involvement of the Ethiopian Investment Commission.

3. But not product specific. No incentive is designed specifically for antibiotics, to address either production-specific issues or AMR-specific issues. As a result, AMR objectives are not incorporated into the design of the incentive package.

d. *Stakeholder survey*

1. Partial capacity utilization seen by local producers as a major challenge. Despite data showing that capacity utilization in antibiotics manufacturing is higher than for other pharmaceutical products, efficient utilization of existing productive capacity is still perceived as a major challenge.

2. Competitive pressures from imported products and forex shortages identified as the main factors undermining capacity utilization. Demand-side and competitive challenges (competition by imported products) is only one factor behind partial capacity utilization. As local producers need to import a wide range of raw materials as well as skilled labour from abroad, they report the process of accessing foreign exchange to be cumbersome and a critical constraint on their operations.

3. Increasing local demand is pushing new investment plans, but prospects are deteriorating. Investment is generally pushed by increasing local demand and intentions to expand the range of antibiotic products. Despite such plans of expansion, however investors' perspectives are becoming more pessimistic with shortage of foreign exchange again indicated as a major barrier to pursue further investment projects.

4. Red tape and administrative inefficiencies weighting heavily on investors. Red tape and administrative inefficiencies in deploying incentives are reported to be hindering the capacity of companies to fully and timely benefit from the incentive package. Lack of market information and regulatory information is also reported as a criticism.

5. Strong support amongst government stakeholders for local production of antibiotics and its potential for health benefits (increasing availability of medicines, reliable quality).

Key recommendations

Ethiopia already has a generous pharmaceuticals incentives package that has facilitated substantial local production of antibiotics, including by a number of foreign-owned firms and joint ventures. Unlike other African countries, the challenge is not to create a whole new package of incentives to kick-start local production of antibiotics. Rather, Ethiopian government agencies should consider improving the functioning of the existing incentives system, pushing some elements in a selective way and potentially re-assessing others, including with a view to integrate health and investment promotion objectives with cost-benefit considerations.

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

1. *Leverage MNE presence and contribution.* MNE contribution is key to a successful promotion of 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. Ethiopian local production of antibiotics already builds on a solid international footprint, mainly through partnership between MNEs and domestic producers. This international dimension should be leveraged in future efforts to expand local production and the incentive system should continue to prioritise measures that promote attracting investment by MNEs.

2. *Review fiscal incentives, with a view to move from profit-based to expenditure-based and non-fiscal incentives.* Fiscal incentives for local production of pharmaceuticals are granted through tax holidays and tax exemptions. These incentives provide tax relief based on earnings and not on new investment. In this regard, they are particularly attractive to mobile FDI. Ethiopia should consider moving from profit-based incentives to expenditure-based incentives - those that reduce the after-tax cost of capital investment expenditure, including for example investment allowance and accelerated depreciation. This class of incentives is more effective to promote reinvestment and therefore further integration into the local economy.[16] Similarly, it should make an effort to integrate key sustainability and GMP considerations in the incentive system.

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

3. *Re-assess market shaping incentives on a cost-benefit basis.* While existing measures of market shaping via public procurement have supported local pharmaceutical production, their long-term costs and benefits should be carefully assessed, and they should be periodically reviewed to ensure continued effectiveness in achieving the desired objectives. As local production has reached half of the market share in antibiotics, Ethiopia may consider gradually scaling down financial commitment, for example by reducing price preference in public procurement from 25 percent – a level higher than most other African countries – or linking it to availability and AMR objectives. To make these evaluations, further and updated analysis of pricing and availability of locally-produced and imported antibiotics is needed.

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

4. *Consider refining pharmaceuticals-sector wide incentive system with product-specific incentives.* Given high risks of infections and AMR, it is critical that pharmaceutical companies, governments and procurers take action to ensure (not only access but) appropriate access to antibiotics. The incentive system can be designed to support this objective. For antibiotics, this could include linking incentives to AMR considerations and following international best practices that prioritise antibiotics (see box). Other therapeutic categories also have varying needs (for example those requiring WHO pre-qualification relative to those not requiring it) that could benefit from tailored support.

5. *Link incentives to 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. GMP-related skills can be promoted by attracting know-how transfer from foreign investors, by hiring foreign consultants and by exploiting existing technologies. "Improve access to medicines through quality local production by implementing the GMP roadmap" is a key pillar of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia.

6. *Use streamlined regulation to facilitate investment.* As generous investment promotion measures are already in place, investment facilitation may prove a cost-effective way to maximize investment impact. 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 for local producers according to the survey 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. *Develop a collaborative mechanism among the 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 potentially competitive. Limitations related to imports of inputs are aggravated in the Ethiopian context by forex shortages as highlighted by multiple producers in the survey. In this context, the government can promote and support the development a collaborative mechanism among the local manufacturers through a joint management team (JMT) and related practices for procurement, storage and supply of APIs and other critical input. This can allow aggregating demand, enabling competitive imports (both in terms of price and quality) and ensuring sustainability of supply. Understandably, manufacturers may want to keep their terms of supply contract for some input secret to maintain a competitive advantage in pricing their final products. Initiating JMT, however, would eventually lead to a better understanding of the needs of each manufacturer. EFDA could also incentivise collaborative efforts by offering to prioritize the certification and marketing authorization of API procured through JMT.

8. *Emphasize the regional approach to reduce costs and expand market.* The long-term sustainability of the business model for local production of antibiotics is highly dependent on the possibility to scale volumes and leverage economies of scale (see also Annex 3). Given the relatively advanced stage of development of the industry, Ethiopia can aspire to become a relevant supplier of antibiotics in its region. Options for pooled regional procurement and harmonization of medical regulations are additional important benefits of regional coordination and integration.

9. Make sure broad trade, investment and industrial policies are conducive. Investment provision requires a conducive policy environment. Challenges in accessing imported intermediary inputs,

due to cumbersome forex procedures, need to be addressed. Feasibility assessment could be conducted of various routes to improving access to required inputs, from facilitating partnerships with key suppliers abroad, to pooled procurement for Ethiopia-based manufacturers, to localising production beyond the formulation stage of the value chain.

Further opportunities for production facilitation include supporting sector-specific skill development, provision of sufficient waste disposal, while regional integration can enhance market size for local manufacturers.

10. *Continue to strengthen coordination between health and investment authorities.* Synergy between health and industrial/investment considerations is common to successful promotion of local pharmaceutical production elsewhere. The establishment of FBPIDI has enhanced coordination across different government interests regarding pharmaceuticals, further progress is needed. This institutional coordination is especially necessary for antibiotics because of AMR considerations. The source of more than half of antibiotics in Ethiopia, local production needs to be factored into any public health strategy concerning stewardship of antibiotics to combat AMR. Conversely, health authorities should work closely with investment promotion, and the EFDA, to guide which antibiotics products are being invested in.

SELECTED REFERENCES

Bjerke L., 2022. Antibiotic geographies and access to medicines: Tracing the role of India's pharmaceutical industry in global trade, Social Science & Medicine. 312: 115386.

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#/

EFMHACA, 2015. Strategy for the prevention and containment of antimicrobial resistance for Ethiopia, 2015-2020. Ethiopian Food, Medicine and Healthcare Administration and Control Authority, Addis Ababa. URL: http://www.fmhaca.gov.et/wp-content/uploads/2019/03/Strategy-for-the-Prevention-and-Containment-of-AMR-in-Ethiopia-Oct-2015.pdf.

Ethiopia, 2015. National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025), Ministry of Health and Ministry of Industry, Addis Ababa.

Ethiopia, 2020. Ethiopian Essential Medicines List Sixth Edition. Ministry of Health and Ethiopian Food and Drug Authority, Addis Ababa. URL: http://www.fmhaca.gov.et/wp-content/uploads/2020/12/EML-sixth-edition.pdf

Ewen, M., Kaplan, W. and Gedif, T. (2016). Prices and availability of locally produced and imported medicines in Ethiopia. World Health Organisation. Available from: http://haiweb.org/wp-content/uploads/2017/01/Local-Prod-vs-Imp-Ethiopia-Report-finJan17.pdf

Fitch Solutions, 2020. Ethiopia Pharmaceuticals & Healthcare Report: Q3 2020.

Guimier, J-M., Lee, E. and Grupper, M. (2004). Processes and issues for improving access to medicines: The evidence base for domestic production and greater access to medicines. DFID Health System Resource Center. Issues Paper – Access to Medicines. September.

Hill, A., M. Barber and D. Gotham, 2018. Estimated costs of production and potential prices for the WHO Essential Medicines List, BMJ Global Health 3 e000571. doi:10.1136/bmjgh-2017-000571

O'Neill J., 2016. Tackling drug-resistant infections globally: Final report and recommendations. HM Government and Welcome Trust: UK. 2018.

UNCTAD, 2020. Ethiopia: Science, Technology and Innovation Policy Review. United Nations, New York and Geneva. URL: https://unctad.org/system/files/official-document/dtlstict2020d3_en.pdf.

World Health Organization, 2019. The 2019 WHO AWaRe classification of antibiotics for evaluation and monitoring of use. Geneva: World Health Organization; 2019. (WHO/EMP/IAU/2019.11).

World Health Organization, 2018. Global antimicrobial resistance surveillance system (GLASS)' report: early implementation 2017-2018. 2018. ISBN 978-92-4-151506-1.

ANNEX 1: IMPORTED AND LOCALLY PRODUCED ANTIBIOTICS

Table A1. Top imported and locally produced antibiotics products (2017-2019)

	Antibiotics Products	Measurement	2019			2018			2017		
			Local production [quantity]	Imports (quantity)	Import share (%)	Local production [quantity]	Imports (quantity)	Import share (%)	Local production [quantity]	Imports (quantity)	Import share (%)
1	Amoxicillin 500mg	50x10	784,720	1,177,044	60	710,000	1,136,406	62	650,000	780,000	55
2	Amoxicillin 250mg	100x10	190,962	271,343	59	171,252	203,932	54	142,300	198,024	58
3	Amoxicillin 250mg/5ml-oral suspension	100ml	1,418,893	4,562,766	76	1,123,000	4,530,991	80	909,000	2,945,038	76
4	Ampicillin 500mg capsule	50x10	340,000	392,439	54	251,125	331,517	57	208,050	302,468	59
5	Ampicillin 250mg capsule	100x10	0	21,799	100	0	36,000	100	0	44,634	100
6	Ampicillin 250mg/5ml-oral suspension	100ml	400,000	489,520	55	347,000	392,159	53	457,000	402,000	47
7	Ampicillin sodium 500mg injection	50 vial	0	32,463	100	0	28,915	100	0	21,410	100
8	Sulphamethoxazole + Trimethoprim-(400mg + 80mg)-Tablet	100x10	333,054	178,000	35	313,213	126,232	29	293,817	145,560	33
9	Sulphamethoxazole + Trimethoprim-(200 mg+400 mg)/5ml Suspension	100ml	3,357,780	2,400,000	42	3,115,457	2,000,000	39	2,945,250	1,122,468	28
10	Cloxacillin 500 mg capsule	50x10	426,740	177,420	29	381,800	160,000	30	259,170	69,890	21
11	Cloxacillin Sodium - 250mg - Capsule	100x10	111,855	88,829	44	99,798	100,933	50	95,250	31,925	25
12	Cloxacillin 250mg/5ml suspension	100ml	4,560,000	576,652	11	3,129,000	192,551	6	2,946,000	15,186	1
13	Cloxacillin 500mg injection	10 Vials	27,500	6,231	18	25,250	4,161	14	21,300	2,445	10
14	Doxycycline-100mg- capsule	20x10	635,193	241,405	28	542,840	276,218	34	327,744	192,000	37
15	Ciprofloxacin - 500mg – Tablet	10x10	1,090,369	565,333	34	850,700	897,381	51	579,824	442,000	43
16	Norfloxacin - 400mg - Tablet	10x10	526,172	238,296	31	462,619	190,458	29	314,195	216,000	41
17	Benzanthine Penicillin 1.2 MIU	100 vial	4000	5,700	59	3800	4,300	53	3200	3,800	54
18	Gentamicin 40mg in 2ml ampoule	100 ampule	133,000	191,870	59	73,180	182,744	71	0	165,255	100
19	Gentamycin 0.3% eye/ear drop	10 ml	0	1,154,872	100	0	942,274	100	0	409,676	100
20	Erythromycine 500mg, tablet	100x10	1,600	82,346	98	1,350	36,000	96	1,185	12,225	91
21	Erythromycin - 200mg/5ml - Oral Suspension	100ml	96,955.00	204,000	68	82560	194,041	70	74890	147,562	66

	Antibiotics Products	Measurement	2019			2018			2017		
			Local production [quantity]	Imports (quantity)	Import share (%)	Local production [quantity]	Imports (quantity)	Import share (%)	Local production [quantity]	Imports (quantity)	Import share (%)
22	Amoxicilline/Clavulanic acid 500/125mg tablet	2x10	0	871,315	100	0	647,864	100	0	200,944	100
23	Amoxicillin 250mg + Clavulanic 62.5mg/5ml, suspension	100ml	0	725,457	100	0	533,725	100	0	412,445	100
24	Ceftriaxone 1g injection with 10ml diluents	Vial	0	11,692,242	100	0	4,491,518	100	0	1,130,841	100
25	Cefotaxime sodium 500mg injection	Vial	0	47,464	100	0	39,412	100	0	36,967	100
26	Chloramphenico1% eye ointment 5gm	Tube	0	845,427	100	0	790,638	100	0	573,629	100
27	Ciprofloxacine (aslactate) 2mg/ml IV infusion (Injection)	100ml bottle	0	183,735	100	0	149,735	100	0	154,141	100
28	Cephalexin 500mg capsule	Capsule	0	271,871	100	0	253,549	100	0	134,134	100
29	Cephalexin 250mg/5ml suspension	100ml	0	201,390	100	0	184,460	100	0	71,253	100
30	Tetracycline 1% eye ointment	5mg	0	2,123,817	100	0	1,949,762	100	0	1,991,076	100
31	Ampicillin sodium 500mg injection	50 vial	0	37,200	100	0	34,000	100	0	21,410	100
32	Azithromycin 200mg/5ml powder for Oral solution	15ml	0	14,340	100	0	8,347	100	0	6,455	100
33	Azithromycine 250mg tablet	10x3	0	6,222	100	0	4,534	100			
34	Clarithromycin 250mg tablet	10x10	0	13,299	100	0	2017	100	0	9,909	100
35	Clarithromycin 500mg tablet	10x10	0	55,681	100	0	50,000	100		41,000	100
36	Metronidazole 125/5ml, 100ml suspension	100ml bottle	32,463	38,472	54	28,915	25,890	47	21,410	21,766	50.4
37	Metronidazole 250mg capsule	100x10	33,284		0	18,327	2017	10	11,540		0
38	Metronidazole 5mg/ml intravenous infusion	100ml	0	1,519,788	100	0	1,216,420	100	0	999,280	100
39	Penicillin G Sodium crystalline 1 MIU powder for injection	50vial	0	5,720	100	0	3,246	100		3000	100

Source: FBPIDI and author's calculations.

ANNEX 2: PUBLIC SECTOR PROCUREMENT PRICES

Table A2. Public sector procurement prices for medicines both locally produced and imported

	Locally produced products				Imported products					
	No. products procured	Unit price Birr	Quantity procured in millions	Median unit price Birr	No. products procured	median Unit Price Birr	Quantity procured millions	Ratio of median price of locally produced product to imported product	Savings if only imported product procured birr	$ saving
Amoxicillin 250mg cap	2	0.32	61.179	0.33	1	0.2617	20	1.26	5,680,836	303.463
		0.34	27							
Amoxicillin 500mg	2	0.665	30	0.6784	1	0.461	20	1.47	32,662,000	1744765
		0.6918	115							
Ciprofloxacin 500mg	5	0.658	0.795	0.6997	1	0.5119	13.6	1.37	9,388,000	501496
		0.693	10							
		0.6997	20							
		0.71	16.5							
		0.73	2							
Doxycyline 100mg	4	0.285	6.5	0.3549	1	0.3504	12	1.01	381,364	20,372
		0.3448	21.84							
		0.365	19.68							
		0.3884	16.88							
Erthromycin 250mg	1	1.1353	15	1.1353	1	0.4853	9.5	2.34	9,750,000	520833
Sulfamethoxazole+ Trimethoprim 400mg+80mg	4	0.2498	40	0.2549	1	0.2217	58	1.15	4,966,104	265283
		0.25	13							
		0.2598	26.858							
		0.3154	26.171							
Total saving									62,828,304	3,356,212

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

- The relevant business model for local production of pharmaceuticals in Africa, including in antibiotics, is commoditized and generally confined to a. "Mixed model" with localization of the formulation stage and imports of APIs; b. Manufacturing of off-patent drug with limited R&D component and value added; c. High volume, low margin production, where economies of scale play a key role.
- Local production can be in principle competitive with the (currently dominant) "full import" model, leading to a reduction of costs of more than 10%, according to a McKinsey study*. This reduction is the result of the lower incidence of import costs – applied only to inputs (APIs) in the mixed model as opposed to the entire manufacturing cost in the full import model. Incidence of API on total manufacturing cost is just above 10 per cent of the total manufacturing costs. In this context, the relative higher cost of producing in Africa would be more than compensated by savings in import costs, provided that scale and utilization are held constant across the two models.
- Notwithstanding business fundamentals, realistically, the context of early-industrializing African countries can be hardly comparable with that of established global exporters (e.g. India and China) in terms of achievable scale and utilization. For this reason, local production in Africa is likely to require some degree of policy support, at least in the initial phase. The nature and size of the government support depends on (public) cost-benefit considerations around 1. Impact; 2. Feasibility; and 3. Public resources.
    - In terms of impact, the value proposition for local production is triple: health (increased access to essential medicine), strategic (national health sovereignty and security of minimal supply) and economic (contribution to economic growth). While strategic and economic impact can be relatively limited and uncertain, especially in the short to medium term, health considerations are paramount for certain categories of essential medicines, including in particular in antibiotics where lack of appropriate access can have significant negative effects both on spread of infectious diseases and antimicrobial resistance.
    - Feasibility is primarily driven by volume production and economies of scale. The integration in global value chain and the presence of MNEs also play an important role, as well as other enablers – such as on the production side: presence of infrastructure, availability of skills; on the market side: procurement model (public, private, donor, …), regional integration. Depending on the size of their domestic market and the level of development of the pharmaceutical industry, African countries can widely differ in their feasibility profiles.
    - When value at stake in terms of impact is relevant, governments can support feasibility by providing a 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-facilitating incentives aimed at making the supply side more attractive (e.g. fiscal incentives, capacity building programs, …).
- In general, African countries with non-existent or nascent pharma industries – the majority in sub-Saharan Africa – will face significant feasibility constraints and will need to employ significant resources to kick-start the industry, including market-shaping incentives (typically quite costly) for a prolonged

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

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