

FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA MINISTRY OF HEALTH

User Guide for Investment in Health Sector

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1. Introduction

1.1 Overview of the Ethiopian Health Sector

- With a population of about 101 million in 2020, Ethiopia is the second most populous country of Africa and ranks 12th in the world (HSTP-II).
- The country is characterized by rapid population growth (2.6%), young age structure, and a high dependency ratio, with a high rural-urban differential. Ethiopia has a high total fertility rate of 4.6 births per woman (2.3 in urban areas and 5.2 in rural areas) and a corresponding crude birth rate of 32 per 1000 in 2016((HSTP-II)
- The resolute leadership and commitment by the Ethiopian Government has impacted at significant economic rise and the development of comprehensive health system strengthening strategies allowed implementation of national coordination mechanisms of disease prevention, health promotion and health facility expansion programs.
- Coupled with growing partnership and support of all stakeholders, the share of private health sector in the National Health Service delivery has increased dramatically and contributed to the substantial expansion of health service coverage throughout the country.
- The performance of major health programs has improved, as seen by an increase in the utilization of certain health services. There has also been impressive progress in prevention and control of major communicable diseases. There has also been progress towards achieving two of the 90-90-90 targets for HIV: 90% of people who know their status were on ART, with 91% achieving viral supersession. Between 2015 and 2019, malaria deaths dropped from 3.6 to 0.3 per 100,000 among populations at risk. Malaria case incidence has dropped from 5.2 million in 2015 to under 1.6 million in 2019/20. Several interventions have been implemented to enhance financial risk protection in accessing essential health services
- To maintain the aforementioned and attain further gains, the Ministry of Health identified the following challenges:
 - Ethiopia is currently facing triple burden of diseases (communicable and non-communicable diseases or NCDs, mental health, and injuries) that affects all age groups, with a disproportionately higher burden among children and women in their reproductive age. In 2019, 58% of disability adjusted life years (DALYs) were due to maternal and neonatal conditions, communicable diseases, and malnutrition (Figure 3). Over the past two decades, the share of NCDs has increased from 17% to 35%.
 - Shortage of qualified human resources, highly specialized health and diagnostic laboratory and imaging services, health commodities as well as financing.

- The resultant physician to population ratio of 0. 8 per 10,000 populations is below the recommended WHO standard (1 physician to 10,000 populations), nurse and midwifery to population ratio stands at 7.1 per 10,000 populations), and pharmacy personnel 0.4 per 10,000 populations [WHO, World Health Statistics, 2021].

1.2 Macro Policy Instruments Relevant to Ethiopian Health Sector

- In addressing these challenges that are requiring committed partnership between the public and private sectors, the Government of the Federal Democratic Republic of Ethiopia has valued the important role of Ethiopian Diasporas and foreign investors in support of the country's development. Accordingly, it has developed conducive policy environment with main purpose of building strong relationship with the Ethiopian Diaspora and foreign investors to participate and support technically and financially the ongoing development.
- As evidenced through four successive Health Sector Development Programs (HSDPs) and Growth and Transformation Plan (GTP-I) and other key policy frameworks, the Government of Ethiopia has been encouraging, open hearted and reassuring private sector investment in health.
- The newly launched Health Sector Transformation Plan (HSTP) and GTP-II that upholds the transformative 2030 Agenda for Sustainability Development has also given an emphasis to bring equity and quality in health care delivery through partnership with Diaspora and foreign investors to ensure optimal utilization of resource
- To this end, the Government of Ethiopia has institutionalized relevant units in the Federal Ministry of Foreign Affairs, Ministry of Health and mainstreamed the same in the federal and regional level initiatives and systems with main purpose to assist and guide the public sector and private health sector build partnership for exchange knowledge and technology transfer and address apparent gaps in the health sector.

2. Rationale for Investment in health sector in Ethiopia

2.1 Low number of tertiary health care services

- The Ethiopian health delivery system, which is structured in to three tiers, tertiary health care at the apex before secondary and primary echelons. Tertiary health care pertaining to specialty and sub-specialty services are available through specialized hospitals and connected with secondary and primary hospitals in the second and first tiers to serve population of 3.5 5.0 million.
- Ethiopia is committed to achieving Universal Health Coverage (UHC 3) through Primary Health Care (PHC). This will require growing investment in expanding health services,

infrastructure, and health workforce. Although the health service coverage has potentially increased from 50.7% in 2000 to more than 90% in 2019, the UHC Service Coverage Index (UHC SCI) remains at 43% and out-of-pocket (OOP) spending on health ranges as high as 31% within total health expenditure (THE) in 2016/17

- In view of the challenges, specialized hospitals face shortage of highly skilled professionals, pharmaceutical products, and medical technology (such as: medical instruments, equipment, advanced labs/diagnosis, tele-medicine, e learning), and facilities for bio-equivalent and quality testing laboratory facilities to deliver quality high-end tertiary health care services.
- Specific to availability of tertiary health care services, evidence suggest that there is a growing number of Ethiopians travelling abroad. Although the exact number who travel for health reasons is not known, local estimates put it well above 10,000 per year out of which many opt for medical checkup and treatment. For example:
- Rak Hospital in Dubai treats up to 240 people from Ethiopia every year for different cases such as orthopedics, joint replacement, neurosurgery, spine treatment, interventional cardiology, cardiac surgery, laparoscopic treatment and bariatric surgery
- The Bangkok Hospital in Thailand treated more than 6,000 Ethiopians in 2011 alone.
- Consequently, such travel involved an estimated average cost of about US \$20,000 per travel.
 As this figure is the tip of the iceberg, it could have been underestimated since many have had likely foreign sources to access payments from relatives residing abroad.
- Based on this, a conservative estimate of the cost of annual outflow in lieu of medical tourism from Ethiopia exceeds US \$100 million to imply a higher degree of opportunity cost that could have been saved and otherwise brought into the country by availing high end tertiary health services.
- Considering Ethiopia's large population and the newly emerging non-communicable diseases and injuries, Diasporas and foreign investors who can contribute in providing tertiary care are needed more than ever.
- There remains significant challenge in meeting growing demand for quality and affordable public health and diagnostic health care services. This requires innovative modality including enabling environment for investment in the health sector to improve access and quality of health care in line with the global initiative of universal health coverage. As a result, the Ethiopian Ministry of Health (FMOH) has prepared investment user guide and revised the guide for the first time.

2.2 Untapped resource in Pharmaceutical Market and Industry

- Pharmaceutical manufacturing is a nascent industry in Ethiopia but has the potential to promote import substitution over the short-term, grow exports in the medium-term, and improve access to medicines.
- Ethiopia has a growing domestic pharmaceutical market (\$450M in 2015), around 85% of which is met by imports.
- Domestic competition is low, as there are only 9 manufacturers of human medicines. In July 2015, the GoE put forth an ambitious 'National Strategy for Pharma manufacturing Development (2015-25),' the first country in Africa to establish a pharmaceutical strategy. Pharmaceuticals is also established as one of the key priority sectors under the 'Growth and Transformation Plan.
- A preliminary study was conducted to assess the feasibility of establishing a pharmaceutical manufacturing hub in Ethiopia and refine the strategy based on key stakeholder inputs. The renewed strategy focuses on developing a regionally competitive pharmaceutical industry by attracting top generic companies to Kilinto Industrial Park to initially serve the domestic market and eventually the regional export market.
- The annual pharmaceutical market in Ethiopia is estimated to worth from US\$ 400 500 million and growing at an impressive rate of 25% per annum. Frost and Sullivan in its 2012 survey estimated that Ethiopian pharmaceutical market will reach around one billion dollars by 2018.
- There are approximately 200 importers of pharmaceutical products and medical consumables in Ethiopia. The local industry comprises 22 pharmaceutical and medical suppliers and manufacturers. Among these, nine are involved directly in the manufacture of pharmaceutical products, out of which only three have WHO's Good Manufacturing Practice (GMP). Most of the manufacturers operate below their capacities and supply only about 20% to the local market.
- Even though the country has planned to produce locally to substitute 50% of imported medical supplies and export pharmaceutical products worth of US \$20 million between 2010 and 2015, it only attained 10% of the export target (earning only two million dollars). The National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025) thus envisages to raise the share of domestic pharmaceuticals industry market to 50% and 60% of the national medicines demand and export of medicines worth of USD 30 and 80 million by end of 2020 and 2025, respectively.
- In summary, the presence of steady economic growth, special benefit packages for local production, improved access to health care and full-scale implementation of community based

health insurance and introduction of social health insurance will lead to growing demand and encourage pharmaceutical companies to invest in Ethiopia

2.3 Political Commitment from the Government

- Improving socio-economic governance with peace & security.
- The government is always working hard to make the investment policy beneficial to the country and the investors. A new investment regulation and proclamation has been enacted in 2020 to improve several issues regarding investment.
- High level political commitment for investment promotion and protection; investment policy
 making is led by the Ethiopian Investment Board chaired by the Prime Minister. Wide-ranging
 incentive packages for priority sectors and export-oriented investments.
- Bold initiative in the development of state-of-the art industrial parks, electric-powered railway connecting the capital and other economic corridors to the port of Djibouti.

2.4 Conducive Economic Factors

- Ethiopia aims to reach lower-middle-income status by 2025. Ethiopia's economy experienced strong, broad-based growth averaging 9.8% a year from 2008/09 to 2018/19, Ethiopia's real gross domestic product (GDP) growth rebounded to 9% in 2018/19
- Stable and conducive macroeconomic environment.
- FDI inflows to Ethiopia were USD 2.5 billion in 2019. In total, FDI stocks were estimated at USD 25 billion in 2019. (UNCTAD's World Investment Report 2020)
- Home grown Economic Reform Program: The Government of Ethiopia (GoE) under the leadership of Prime Minister Abiy Ahmed (PHD) unveiled a "Homegrown Economic Reform Program" aimed at unlocking the country's development potentials designed to propel Ethiopia into becoming the African icon of prosperity by 2030.

2.5 Favorable Market Factors

- Africa's second most populous nation with a population size of over 100 million.
- 54 million active labor forces, trainable and available at competitive wage rate.
- Duty-free, quota-free access to the USA and EU markets through AGOA and EBA, respectively
- Duty-free, quota-free access to Japan, Canada, China, Turkey, Australia, and New Zealand – covering substantially all export goods from Ethiopia. Preferential market access to India.

- Ethiopia is a member of ACFTA (African Continental Free Trade Area) which is very beneficial for investors in terms of trade activities within African continent.
- Member of COMESA with preferential market access to a regional market of 400 million people.
- Strategic location with proximity to the Middle East, Europe, and Asia.

2.6 Improving Infrastructure

- The newly built Addis-Djibouti electric-powered railway is fully operational
- Ethiopian Airlines Group, the Largest Aviation Group in has successfully completed a new passenger terminal at its hub Addis Ababa, Bole International Airport with emphasis on biosecurity and biosafety measures. It operates the youngest and most modern fleet to 127 international passenger and cargo destinations across five continents. From its hub at Addis Ababa, Ethiopian Airlines serves 117 international and 23 domestic destinations.
- Huge investment potential in renewable energy including hydro solar, wind and geothermal;
 Grand Ethiopian Renaissance Dam the largest hydroelectric power dam in Africa under construction (close to 79% completed), expected to generate additional 6,000MW electricity.
- Expanding telecommunication services.
- Expansive road networks connecting national and regional markets.
- Nine operational and six upcoming government industrial parks; Six operational & one upcoming private industrial parks in the pipeline

2.7 Access to Preferential Markets:

Ethiopia benefits from preferential trade agreements with key international markets, which investors can access freely. These agreements include the following.

- Duty-free, quota-free access to the USA and EU markets through African Growth and Opportunity Act (AGOA) and Everything But Arms (EBA).
- Duty-free, quota-free access to China, Japan, Canada, Turkey, Australia, and New Zealand covering substantially all export goods from Ethiopia.
- Preferential market access to India.
- Member of Common Market for Eastern and Southern Africa (COMESA) with preferential access to regional market of 400 million people

2.8 Investment Facilitation, Protection & Guarantee

Facilitation

• One-stop shop and aftercare services under EIC (head office and industrial park branches).

- Customs facilitation through bonded warehouse and voucher schemes Expedited visa procedure- expedited procedure of securing entry, work permit and certificate of residency.
- Online visa and multiple visa services
- Online investment application services
- The right to own immovable property as per investment needs.
- The right to open and operate foreign currency accounts.
- The right to employ expatriate managers and experts.

Protection and Guarantee

- Constitutional guarantee to property rights
- Guarantee for repatriation of profits, dividends, and other funds.
- Ethiopia is a member of the Multilateral Investment Guarantee Agency (MIGA) and the World Intellectual Property Organization (WIPO)
- Ethiopia has signed over 30 Bilateral Investment Treaties and several Double Taxation Avoidance Agreements- Providing investors with utmost protection.
- Ranked 67/190 economies for ease of enforcing commercial contracts-rating of OECD standard (World banks' Doing Business Report,2020
- The right to own a dwelling house when investing a minimum of 10,000,000 USD.
- The right to open and operate foreign currency accounts.
- The right to employ expatriate managers and experts Ethiopia has established legal and institutional regimes safeguarding intellectual property rights.
- The protection of intellectual property rights which include trademarks, certification, and collective marks

2.9 Stable economic environment

- ✓ Ethiopia has registered a rapid and sustained economic growth.
- ✓ Safe and secure working and living environments as identified by the U.N. and the International Chamber of Commerce (ICC) as key assets for investors in Ethiopia.

2.10 Liberalized economy

- ✓ Major economic sectors are open for investment and marketing.
- ✓ Remittance out of Ethiopia from invested capital (dividends and interest) is permitted.
- ✓ Remittance also permitted for principal and interest with technology transfer, proceeds from sales or liquidation of an enterprise, salaries and other payments.

Security of Investment

- ✓ Government guarantees (Investment Code 1991) and constitutional protection from expropriation.
- ✓ Ethiopia is a member of World Intellectual Property Organization (WIPO) and Multilateral Investment Guarantee Agency (MIGA), and has conducted Bilateral Investment Treaties (BITs) and Double Taxation Treaties (DTTs).
- ✓ Ethiopia is also a signatory of the Convention on the Settlement of Investment Disputes between States and Nationals of Other States.
- ✓ Professional one-stop-shop for foreign investment through the Ethiopian Investment Commission (EIC).

Strong and wide market access

- ✓ Ethiopia is the seat of many Embassies, African Union, and United Nations Organizations.
- ✓ Membership of the Common Market for Eastern and Southern Africa (COMESA) that comprises 23 countries with a population of more than 420 million positions Ethiopia to enjoy the benefits of preferential tariff rates from exports to these countries.
- ✓ Duty-free, quota-free access to the USA and EU markets through AGOA and EBA, respectively.
- ✓ Duty-free, quota-free access to Japan, Canada, China, Turkey, Australia and New Zealand covering substantially all export goods from Ethiopia, and preferential market access to India.
- ✓ Strategic location with proximity to the Middle East, Europe and Asia.
- ✓ Unmet pharmaceutical needs in neighboring countries are also opportunities.

Luxuriant Infrastructural development

- ✓ Newly built Addis-Djibouti electric-powered railway.
- ✓ Africa's world-class and Star Alliance member Ethiopian Airlines flying to about 100 international passenger and 36 dedicated cargo destinations; also flies to over 20 domestic passenger destinations.
- ✓ Huge investment potential in renewable energy.
- ✓ Expanding telecommunication services.
- ✓ Expansive road networks connecting national and regional markets.
- ✓ Two operational and seven upcoming government industrial parks; four privately developed industrial parks.

Abundant & affordable labor

- ✓ Ethiopia has a growing educated labor force over 50 Universities.
- ✓ Government-supported provision of skills trainings through industry development institutes.

3. Investment incentives

✓ The Council of Ministers Regulations No.474/2020 specifies the areas of investment eligible for investment incentives.

3.1 Common incentives investment

Incentives

Fiscal Investment Incentives

Type of	<u>Incentive description</u>
<u>incentives</u>	
Corporate	 Exemption from corporate income tax up to 10 years depending on the sector
Income Tax	engagements.
Exemption:	 Additional 2-4 years exemption for industrial park enterprises with at least
	80% export or input supply to exporters:
	 Additional 30% deduction for 3 consecutive years if investment in
	underdeveloped regions).
	 Exemption from income tax up to 15 years for Industry Park developers
Import	 Capital Goods: 100% exemption from duties and other taxes on imports of
Exemption:	capital goods (machinery & equipment)
	 Construction Materials: Full exemption from duties and other taxes on imports
	of construction & finishing materials (for companies who construct their own
	factory)
	• Spare parts: with a value up to 15% of the total value of capital goods (100%
	of total value of capital goods for industrial park enterprises that are fully
	exporters)
	 Vehicles: Pickups, delivery vans and trucks are duty free for sectors eligible
	according to the investment regulation of the country. However, the number
	of the vehicles depending on the sector.
Export	■ Companies who produce their products in Ethiopia and export have the
Incentives:	following incentives: -Companies who produce their products in Ethiopia and
	export have the following incentives: -
	■ Full export duty exemption.
	• Full import duty exemption on raw materials needed to produce export
	commodities. Additional 2 years exemption for 60% exporters or input
	suppliers to exporters within or outside of industrial parks:

Loss Carry	 a right to carry for after the base income tax exemption period expires.
Forward:	 Suffered losses during the applicable income tax exemption period can be
	carried forward following the expiry of the income taxation period, for half of
	the tax exemption period.

Type of	Non-Fiscal Incentive
incentives	
Non-Fiscal	 Customs facilitation through bonded export factory and similar other schemes.
Incentive	Guarantee against expropriation.
	• Guarantee for repatriation of funds.
	• Relaxed Industrial Park land regime 60-80 years charge free lease for IP
	developers.
	• Discounted lease rate for IP enterprises.

Type of	Other Incentives
incentives	
<u>Other</u>	 Personal effects for residents in industrial parks.
<u>Incentives</u>	• Investors buying above items from the local market can seek fund of the duty
	paid.
	• Export duty exemption- on all products except semi-processed hides and skins
	• Loss carries forward- a right to carry forward loss incurred within the period
	of income tax exemption for half of the income tax exemption period after
	expiry, maximum being 5 years.

3.2 Specific incentives for Investment in Health Sector

Investment	Incentive Description		
Chemical and chemical	Exemption of income	In Addis Ababa and Special Zone of Oromia	
products industry	tax	surrounding Addis Ababa for 2-5 years	
		Other areas for 3-6 years	
Basic pharmaceutical	Exemption of income	In Addis Ababa and Special Zone of Oromia	
products and	tax	surrounding Addis Ababa for 4 and 5 years	
		Other areas for 5 and 6 years	

pharmaceutical		
preparations industry		
Manufacture of medical	Exemption of income	In Addis Ababa and Special Zone of Oromia
equipment	tax	surrounding Addis Ababa for 5 years
(irradiation, electro-		Other areas for 6 years
medical or		·
electrotherapeutic		
equipment)		
Basic pharmaceutical	Exemption of income	Basic pharmaceutical products and
products and	tax	pharmaceutical preparations in Addis
pharmaceutical		Ababa/special Zone of Oromia surrounding AA
preparations industry		and Other areas for 4-5 and 5-6 years
		respectively.
	Local market supply	PFSA grants local manufacturers a 25% price
		preference/protection when competing with foreign
		suppliers.
		PFSA will provide 30% advance payment of the
		tender value on signing the contract; 70% balance
		to be accessed through the Development Bank of
		Ethiopia in a tripartite agreement
		Supplier/PFSA/Development Bank.
		Special tender packages floated by PFSA for local
		manufacturers only(National competitive Bidding)
		• Future plan to restrict importation of 20 - 30
		Essential Medicines products for local production
		and procurement by PFSA and the private sector for
		three years.
		Long-term fixed supply contracts (framework
		agreement three-five years) to local producers
		to facilitate better planning and attract foreign
		direct investment.
	Technology	Provision of capital goods acquisition loan (e.g.
	acquisition grants	80%) payable in five years.

	Human resource development facilitation	 Benefit from negotiated preferred supplier status with three to five leading suppliers of pharmaceutical manufacturing technology. Provision of grant/soft loan (up to a maximum of 5% of a company's annual turnover) for training and retraining of staff. Incentives such as cash grants for companies that send employees abroad for sector specific training and other up-skilling initiatives. One-off cash grant for every industrial pharmacy student placed with the company for experiential learning. Collaboration with academia to launch a pharmaceutical management and production management program such as MBA.
Manufacturers in industrial park	Exemption of income tax	 Manufacture of inputs of basic pharmaceutical products and pharmaceutical preparations in Addis Ababa/special Zone of Oromia surrounding AA and Other areas for 8 and 10 years respectively. Manufacture or formulation of pharmaceuticals in Addis Ababa/special Zone of Oromia surrounding Addis Ababa and Other areas for 6 and 8 years, respectively. Primary packaging for Pharmaceutical products in Addis Ababa/special Zone of Oromia surrounding Addis Ababa and Other areas for 3 and 4 years, respectively Facilitate for customs duty exemptions on imports of capital goods to attain WHO GMP.

Improve incentives and government support for investment in the pharma industry

The below key policy recommendations to realize this strategy are approved by the Ethiopian Investment

Board in is meeting on 15 June 2017 and currently implemented as per the board approval.

1.1. Income tax exemptions for formulation/final medicine and API manufacturers

Formulation/final medicine production inside of industrial parks		
	In Addis/surrounding areas	Outside of Addis/surrounding areas
Base	6 years	8 years
30% export (in terms of value, successively for 3 years) ¹	+ 2 years	+ 2 years
60% export (in terms of value, successively for 3 years)	+ 2 years	+ 2 years
TOTAL ²	Up to 10 years	Up to 12 years

Active Pharmaceutical Ingredient (API) production inside of industrial parks			
	In Addis/surrounding areas	Outside of Addis/surrounding areas	
Base	8 years	10 years	
30% export (in terms of value, successively for 3 years)	+ 2 years	+ 2 years	
60% export (in terms of value, successively for 3 years)	+ 2 years	+ 2 years	
TOTAL	Up to 12 years	Up to 14 years	

<u>Use of long-term procurement guarantee frameworks to incentivize strategic investors and promote exports</u>

- Provide a framework for long-term procurement guarantees in exchange for strategically important investment (in terms of product portfolio). EIB will determine cases in which a longterm guarantee is warranted because an investor will make large capital investment or produce critical drugs.
- Leverage the existing long-term guarantee mechanism to incentivize exports. In the case that a pharmaceutical manufacturer already operating in Ethiopia wins a PFSA tender (paid for through PFSA's Revolving Drug Fund), it can enter into an agreement with PFSA to supply that

¹ Current practice across industries is that the requirement of 3 years of consecutive export must take place within the base tax holiday period.

² Firms that export 100% of their production will be considered for additional incentives by the Ethiopian Investment Board

product for the subsequent 3-5 years. This mechanism should be formalized and should only be available to exporters: up to 3 years for 30% exporters and up to 5 years for 60% exporters. Only products that the manufacturer exports should be eligible for this mechanism.

3.3 Incentives for talent attraction and development

- a) Provide up to 5 years of income tax exemption for expat employees not working in R&D.
- b) Provide up to 10 years of income tax exemption and a 10-year residence permit for expat employees specifically working in R&D.

To avail the previous two incentives, foreign manufacturers should be required to implement short- and long-term capacity development programs.

- c) EIC should facilitate simplified access to long-term employment visas and work permits, such as multiple entry business visas and 5-10 year work permits.
- d) Import of personal effects by expatriate employees should be exempted from duties and other charges, irrespective of their place of residence.

Export Facilitation

Thus, the following recommendations seek to provide incentives and other support to pharmaceutical manufacturers so that Ethiopia can successfully export pharmaceuticals to the region and elsewhere in the near future.

Lead regional efforts to achieve regulatory harmonization

Negotiate for regional harmonization of standards and procedures, common regulatory databases, joint GMP inspection, and joint assessment in the IGAD and COMESA regions.

Enhance and optimize export logistics

Logistics for the pharmaceutical manufacturing sector currently suffers from problems related to weak supply chain management, uncompetitive rates, and limited expertise among existing local manufacturers. The following cross-cutting and logistics-specific recommendations aim to remedy these weaknesses:

- a) MoI and FBPIDI should develop an integrated logistics plan specific to the pharmaceutical manufacturing sector with the relevant service providers.
- **b)** Link EAL, ESLSE and ERC services to pharma hubs for door-to-door service delivery. Consultation and joint planning, led by Ministry of Industry (MoI), should start as industrial parks are being developed.
- c) EAL, ESLSE, and ERC services should adopt international procedures and standards for pharmaceutical care logistics.
- d) FDA should regulate the care service provision of logistics service providers.

- e) FBPIDI should make regular risk assessments, report gaps, suggest reform measures, and facilitate capacity building for local manufacturers on logistics planning and management.
- f) EAL should set a more competitive rate. Its rates are relatively high priced compared to sea transport. In order to promote pharmaceutical exports, consideration should be made to lower the rate.
- g) EAL should advance in its IATA CEIV certification process and invest in care logistics. EAL has yet to meet international standards for care logistics.
- h) MoI should assess the demand for refrigerated containers in the pharmaceutical, food, and other industries to inform investment by ESLSE. Currently, ESLSE lacks refrigerated containers, limiting transportation options for sensitive products.
- i) Based on MoI's assessment, ESLSE should consider investing in refrigerated containers.
- j) ERC should revisit its care transport service for the pharmaceutical manufacturing industry (cold chain supply and door-to-door service) through joint consultation with MoI.

Facilitate market information and linkages

FBPIDI should work more closely with the private sector and FMHACA to facilitate exports by: providing consolidated market and regularity information on targeted export destination countries; analyzing export market opportunities; supporting companies' export capability; and facilitating public-private dialogue to drive policy reform. These measures can fill gaps in the information base on regional demand, promote market linkages, and institutionalize the existing knowledge of various stakeholders. Provide stronger market assurances through PFSA

- a) The Public Procurement Proclamation 649/2009 should be amended to guarantee a consistent preference for pharmaceutical manufacturers operating in Ethiopia (existing and new entrants). This amendment would provide the legal mandate for national competitive bidding processes in which only domestic manufacturers could participate. (National competitive bidding applies to those products that are produced by one or more domestic manufacturers.)
- b) A National Competitive Bidding Directive, developed by PFSA, should also formalize the existing incentives that are on offer for domestic manufacturers, such as:
 - 70-30 tripartite credit arrangement, which has thus far been ineffective due to strict collateral requirements imposed by the Development Bank of Ethiopia
 - 25% price premium offered by PFSA in international tenders
- c) Procurement results should be made public so that domestic manufacturers (and other suppliers) are able to submit objections.

4. Legal framework for investment

4.1 Legal and Juridical System

- The commercial code of 1960 provides the legal framework for understanding business activities in Ethiopia.
- The investment proclamation (1180/2020) allows, any investor may engage in any area of investment except where it is contrary to law, moral, public health or security.
- The investment proclamation (1180/2020) allows, areas of investment reserved for joint investment with the Government, for domestic investors, and for joint investment with domestic investors shall be specified by Regulation.
- The investment proclamation (1180/2020) allows foreign investors the right to own a dwelling house and other immovable property necessary for their investment.
- The investment proclamation (1180/2020) guarantees investors against measures of expropriation or nationalization and specifies advance payment of compensation corresponding to the prevailing market value of a private property earmarked for expropriation or nationalization for public interest.

4.2 Institutional framework

Regulation No. 474/2020 specified the regulations on investment incentives and investment areas reserved for domestic investors are the main legal framework for both foreign and domestic investment in Ethiopia.

5. Ethiopian Investment Commission services

5.1 Major activities of the EIC for investors

- Promoting the country's investment opportunities and conditions to foreign and domestic investors.
- Issuing investment permits, business licenses and construction permits.
- Notarizing memorandum and articles of association and amendment.
- Issuing commercial registration certificates and effecting renewal, amendment, replacement or cancellation.
- Effecting registration of trade or firm name and amendment, replacement or cancellation
- Issuing work permit, renewal, replacement, suspension or cancellation.
- Grading first grade construction contractors.

- Registering technology transfer agreements and export-oriented non-equity-based foreign enterprise collaborations with domestic investors.
- Negotiating and, upon government approval, signing bilateral investment promotion and protection treaties with other countries.
- Advising the Government on policy measures needed to create an attractive investment climate for investors.
- Provision, through website, various publications, or through direct response to investor's inquiries, of information on sector-specific business opportunities, business incorporation procedures and related regulations, employment regulations
- Handholding and supporting the investor during the acquisition of land and utilities (water, electrical power and telecom services); the processing of loans and residence permit applications; the approval of environmental impact assessments studies for investment projects; and the issuance of a tax identification number (TIN).

Setting up an Investment

Foreign investor(s) can be engaged in the following investment types:

A. Greenfield Investments:

Ethiopian investment Commission will give an investment license for greenfield investments made by foreign investor(s) & joint investments made between foreign investor(s) & local investor(s). A foreign company or investor can form the business as a:

- Sole Proprietorship: an individual is the owner of the company.
- ➤ Private Limited Company: A new company formed by two or more shareholders. The shareholders can be: -
 - Two or more companies
 - Company(s) and a person(s)
 - Two or more individuals (The documentation will be the same as the sole proprietorship company registration)
- > Branch Company: Existing foreign company can open a branch company in Ethiopia.

B. Brownfield Investments

According to the investment regulation no. 474/2020, foreign investor(s) interested to buy an existing enterprise or shares should seek approval from Ethiopian Investment Commission.

The initial step is to acquire investment permit from Ethiopian Investment Commission. The requirements and procedures are explained detail in the following pages.

The initial step for foreign investor(s) to form a company in Ethiopia is to get an investment permit from EIC. Investor(s) can apply for an investment permit in person at Ethiopian Investment Commission HQ or online via this link; www.investethiopia.com. In doing so, investor(s) must comply with the following requirements:

Sectorial Opening

Many previously closed investment sectors are now open for foreign investors. Foreign investor(s) can engage in several investment activities based on the Investment Proclamation No. 1180/2020 and Regulation No. 474/2020 (except the few sectors reserved for domestic investors, joint investment with domestic investors and the government in the same laws

5.2 Registration requirements

- ✓ The minimum entry capital required of a foreign investor per project is US\$ 200,000.
- ✓ If a foreign investor invests in partnership with domestic investor(s), the minimum capital required is US\$ 150,000 per project.
- ✓ the minimum capital required of a foreign investor investing in architectural or
 engineering works or related technical consultancy services, technical testing and
 analysis or in publishing works shall be: a) USD 100,000.00 (one hundred thousand) if
 the investment is made on his own; b) USD 50,000.00 (fifty thousand) if the investment
 is made jointly with a domestic investor.
- ✓ The minimum capital requirement shall not apply to:
- a) Foreign investor re-investing his profits or dividends generated from his existing enterprise in any investment area open for foreign investors;
- b) Persons elected as members of board of directors following the change of a private limited company to share company; and
- c) A foreign investor buying the entirety of an existing enterprise owned by a foreign investor or the shares therein.
- d/ Any foreign investor bringing investment capital into the country shall have such capital registered by the appropriate investment organ within one year and obtain a certificate of registration. The appropriate investment organ shall send a copy of the certificate to the National Bank of Ethiopia.

6. Investment process

6.1 Visa requirements

- Business or investment visa is required for all foreign visitors to Ethiopia, except for nationals of Kenya.
- Visa applications can be obtained at Ethiopia's diplomatic missions overseas
- The Main Department for Immigration and Nationality Affairs issues a residence permit to a foreign investor up on submission of an investment permit issued in his/her name.
- A foreign investor who is a shareholder of a company or Branch Company as well as expatriate personnel who have work permit is entitled to get residence permit.
- Favorable visa terms for investors in industrial parks: Multiple entry visas valid for up to five years is given for foreign investors; up to three years long visa for industrial park service providers, managers, board members and senior experts employed by foreign investors.

6.2 Registration and licensing processes

- ✓ To establish a new business (Greenfield), start your application process at the Ethiopian Investment Commission (EIC) which provides a streamlined one-stop service for licensing and other processes related to establishment of a foreign investment.
- ✓ To buy an existing enterprise or shares (Brownfield), start with seeking approval from the Ministry of Trade.
- ✓ Collect application form and relevant documents from EIC Information Desk
 - ✓ Submit filled application to EIC Registration and Licensing Department. Required documents:
 - o Sole proprietorship: Valid passport; business or investment visa
 - PLC: Draft memorandum and articles of association; valid passport and visa (if
 the shareholders are individuals); notarized parent company documents including
 certificate of incorporation, minutes of resolution passed by the parent company
 to invest in Ethiopia, memorandum and articles of association and power of
 attorney (if the shareholders are companies)
 - Opening a branch company: Authenticated parent company documents; general manager's passport and visa for the new company
 - ✓ Additional steps only for a PLC
 - Check uniqueness of the company name at EIC

- Edit and authenticate memorandum and articles of association at EIC
 ✓ Collect a bank letter from EIC
 ✓ Open a local bank account and transfer the minimum capital required
 ✓ Collect bank transfer advice and submit it to EIC
 ✓ Additional step only for a PLC a. Submit an authenticated office lease agreement and TIN certificate to EIC
 - ✓ Collect investment permit and commercial registration certificate from EIC

Note: All documents issued outside of Ethiopia need to be authenticated by the foreign public notary, Ethiopian Embassy, Ministry of foreign Affairs of Ethiopia and/or domestic public notary.

- Investors planning to develop an industrial park or make other forms of investment within industrial parks will have to go through few additional steps.

6.3 Industrial Park Enterprise/Tenant

- ✓ Application to EIC
- ✓ Sign an MoU with EIC
- ✓ Deposit commitment fee of USD 200,000 in IP Developer's account: to be accounted as part of initial capital on licensing
- ✓ Registration and licensing at EIC
- ✓ Shed rental/sub-lease agreement with IP Developer
- ✓ Handover by IP developer

7. Priority areas of investment in health sector

- Manufacturing of basic Pharmaceutical Products (drugs, medical supplies, and reagents)
 and Pharmaceutical Preparations API (Active Pharmaceuticals Ingredients)
- Chemical and chemical products industry
- Manufacturing of medical equipment
- High end tertiary health services and diagnostic services
 N.B- Tertiary health service is not eligible for income tax exemption in Addis Ababa & in the regions.

8. Relevant Agencies and their role in investment

Public	Role and responsibility
Sectors/Agencies	
Ethiopian Food and	Undertake inspection of pharmaceutical premises, establishments and port of
Drug Authority	entry and exit.
	Undertake and coordinate post marketing surveillance to ensure the safety and
	quality of food and safety, efficacy and quality of medicines
	Issues license for conducting clinical trials, monitors and evaluates the process
	and authorizes the use of results.
	Issue license for health professionals, complementary or alternative medicines
	practitioners and health professionals (Now the Mandate given to MOH,
	Human Resource Professionals Competency Assessment and Licensure
	Directorate).
	Give import or export permit for food, medicines, raw materials and packaging
	materials.
MOH, Health and	Issue certificate of competence for specialized health institutions, food or
Heath Related	medicines processing plants, quality control laboratories, importer, exporters,
Institution	storage or distributors and trans-regional health service institutions (Now the
Regulatory	Mandate given to).
Directorate	
	Provides commercial registration and licensing services (delegated to EIC as
Ministry of Health	regards foreign direct investment
	Registers Brownfield investments (purchase of existing enterprise or shares)
	by foreign investors
	Registers and certifies commercial representatives –issues import /export
	release permit
Pharmaceutical	Procurement (from foreign and domestic sources), stores (builds and manages
Supply Agency –	warehouses) and directly distribute (including transportation) pharmaceuticals
PSA	to public facilities.
	Management of the entire finance allocated by the government, bi-lateral and
	multilateral donor agencies.

Provide procurement, warehousing and distribution services with minimum service fee to cover operation cost

In collaboration with DP and programs, forecast the national need

Avail health commodities to public health facilities and provide capacity at facility level

Ministry of Industry

Ensures the growth of industrial productivity through facilitation of technology transfer, skills development and extension services

Establishes sector-specific industry development institutes which provide support in areas such as market facilitation, labor screening and recruitment, knowledge and skills development etc. Currently operational institutes include: Ethiopian Textile Industry Development Institute - Ethiopian Leather Industry Development Institute

Ethiopian Food, Beverages and Pharmaceutical Industry Development Institute Ethiopian Meat and Dairy Industry Development Institute Issues export trade duty incentive certificates

Ethiopian Ministry of Revenue

Ministry of revenues is the body responsible for collecting revenue from domestic taxes

Administers tax incentives given to investors

Ethiopian Customs

Commissions

Provides customs clearance and facilitation service for import and export items; provides on-site customs clearance in industrial parks

Customs clearance time has been reduced to an average of less than 21 days. The Government of Ethiopia (GOE) is working toward establishing an electronic single-window service delivery for international trade and one-stop border posts at the Ethio-Kenya and Ethio-Djibouti borders. Several customs offices have also been located inside industrial parks (IPs), facilitating customs processing for exporting firms established in IPs. The Customs Proclamation No. 859/2014 has been reformed under the Revised Kyoto Convention (RKC) and focuses more on facilitating goods at the port than controlling licensed traders. The customs procedures allow authorized importers to finalize customs procedures using minimal available documentation and significantly reduced time.

The maximum number of days given to collect goods from a dry port is 15 days. Otherwise 20% of the tax amount will be charged as a penalty.

	A specialized financial institution established to promote the national	
Development Bank	development agenda through development finance and technical support to	
of Ethiopia	viable investment projects in priority sectors such as agriculture, agro-	
	processing and manufacturing Provides medium and long-term loans for	
	export-oriented investment projects in priority sectors. Avail 70 % loan for	
	pharmaceutical supplies from local manufacturers through a tripartite	
	agreement with PFSA.	
National Bank of	Manages the country's foreign exchange reserve; ensures effective use of such	
Ethiopia	reserve through monetary and financial regulations	
	Issues approval of transactions involving foreign hard currency (investment	
	capital inflow, repatriation of funds, suppliers credit, export/ import bank	
	permit etc)	
Industrial Parks	Develops public industrial parks - Rents or sells pre-built factory sheds to	
Development	industrial park enterprises -Sub-leases developed land	
Corporation	Operates, manages and maintains parks	
	Servers as a land bank for industrial park development	
Main Department	Issues a residence permit to a foreign investor, upon submission of an	
for Immigration and	Investment Permit issued in his/her name. Residence permit is valid for a period	
Nationality Affairs	of one year from the date of his registration. The residence permits renewable	
	provided that the foreigner presents the required documents such as renewed	
	investment license work permit, etc.	
Environmental	Require ,review and approve environmental Impact Assessment studies of	
Protection Agency	industrial projects to confer land	

9. Contact offices addresses

Name of the organization	Address
Ethiopian Investment Commission	P.O. Box 2313 Tel: +251-11-551 0033
	Fax: +251-11-551 4396
	E-mail: ethioinvest@investethiopia.gov.et
	Website: http://www.investethiopia.gov.et/ investethiopia.gov.et/
Ministry of Health	PO Box 1234, Addis Ababa
	Email: moh@moh.gov.et
	Website: www.moh.gov.et
Ministry of Industry	P.O. Box 6945
	Tel: +251-11-550 7542
	Fax:+ 251-11-575 9871
	Website: www.moin.gov.et
Ministry of Foreign Affairs	P.O.Box 393
	Tel: +251-11-551-7345
	Fax:+251-11-551-4300
	Email: MFA.Addis@ethionet.et
	www.mfa.gov.et
Ministry of Trade	P.O. Box 704
	Tel: +251-11-551 8025
	Fax:+ 251-11-551 5411
	Website: www.mot.gov.et
	Tel: +251- <u>11 552 8577</u>
Ethiopian Ministry of Revenue	E-mail: ercawebadmin@revenue.gov.et
	Website: http://www.mor.gov.et/
	Tel: +251-11-667 3970
Ethiopian Customs Commissions	Fax:+ 251-11-662 9842
	Website: http://www.ecc.gov.et/
Ministry of Education	PO Box 1367
	Tel: 00251-11-155-3133
	Fax: 00251-11-155-0877/156-5565/157-0686
	Website: http://www.moe.gov.et/
Ministry of Labor and Social Affairs	P.O. Box 2056
	Tel: +251-11-551 7080
	Fax: +251-11-551 8396
	E-mail: molsa.comt@ethionet.et
	Website: http://www.molsa.gov.et/

Name of the organization	Address
Industrial Parks Development	Tel: +251-11-661 6986 / 661 6674
Corporation	E-mail: info@ipdc.gov.et
	Website: http://www.ipdc.gov.et/index.php/en/
National Bank of Ethiopia	P.O. Box 5550
	Tel: +251-11-551 7430
	Fax: +251-1-551 4588
	E-mail: <u>nbe.excd@ethionet.et</u>
	Website: http://www.nbe.gov.et/
Development Bank of Ethiopia	P.O.Box 1900
	Tel: 251-11-51 1188/89
	Fax: 251-11-511606
	E-mail: dbe@telecom.net.et Website: http://www.dbe.com.et/
Ethiopian Food and Drug Authority	P.O. Box 5681
	Tel: +251-11-552-41-22
	Fax: +251-11-552-13-92
	E-mail: efdamedia@efda.gov.et
	Website: http://www.fmhac.gov.et/
Pharmaceuticals Supply Agency	P.O. Box 21904
	<u>Tel</u> : +251 112 75 17 70/760676
	<u>Fax</u> :+251 111553277/112752555
	Email: pfsa@ethionet.et
	Website: http://www.pfsa.gov.et
HIV/AIDS Prevention and Control	P.O. Box 122326
<u>Office</u>	<u>Tel</u> : +251 115 50-35-06/08
	<u>Fax</u> : +251 115 50 33 58
	Website: http://www.hapco.gov.et
Ethiopian Public Health Institute	Tel: +251 112 75-15-22/75 34 70
	<u>Fax</u> : +251 112 75-47-44
	Website: http://www.ephi.gov.et/

10. Appendix

Type of information	Source of information
	Investment Guide to Ethiopia (EIC, 2021).pdf. Investment Proclamation No.
	1180/2020 pdf. Available from:
	file:///C:/Users/user/Downloads/Documents/Investment%20Guide%20to%20Et
Investment	hiopia%20(EIC,%202017).pdf
	An investment guide to Ethiopia, 2021 in Pdf. Available from:
	http://www.ethiopianembassy.org/PDF/Ethiopia_Investment_Guide_2021.pdf
	Investment Incentives. Available from:
	http://www.investethiopia.gov.et/images/pdf/incentives.pdf
	Investing in Ethiopia: Ten reasons to invest in Ethiopia. Available
	from: http://www.ethiopianembassy.org/PDF/10ReasonstoInvestCombo.pdf
	Formoreinformationlootathttp://www.investethiopia.gov.et/
	Directive for Medicine Manufacturing Establishment, 2013 in pdf. Available
	from: http://www.fmhaca.gov.et/documents/Directive%20%20for%20Medicine
	%20Manufucturing%20Establishmen%20%20 2013.pdf
	Health Professionals Registration and Licensing Directive, 2014. Available from:
	http://www.fmhaca.gov.et/documents/Health%20Professionals%20Registration
	%20and%20Licensing%20Directive%202014.pdf
Ethiopian Food and Drug	National medical instrument list with minim spec. 2013. Available from:
Authority (FDA)	http://www.fmhaca.gov.et/documents/ETHOPIAN_LIST_OF_MEDICAL_INS
	TRUMENT_WITH_MINIMUM_SPECIFICATION.pdf
	FMHACA GOOD MANUFACTURING PRACTICE GUIDELINE FOR
	PHARMACEUTICAL PRODUCTS MAIN PRINCIPLES, First Edition, 2014.
	Available from: http://www.fmhaca.gov.et/documents/GMP%20Guideliens.pdf
	CITIZEN CHARTER. Available from:
	http://www.fmhaca.gov.et/documents/Citizen_Charter.pdf
	For further information look at http://www.fmhaca.gov.et/
Ethiopian Ministry of	Download <u>Directives Articles</u> , <u>Proclamations</u> , <u>Regulation</u> .
Revenue	Available from: http://www.mor.gov.et/

	Investment in opportunities in industrial park development corporation. Available
	from: http://www.ipdc.gov.et/index.php/en/investment-opportunitiesmm/priority-
	sectors/
	Incentives applicable to industrial parks.
	Available from: http://www.investethiopia.gov.et/investment-opportunities/strategic-
	sectors/industry-zone-development.
Pharmaceutical	National Strategy and Plan of Action for Pharmaceutical Manufacturing Development
manufacturing	in Ethiopia (2015–2025). Available
	from:http://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf
	Manufacturing - Invest In Ethiopia. Available from:
	http://www.investinethiopia.net/index.php/component/k2/item/177-manufacturing
	Pharmaceutical supply chain in Ethiopia. Available
	from:http://mau.addischamber.com/sites/default/files/Pharmaceutical%20supply%20ch
	ain%20in%20Ethiopia.pdf
	Annual procurement plan and report, procurement directive, proclamation & other
	documents. Available from :http://www.pfsa.gov.et/
Bank	Download various guideline, regulation and proclamations related to foreign exchange
	managements from National Bank of Ethiopia. Available from:
	http://www.nbe.gov.et/
National Diaspora Policy	Diaspora policy, 2013 in pdf.
	Available from: http://www.ethiopianembassy.org/PDF/diaspora%20policy.pdf



Federal Ministry of Health, Partnership and Cooperation Directorate

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Email: moh@moh.gov.et
Website: www.moh.gov.et
PO Box 1234, Addis Ababa