



Embassy of the Federal Democratic Republic of Ethiopia

Investment Opportunity in the Pharmaceutical Sector in Ethiopia



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1. Introduction

The Government of the Federal Democratic Republic of Ethiopia has formulated and implemented a five year Growth and Transformation Plan (GTP) from 2010/11-2014/15. The performance of the GTP so far has shown that Ethiopia can achieve her long term plan of becoming a middle income country by the year 2025. The 2nd GTP is being formulated with sound development policy and has sets an ambitious but achievable plan in its priority areas. Ethiopia has registered a double digit GDP annual growth rate for the last ten years. By sustaining the economic growth over the GTP periods, the government aims to achieve the MDG targets by 2015, and its longer term vision of being a middle income country by 2020-2023.

In the Industrial Development Strategy of Ethiopia, it is clearly stated that the private sector is considered as the engine of the sector's growth. Furthermore, the investment policy encourages Foreign Direct Investment (FDI) and special incentives are given to companies who are investing the manufacturing industries.

Pharmaceutical Industry is one of the main sub-sectors that is given priority in the manufacturing sector. The objectives of the industry sector plan are to create capacity to produce for products that substitute for imported products and also supply export markets. This involves improving the utilization of existing capacity and the establishment of new industries.

2. Supply/Demand Gap

The Government of Federal Democratic Republic of Ethiopia has recognized the importance of strengthening Ethiopia's pharmaceutical sub-sector because there is a vast demand for pharmaceutical products.

The pharmaceutical industry of Ethiopia contributes only 15% of the total market share while 85% of pharmaceutical and medical supplies products are imported. According to Industrial Projects Studies (IPS) of pharmaceutical formulation study, the annual demand for the six essential drugs (Table, Capsules, Ampoules, Vials, Ointments and Syrups) is assumed to grow by 25%.

The existing industries produce only generic and similar drugs in small quantities. The National Essential Drug List shows the availability requirement of 300 drugs in the country. Only 90 of them are produced by the local manufacturers. However, there is no production of

active pharmaceutical ingredients (API) in the country. Government and private clinics and hospitals in the country are coming up, and the demand for drugs and pharmaceutical products has increased. In order to meet this growing demand, a large amount of drugs are imported by different actors i.e. Ministry of Health, PHARMID, NGOs and Private importers. The Ministry of Health and NGOs Purchases/Imports TB, HIV and malaria drugs and general medicines through tenders. Pharmaceuticals and Medical Supplies Import and Wholesale Enterprises (PHARMID) imports and supplies medicines and medical equipment to government and private hospitals, clinics, health centers and pharmacies in Ethiopia. It procures its supplies through tenders.

Ethiopian pharmaceutical imports include products falling under Chapter HS No.30; Antibiotics, vaccines, penicillin, medicaments of other hormones, anaesthetics medicament, medicaments of alkaloids or derivatives, vitamins, adhesive dressings for medical purposes, wadding, gauze, materials for surgical suture, absorbable haemostatic, blood-grouping reagents, dental cements and other dental fillings and first aid boxes and kits.

Ethiopia imports mainly from India, USA, France, Belgium, Korea Republic, Denmark, Switzerland, Germany, UK, Netherlands, China and Cyprus. Most major international companies have presence in Ethiopian market. Some of the leading Indian companies such as Cadila, Zydus Cadila, Cipla, Ranbaxy, Ipca Laboratories, Lupin Labs., Torrent Pharma, Alembic, Sarabhai Chemicals etc. are already actively engaged in exporting pharmaceuticals to Ethiopia.

With the increasing demand for pharmaceutical products, Ethiopia needs Companies to set up a production unit. Currently, 20 pharmaceutical and medical supplies manufacturing industries exist in the country most of which being confined in the capital, Addis Ababa. Among them an Indian pharmaceutical factory, Cadilla Pharma, became operational in 2007. Cadila Pharmaceuticals Ethiopia PLC (CPEL) mainly focuses on therapeutic areas such as Cardiovascular, Anti Diabetes, gastroenterology (anti-acids, anti-ulcerative), Anti-Infective, Anti-Depressants, Anti Fungal, Anti-TB, Anti Malarial, Anti Retroviral.

3. Opportunity areas in the Pharmaceutical Industry

Opportunities for investment in the pharmaceutical and medical supplies sub-sector in Ethiopia include :

- A. Production of essential drugs,
- B. Production of raw materials and,

C. Production of medical supplies.

A. Production of Essential Drugs

Essential drugs that satisfy the priority health care needs of the population are selected with due regard to public health relevance, evidence on safety, efficacy, quality and comparative cost effectiveness. List of essential drugs guides the procurement, selection, production, distribution and storage of drugs, and furthermore, are widely used as informational and educational tools by health professionals involved in diagnosis and treatment of disease and dispensing of drug. The list aims to encourage the best use of clinically proven drugs and to identify cost-effective drugs for priority condition. This drug list simply implies that in a given situation these drugs are the most needed for the population and therefore, should be available at all time in adequate amount and reasonable cost. (See Annex I)

B. Production of Raw Materials

Local pharmaceutical and medical supplies industries depend a lot on imported sources. The industry imports over 95% of the required raw materials. Availability of raw materials locally is limited to only about 5% of the total industrial requirements.

There is high opportunity for local production of raw materials for pharmaceutical industries in the country. Most of them need only further processing of the products of already existing factories to pharmaceutical grade suitable for pharmaceutical industry use while others require new investments. Following are possible potential of raw material production:

- Maize starch
- Refined sugar
- Glucose syrup
- Rectified spirit and ethanol
- Sodium chloride
- Packaging materials

C. Production of Medical Supplies

There is no industry in the country that produces surgical gloves, latex gloves and condoms. Thus, large amount of these products are imported from outside. There is a real gap between the demand and supply of medical equipments. Hence, investment in this area is highly encouraged.

4. Market Opportunity

It is a natural consensus to annex the production of pharmaceuticals with the issue of public health. Essentially, public health has been the very priority of the Ethiopian government which synonymously brings about an issue of having pharmaceutical production with the required safety, quality & efficacy. In order to attract investors and increase the capacity of the local manufacturers, the government provides incentives to pharmaceutical manufacturers.

Ethiopia has one of the largest population in Africa thus potentially the second largest domestic markets in the continent. Beyond the domestic market, by virtue of its membership of the Common Market for Eastern and Southern Africa (COMESA), Ethiopia enjoys market access to 19 member countries with close to 400 million populations at a preferential tariffs. Furthermore, Ethiopia's proximity to the Middle East also offers potential market opportunities.

5. Investment Policy and Incentives

- A foreign investor can undertake investment, either as a sole proprietor; or jointly with domestic investors
- Capital requirement for foreign investors (As a sole proprietor)
 - USD 200,000 for a single and wholly foreign owned investment
 - USD 100,000 per project in areas of engineering, architecture, accounting & audit services, project studies, consultancy services
- Capital requirement for investment in partnership with domestic investors:
 - USD 150,000 per project
 - USD 50,000 in areas of engineering, architecture, accounting & audit services, project studies, consultancy services
- No capital requirement for an investor who reinvests his profits or dividends generating from the existing enterprise.
- Land is leased out by the government.
- Repatriation and remittances are granted to foreign investors to be made in convertible foreign currency at the prevailing exchange rate on the date of remittance:

Guarantees

- The Constitution of Ethiopia and the Investment Proclamation and the legal system protect private property

- Ethiopia is a member of Multilateral Investment Guarantee Agency (MIGA) which issues guarantees against risks to entrepreneurs that invest in signatory countries,
- Ethiopia has signed Bilateral Investment Promotion and Protection Agreements as well as Avoidance of Double Taxation with many countries including India.

Investment Incentives

Customs duty exemption

- 100% exemption from payment of import customs duties and other taxes levied on imports to import all investment capital goods, such as plant machinery and equipment, construction materials, as well as spare parts up to 15% of the value of capital goods imported

Income Tax Exemption

- Exemption from income tax for basic pharmaceutical products and pharmaceutical preparations Industry.

Investment Area	In Addis Ababa and Special zone of Oromia surrounding Addis Ababa	In other areas
Manufacture of basic of basic pharmaceutical products and pharmaceutical preparation	5 years	6 years
Manufacture or formulation of pharmaceuticals	4 years	5 years

- Any investor who invests to establish a new enterprise in Gambela, Benshangul/Gumuz, Afar, Somali, Guji & Borena Zones (Oromia), and in some zones in the State of South Nations and Nationalities and Peoples' (SNNP), shall be entitled to an income tax deduction of 30% for 3 consecutive years after the expiry of the income tax exemption period.
- The period of exemption for income tax shall begin from the commencement date of production or provision of service by the investor.
- An investor who has incurred loss within the period of income tax exemption shall be allowed to carry forward such loss for half of the income tax exemption period after the expiry of such period.

Export Incentives

- **Duty Draw-back Scheme:** Duty paid at the port of entry and locally on raw materials used in the production commodities is refunded, 100 percent, upon exportation of the commodity processed.
- **Voucher Scheme:** It is a printed document to be used for recording balance of duty payable on raw materials imported for use in the production of goods for external market. The beneficiaries of the voucher scheme are also exporters.
- **Bonded Manufacturing Warehouse:** Producers wholly engaged in exporting their products who are not eligible to use the Voucher Scheme and who have license that enable them to operate such warehouse.

6. Land Lease

In Ethiopia land is public property. Both urban and rural land is available for investment on leasehold basis. Lease right over land can be transferred, mortgaged or sub-leased together with on-build facilities. The period of lease may also be renewed.

The rental value and the lease period of rural land are determined and fixed by land use regulations of each regional state.

7. Tax Regime

Type of Tax	Rate in %
Direct	
Corporate Income Tax	30
Personal Income Tax	0 up to 35
Business Income Tax	0 up to 35
Customs Duties	0 up to 35
Withholding Tax	2
Export Tax	Nil
Royalty Tax	5
Dividend Tax	10
Interest Income	5
Indirect Tax	
Value Added Tax	15
Excise Tax	10 up to 100
Turn over Tax	2 and 10

8. Why Invest in Ethiopia?

Stable Political and Economic condition

- Mature and stable political environment
- Stable social and economic environment
- Peaceful and friendly people

- Zero-tolerance to corruption
- Fastest growing economy with a double digit GDP growth rate for the last ten years.
- Third largest economy in Sub-Saharan Africa, after South Africa and Nigeria and the third fastest growing economy in the world.

Strategic location and Market Access

- Strategically located in Eastern Africa with easy access to the lucrative markets of the Middle East, Europe and Asia,
- Vast market opportunities to domestic, regional and international markets.
- Second largest domestic market in Africa with 90 million consumers,
- Access to markets of 19 member states of COMESA, Common Market for Eastern and South Africa, with a population of over 400 million with a preferential tariff rates,
- Preferential access to European Market under EU's everything-But-Arms (EBA),
- Preferential access to Austria, Canada, Finland, Japan, Norway, Sweden, USA and most other EU countries under Generalized System of Preference (GSP),
- Under the African Growth and Opportunity Act (AGOA) program, Ethiopia is entitled to duty-free U.S. market access.

Natural Resource

- Exceptional climate due to location on highlands, half the country experiences average annual temperatures of 20°C to 30°C,
- Untapped natural resources and fertile soils,
- Sufficient surface and ground water resource

Investor friendly policies

- Government policies encourages and supports FDI,
- Government invests on infrastructure, telecommunications and other facilities,
- Industrial zones are being prepared with the necessary infrastructure and facilities.
- A one stop shop service is provided by the Ethiopian Investment Agency.

Labor

- Ethiopia has abundant, hard working, disciplined and easily trainable workforce,
- Universities, engineering colleges and technical and vocational training schools annually providing trained personnel,
- English is medium of instruction in schools and is understood by many people.

- The minimum wage for labor is Birr \$60.

9.Regulatory Authorities

A. Ethiopian Investment Agency

The Ethiopian Investment Agency is a government body that issues investment license, work permit, tin number etc...

B. Minimum requirements by FMHACA to establish pharmaceutical industry in Ethiopia include:

- Investors should collect establishment and GMP guideline from the authority. Here the authority provides technical support starting from the design and location of the premises.
- Once the manufacturer comply with GMP and start manufacturing the products should be registered by the authority to be marketed in Ethiopia (according to the national registration guideline)
- For those manufacturers engaged in exportation of pharmaceuticals, the authority will give certificate of pharmaceutical product (CPP) if the manufacturer requests it and submit all necessary information about the product to be exported.
- The authority gives special attention for local manufacturer and it will give priority for registration of products manufactured locally.

C. Good Manufacturing Practice /GMP/

Good Manufacturing Practice /GMP/ is part of Quality Assurance which ensures products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by marketing authorization or product specification. Good Manufacturing Practice is concerned with both production and quality control. It is the most widespread quality system followed across the pharmaceutical industry as a whole. GMP is also often referred to as “cGMP,” which simply stands for “current Good Manufacturing Practices.” the “current” references GMP’s requirement that manufacturers be up to date with their practices and procedures. GMP compliance is a requirement within pharmaceutical manufacture and testing of these materials for human and animal consumption.

Some of the advantages of GMP certification for Ethiopian pharmaceutical industries are:-

- GMP certified factories guaranty safe and quality products.
- Getting GMP certificate is one of the criteria to access to donor funded market potentials like Global fund, UNICEF etc...

- The GMP compliance will help local pharmaceutical companies to export their products and to be competitive in the international market.
- Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA) is entrusted with the task of administrating and controlling of the GMP of pharmaceutical sector.

D. Drugs Regulatory Authority

All manufacturers intending to export drugs and pharmaceutical products to Ethiopia are required to register with The Drug Administration and Control Authority (DACA) which is government regulatory authority. For registration with DACA, a company should have a WHO-GMP certification. The registration is granted keeping in view the requirements of the Ethiopia's Essential Drugs List.

1. Essential Drugs List		
Pharmacological group	S.N.	Name of the medicine
A. Under essential drug list		
1. Antihistamines and	1.	Promethazin 25mg
Antiallergics	2.	Cetirizine 10mg
	3.	Chlorpheniramine Syrup
	4.	Diphenhydramine 125ml syrup
	5.	Loratidine 10mg
2. Anti-infective	1.	Albendazole
	2.	Amoxicillin 125mg/5ml Dry.Susp
	3.	Ampicillin 125mg/5ml
	4.	Benzantin penicillin 1.2MIU
	5.	Cephalexin*
	6.	Chloquine Phosphate 250mg Tab.
	7.	Chloramphenicol

	8.	Chloroquine phospahte 250mg
	9.	Ciprofloxacin 500 & 250 mg
	10.	Cloxacillin 250mg
	11.	Crystalline Penicillin 1MIU
	12.	Doxycycline
	13.	Erythromycin
	14.	Ethambutol+ Isoniazid
	15.	Fluconazol
	16.	Isoniazide
	17.	Ketoconazole 200mg Tablet
	18.	Levamisol 40mg
	19.	Mebendazole
	20.	Metronidazole
	21.	Niclosamdie
	22.	Norfloxacin 400 mg
	23.	Peniciline G.Sodium 1miu
	24.	Piperazine Citrate Elx.700mg/5ml,29ml
	25.	Primaquine Phosphate 15mg Tablet
	26.	Procaine Penicillin 4miu
	27.	Pyrazinamide
	28.	Quinine dihydrochloride 300gm
	29.	Rifampicine
	30.	Sulfadoxine+Pyrimethamine Tablet 525mg
	31.	sulphamethoxazole
	32.	Tetracycline HCl
	33.	Tinidazol
3. Cardiovascular drugs	1.	Amlodipine 10mg Tablet

	2.	Enalapril 5mg & 10mg
	3.	Frusemide 40mg
	4.	Methyldopa 250mg Tablet
	5.	Quinidine Sulphate 300mg Tblet
4. Central nervous system	1.	Acetyl Salicylic Acid
	2.	Amitriptyline
	3.	Chlorpromazine 100mg
	4.	Dextromethorphan
	5.	Dipyron injection (2ml)
	6.	Fluoxetine 20mg
	7.	Paracetamol
	8.	phenobarbiton 100mg
5. Dermatological agent	1.	Ichtamol 10% 20% oint.
	2.	Methyisalicylate 25%
	3.	Sulphur 10%
	4.	Zinc Oxide Ointment 15%
6. Drugs used for correcting water, electrolyte and acid base balance.	1.	Allopurinol 100mg Tablet
	2.	Chloramphenicol
	3.	Dextrose 5% in Normal Salin
	4.	Diclofenac 25mg Tablet
	5.	Ibuprofen 400mg
	6.	Indomethacine
	7.	Lactated Ringer's Solution
	8.	Prednisolon 5mg
	9.	Sildenafil *Citrate
7. Ear, Nose and Throat Preparation, Antihistamines and		Pseudoephedrine+ Triprolidine
	1	

Antiallergic*		
8. Gastrointestinal drugs	1.	Aluminium Hydroxide + Magnesium Hydroxide
	2.	Aluminium hydroxide + magnesium trisilicate
	3.	Cimetidine 400mg Tablet
	4.	Famotidin 40g Tablet
	5.	Magnesium trisilicate compounmd
	6.	Magnisum Sulphate
	7.	Metoclopramide Syrup
	8.	O.R.S.
	9.	Omeprazole 20mg
	10.	Ranitidine 150 mg & 300mg
9. Gastrointestinal drugs and drugs used in anaesthesia	1	Hyoscine BB.Tablet
10. Obsteric and gynaecological medication		
	1	Clotrimazole
11. Ophthalmic agents*	1	DextromethorphaHBR syrpl25ml
12. Respiratory drugs	1.	Ephedrine + theophyline 12mg + 15mg/5ml syrup
	2.	Procaine HCl 100mg
	3.	Salbutamol Syrup
13. Vitamin	1.	Ascorbic acid 500mg
	2.	Multi vitamin syrup
	3.	Vitamin B12 & Mineral liquid
B. Under National Drug list		
14. Antiviral	1	Arthemeter20mg+Lumefantrine 120mg Tablets
15. Drugs for Toxoplasmosis	1	Albendazole

C. Others		
16. Other Pharmaceuticals	1.	Normal Saline
	2.	Water for Injection
	3.	White Petrolatum
	4.	Whitefield Compound

10. List of Pharmaceutical Manufacturing Companies in Ethiopia

1. Addis Ababa Pharmaceutical
2. Asmi PLC
3. Cadila Pharmaceuticals (Ethiopia) PLC
4. Dana Trading
5. East Africa
6. Ethiopia Pharmaceutical
7. National Veterinary
8. Pharmacure
9. Rx Africa
10. Sino –Ethiopia Associate Africa PLC
11. Moab
12. Desta
13. Bethelhem Pharmaceutical
14. Etab Syringe
15. Bisol
16. Life Line
17. Access Bio, Inc. (Ethiopian branch)
18. Zenith Gebes Eshet PLC

11. Important Addresses

1. Ministry of Industry (Mol)
 Tel: 251- (01) -1- 5508775
www.moti.gov.et

2. Ministry of Health
 Tel. 251- (01) -1- 5517011
 Email: moh@ethionet.et
www.moh.gov.et

3. Ethiopia Investment Agency (EIA)
Tel: 251- (01) -1- 5510033
Email: Ethiopia.invest@ethioinvest.org
www.ethioinvest.org

4. Food, Medicine and Health care Administration
and Control Authority (FMHACA)
Tel: 251- (01) -1- 5522750
www.daca.gov.et

5. Pharmaceuticals Fund and Supply Agency (PFSA)
Tel: 251- (01) -1- 275
Email: pfsa@ethionet.et

6. Ethiopian Pharmaceuticals & Medical Supplies
Manufacturers Association,
P.O. Box 8384,
Addis Ababa (Ethiopia)
Tel. No. 00251-11-5512106/5523691
Fax No. 00251-11-5511662
E-mail: etab.int.med@ethionet.et

7. The Drug Administration and Control Authority (DACA),
Ministry of Health,
Government of the Federal Democratic Republic of Ethiopia,
P.O.Box 5681,
Addis Ababa (Ethiopia)
Telephone No.: 00-251-11-5524122
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E-mail daca@ethionet.et
Web site: www.daca.gov.et

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