Investment oppor tunity in Mekelle, Regional State of Tigray, Ethiopia

Pharmaceutical Formulation Plant

Executive Summary

Ethiopia is one of the most populous countries of Africa and demand for pharmaceutical products in the country is high. The manufacturing of pharmaceutical products in Ethiopia, however, is quite small and covers between 10 and 20 per cent of the domestic market (Sutton et.al 2010, Cardno Emerging Markets, Belgium s.a. and Enabling Environments Ltd, 2011) The rest of the market is satisfied through imports. The annual imported value of pharmaceutical products increased from approximatelly 41 million USD in 2002 to 350 million USD in 2011. On average, the import grew by 29% each year.

This project proposes the establishment of a pharmaceutical manufacturing plant. The market study shows that there is sufficient market in the country. The total volume of the domestic market in pharmaceutical products, which is around 400 million USD, is expected to grow in the future. Frost & Sullivan expect the Ethiopian pharmaceutical market to reach an approximate value of just under USD 1 billion in the year 2018 (*Shalena Naidoo, Healthcare Research Analyst, Frost and Sullivan*).

The Government of Ethiopia has clearly identified the sector as one of its strategic sectors. It targets raising the share of the domestic market held by local pharmaceutical manufacturers to 50% by year 2015. To this effect, the Government is taking measures to support the existing local pharmaceutical manufacturers to achieve full utilization of their capacity and attract new investment.

Introduction to Mekelle

Mekelle is the capital of the Tigray region, located at about 780 km from Addis Ababa. The city is one of the fastest growing urban areas in Ethiopia and in the recent years, the city has become an important investment destination.

Demography

According the 2007 census, the population of Mekelle was 215,546 of which 51.3 percent were women. The 2013 population, assuming a 5.4 percent growth rate, is projected to reach around 300,000.

Table 1: Mekelle Population Growth Scenarios

	2007	2008	2009	2010	2011	2012	2013	2014	2015
High growth (6.3%)	215,546	229,562	244,49	260,38	277,32	295,35	314,560	335,015	356,80
Medium growth	215,546	227,505	240,12	253,45	267,51	282,35	298,024	314,560	332,01
Low Growth (4.4%)	215,546	225,242	235,37	245,96	257,02	268,58	280,669	293,294	306,48

Source: Millennium Cities Initiative, The Earth Institute, Columbia University (2011) Draft of a comprehensive City Development Strategy based on the Millennium Development Goals (MDG) for Mekelle, Ethiopia.

Economy and Infrastructure

Mekelle is becoming an industrial hub of northern Ethiopia. A survey of the Central Statistical Agency of Ethiopia (2011) revealed that the number of large and medium scale manufacturing[1] firms in Ethiopia has increased by 74% during 2005/6 - 2009/10 but in Tigray it has nearly doubled (increased by 91%) during that period. The private sector in Mekelle is therefore growing faster than the national average. In 2009/10, nearly 10% of Ethiopia´s larger firms were based in the Tigray Region (199 firms), with the majority of them located in Mekelle. The

[1]Manufacturing industries covered in the survey were all enterprises, which engaged ten persons and more and used power-driven machinery.

business of these firms is the manufacture of food products and beverages, non-metallic mineral products, fabricated metal products, furniture, motor vehicles, trailers and semi-trailers, rubber and plastic products, and chemicals and chemical products.

Mekelle is connected by road and air to other major cities of Ethiopia, and to the ports of neighboring countries via road. It is connected to Addis Ababa and other renowned tourist destinations such as Axum by asphalt road. Mekelle is relatively closer to most seaports of neighboring countries than Addis Ababa and other major cities of Ethiopia. The road distance from the city to the port of Djibouti is about 837 Km which makes it closer than that of Addis Ababa, which is 910 km. Two new asphalt roads from Mekelle to Djibouti are under construction, which could further shorten the distance to 680 Km upon their completion by late 2013. The city's Alula Aba Nega International Airport currently serves domestic flights. There are 2-3 daily scheduled flights, 7 days a week to Addis Ababa. There is also a daily flight to Axum and Shire Enda Selassie.

Growing Higher Learning Institutions and Skilled Personnel
Mekelle University, Mekelle Institute of Technology and other public and private higher learning institutions are producing skilled labor in many fields. In 2010/11, 34,299 students were enrolled in higher learning institutions, of which, more than 3,300 were studying health science fields such as nursing, pharmacy, laboratory technicians and medicine (Source: Ethiopian Ministry of Education: Educational Statistics 2011; G/Giorgis H. and Murutse D., Talent Development Consultants, 2011).

Health sector
Mekelle and the Tigray Region in general have achieved progress in the health sector. There are now 17 hospitals with 3,690 beds, 200 health centers and 568 health posts[2]. In 2009, the total number of employees in the health sector was 5,859, which is nearly 10% of the total regional employees. The health personnel to population ratio in Tigray was 1:16,000 for physicians (including health officers) and 1:3000 for nurses, for the same year.

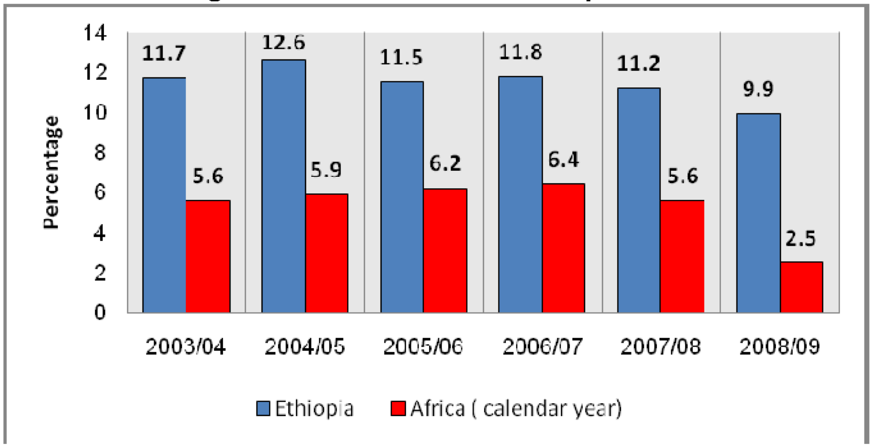
Market opportunity

Ethiopia: economic landscape
Ethiopia has experienced strong economic growth in recent years. With real GDP growth at or near double-digit levels since 2003/04, the country has consistently outperformed most other countries in Africa and expanded much faster than the continent-wide average (Figure 1). This growth performance is well in excess of the population growth rate and the 7 percent rate required for attaining the MDG goal of halving poverty by 2015.

As a result, the Ethiopian economy which ranked as the 10th largest economy of sub Saharan African countries in 2003 has jumped to the 5th place in 2009. This combined with a growing population of the country (accounts for about 9.9 of African population in 2011) indicate a growing market. According to the Ernst & Young report October 2009, by the year 2023, Ethiopia is expected to hit an approximate USD 472 billion GDP per purchasing power and will become the third largest economy in Sub-Saharan Africa.

[2] Health Station: The smallest health units in the conventional Health Service structure and are staffed with 1-3 Health Assistants. Health Post: One of the satellite facilities in the primary Health care unit.

Figure 1: GDP Growth Rate Comparison



Source: African Development Bank, Economic Brief Vol.1, Iss. 5, 17 September, 2010.

The health sector

The health care delivery system is guided by a National Health Policy (NHP), which was issued in September 1993, and a Health Sector Development Program (HSDP) as of 1997/ 98. The HSDP, which was designed for a period of 20 years with rolling five–year programs, has provided a long–term plan framework for the heath sector. The first phase of HSDP covered the period 1997/98 – 2001/02. The second phase was started on July 2002 and it covers a three-year period, 2002/03–2004/05 in order to synchronize it with the Five–year national development plan of the government.

The main objectives of the health sector component of the third phase plan (2005/06-2009/10) were to reduce child mortality, improve mothers' health and combat the spread and prevalence of HIV/AIDS, TB and malaria. To achieve the objectives and ensure full health service coverage throughout the country, a health extension strategy was designed and implemented. In this five years plan period, about 33,819 health extension workers were trained and deployed all over the country. The number of health posts and health centers increased from 4,211 and 644 in 2004/05 to 14,416 and 1,787in 2009/10, respectively. The number of public hospitals increased from 79 to 111.

The Health Sector Development Program brought considerable success, as can be seen from the statistical data in the table below - Ethiopia ranks above the African average in most indicators.

Table 2: Ethiopia: health statistics

Indicator for 2011 (unless otherwise indicated)	**Ethiopia**	**African average**	**Global average**
Population	84,734	-	-
Life expectancy at birth	60	56	70
Infant mortality rate (per 1000 live births)	52	68	37
Under-5 mortality rate (per 1000 children)	77	107	51
Maternal mortality ratio (per 100,000 live births)(2010)	350	480	210
Total health expenditure (THE) as % GDP (2010)	4.8	6.2	9.2
Total health expenditure per capita at average exchange rate (USD) 2010	15	89	941
Private expenditure as % of THE 2010	47.1	52.8	41.1
Physicians per 10,000 population (2009)	0.3	2.5	13.9
Nurses and midwives per 10,000 population	2.5	9.1	29.0
Hospital beds per 10,000 population	63	....	30

Source: WHO, World Health Statistics 2013

The pharmaceutical sector

Ethiopia is one of the most populous countries of Africa with a high demand for pharmaceutical products. The manufacturing of pharmaceutical products in Ethiopia, however, is quite small. Currently, the industry consists of 12 pharmaceutical and medical supply manufacturers and the country produces only between 10 and 20% of its consumption of pharmaceuticals.

Ethiopian Pharmaceutical Manufacturing and Addis Pharmaceutical Factory are the largest and oldest firms, and produce various medicines in relatively large quantities. The first pharmaceutical factory in the country is **Ethiopian Pharmaceutical Manufacturing (EPHARM),** which was established in 1972 as a public company by the Ethiopian government and investors from England. The firm is located in Addis Ababa and employs about 570 employees. It has eight product lines and produces 50 products. **Addis Pharmaceutical Factory** was established in 1992 as a share company in Adigrat, 120 km north of Mekelle or 898 km north of Addis Ababa. The firm produces various types of tablets, capsules, vials, ampoules, syrups, suspensions, elixirs and dermatological preparations. It has about 600 employees.

The rest of the firms in the pharmaceutical industry fall in the mid-size category, with numbers employed ranging from 50 to 150. This include: **East African Pharmaceuticals (EAP) PLC** - a wholly-owned British–Sudanese joint venture; **Sino Ethiop Associate (Africa) PLC** - established in 2001 as a strategic partnership between two Chinese Companies (China Associate Group and the Dandong JINWAN Group) and an Ethiopian Company, ZAF Pharmaceuticals PLC; **Asmi Pharmaceuticals PLC** - established in 1995 by Asmelash Gebre, who also acts as a general manager.

Table 3: Manufacture of pharmaceuticals, medicinal chemicals and botanical products

		2005/06	2006/07	2007/08	2008/09	2009/10
Number of Establishments		4	6	7	8	11
Number of Employees		1,091	1,184	1,293	1,441	2,076
Wages and Salaries Paid (IN '000 BIRR)		17,907	25,297	29,908	32,759	56,151
Gross Value of Production (IN '000 BIRR)		216,395	257,064	311,711	498,749	682,979
Production of Major Products	Capsules ('000 PCS)	370,445	389,997	275,781	206,085	991,731
	Tablets ('000 PCS)	602,887	573,412	501,758	462,519	505,022
	Antibiotics ('000 PCS)	-	-	25	66	7,144
	Syrup ('000 LTR)	191	1,638	1,653	2,534	1,444
	Ointment (in tons)	55	45	52	83	37
	Injection of 100 A ('000 PCS)	4,481	4,277	2,731	25,578	9,464
Ratio of Imported to Consumed Total Raw Material		.911	.980	.964	.697	.719

Source: CSA (2011) Large and Medium-Sized Manufacturing Industries Survey

Out of the total firms in the pharmaceutical industry, about 10 produce pharmaceuticals while the rest are engaged in producing medical supplies such as syringes, absorbent cottons and lab equipment. More than 100 types of medicines, mainly generic, are produced in Ethiopia.

Supply of inputs

Production of medicines in Ethiopia is limited to secondary manufacturing that involves combining various active ingredients and processing bulk medicines into dosage forms. The majority of the inputs used for producing pharmaceuticals are imported. As shown in Table 4, the ratio of imported to consumed-total raw materials, on average for the period covered is

0.844, meaning that approximatelly 85% of the raw materials are imported. A few inputs, such as sugar (used for syrup production) and starch are procured locally.

Table 4: Ratio of Imported to Consumed Total Raw Material

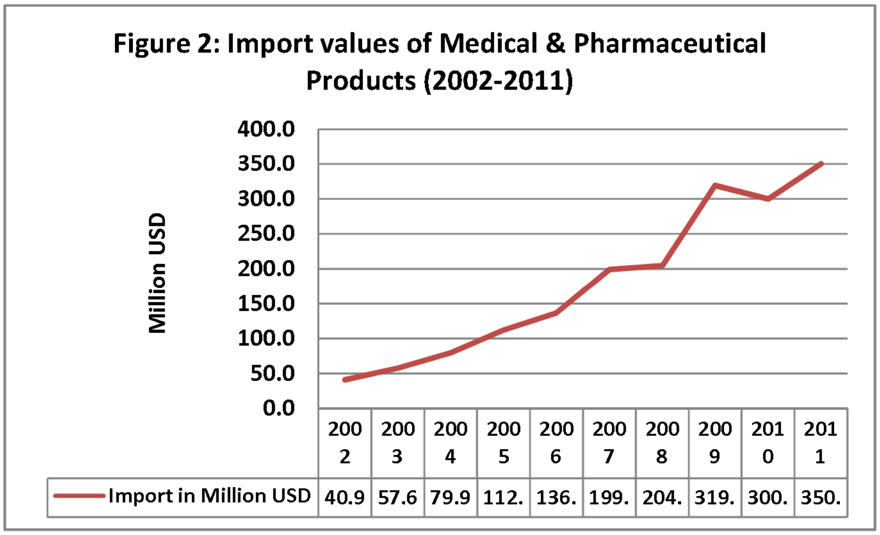
	2005/06	2006/07	2007/08	2008/09	2009/10
Ratio of Imported to Consumed Total Raw Material	0.911	0.980	0.964	0.697	0.719

Source: CSA (2011) Large and Medium-Sized Manufacturing Industries Survey

Ethiopian pharmaceutical firms import inputs from Europe, China and India. Most packaging such as PVC and bottles are also imported, except for carton packaging, which is manufactured domestically. Asmi Pharmaceutical produces bottles for its own use.

Domestic demand & imports of pharmaceuticals

Considering the present population size and the growing number of public and private clinics and hospitals in the country, it is evident that there is a shortage of drugs. The local industry serves only a small part of the domestic market (less than 20%). To meet this growing demand, the country is forced to import drugs in which case the annual expenditure on importing drugs, on average, increased by nearly 29% yearly for the last decade (Figure 2).



Source: Ethiopian Revenue Customs Authority

The import and distribution of pharmaceutical products is done through public sector, private sector, NGOs and international organizations. There are 246 importers and wholesalers registered by the Drugs Administration and Control Authority and 3,433 drug retailers (pharmacies and drug stores) registered in the country.

Most of the imports consist of medicines for tuberculosis, HIV/AIDS and malaria; the procurement process is administered by the Ministry of Health. The Pharmaceutical Administration and Supply Service (PASS) of the Ministry of Health and the Pharmaceutical and Medical Supply Import and Wholesale Share Company (PHARMID) are responsible for importation and distribution to the public sector. The public procurement is done through international and local tenders as well as by direct purchasing or negotiation. Private companies import directly but have to abide by the list of authorized products. The list is availavble at http://www.fmhaca.gov.et/listofdrugsandformularies.html The largest buyer of pharmaceuticals is the Government's Pharmaceutical Fund Supply Agency, which is reporting to the Ministry of Health.

Export

Although Ethiopia is a net importer of pharmaceuticals, some local firms export their products. East African Pharmaceuticals has been exporting to neighboring African (Sudan) and Middle East markets since 2004. The firm envisages that 55% of its output, in the medium term, will be consumed domestically and 45% will be exported. Sino Ethiop Associate exports 30% of its products to African (Zambia, DRC & Kenya) and Middle Eastern countries (RSA & Yemen).

The Central Statistical Agency, CSA, (2011) survey showed that out of the total annual revenue of Ethiopian Birr 651,216,000 (about USD 50,517,497)[3] that the pharmaceutical industry generated in 2009/10 fiscal year, about 1.5% was earned from export. The value of the pharmaceutical industry exported in the last 10 years is presented below.

Table 5: Export Values of Medical & Pharmaceutical Products

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Export Value ('000' USD)	4.4	107.2	89.6	169.8	362.3	443.1	1,951.7	562.1	1,420.3	1,331.2

Source: Ethiopian Revenue Customs Authority

The Pharmaceutical Sector in the Common Market for Eastern and Southern Africa (COMESA) region

A study on Pharmaceutical Production in Developing Countries, conducted in 2006, estimated that the sub-Saharan market with pharmaceuticals was about USD 3,800 million (2006), out of which local manufacturing supplied 28 per cent, imported generics 28 per cent, and imported original brands 44 per cent. Of the 49 LDCs in the world, most are in sub- Saharan Africa and they represent a large market, which is currently dominated by imports of pharmaceuticals.

Table 6: Pharma Market in sub-Saharan Africa—2006

Local manufacturing	**28 per cent**	**$ 1,064 million**
Imported generics	28 per cent	$ 1,064 million
Imported original brands	44 per cent	$ 1,672 million
Total Market Value		US $ 3,800 million

Source: UNIDO survey (IFC Report Pharmaceuticals Production in developing countries 2009.

Ethiopia is a member of COMESA which has a large and growing regional market. COMESA's current strategy can be summed up in the phrase 'economic prosperity through regional integration'. With its 19 member states, population of over 389 million, annual imports of around US$32 billion and exports of US$82 billion, COMESA forms a major market place for both internal and external trading. By manufacturing in Ethiopia, suppliers of pharmaceuticals could gain access to this large and growing market while taking advantage of lower costs of production and transportation.

[3] Converted at the period weighted average rate, Birr/USD = 12.8909.

Map of COMESA Member States

Policy context

Ethiopia´s regulatory system is more effective than in most sub-Saharan African countries (Healthcare Industry Overview in Ethiopia, *2010* available at www.reportbuyer.com/go/FRS01952). Better regulations have been one of the most important factors that contributed to Ethiopia's thriving pharmaceutical industry. The industry is administered and controlled by the Ethiopian Food Medicine and Health Care Administration and Control Authority, FMHACA (formerly Drug Administration and Control Authority DACA). FMHACA issues mandatory certificates of competence to manufacturers, importers, wholesalers and retailers and enforces standards.

Government supports & business facilitations

The government of Ethiopia identified the sector as one of its strategic sectors. In its five year Growth and Transformation Plan, the federal government plans to raise the share of the domestic market held by local pharmaceutical and medical supplies manufacturers to 50% by the year 2015. The government announced provision of all round support for existing local pharmaceutical manufacturers to achieve full utilization of their capacity and exert efforts to attract new investment.

Currently, the pharmaceutical sector is supported by the Engineering Capacity Building Program (ECBP) – a joint project by the Ethiopian government and the German development cooperative, GIZ. The ECBP supports manufacturers, institutions and associations in regard to the transfer of qualifications and know-how, as well as providing contacts to international buyers and investors. As a result, Cedilla Pharmaceutical Ltd. and Sino-Ethiop Associate are now compliant or close to compliance with the World Health Organization's basic Good Manufacturing Practice (GMP) standards (UNCTAD, 2011).

In the past, the sector had a poor credit reputation among banks due to its lack of competitiveness against imported medicines. Banks were reluctant to lend to the sector. Recently the government announced some measures:

- Any foreign investment is matched by loan of Ethiopian Development Bank up to 70%.
- Pharmaceutical manufacturers were recently exempted from duty tax payment on 80%

of their imported raw materials (previously they used to pay up to 35% duty tax on all imported materials).

- The government gives preferential treatment to local manufacturers (Ethiopian based) in its own procurement. It has put in place a system of paying a 30% advance in respect of payments.
- A regional bioequivalence testing centre for Kenya, Ethiopia and the United Republic of Tanzania was recently established at Addis Ababa University with the assistance of German bilateral official development assistance. Pharmaceutical firms in these countries can share the use of this facility in order to undertake bioequivalence testing.

Government's dedication in supporting the sector has been acknowledged:

> *Among LDCs, Ethiopia has been considered as having potential to manufacture quality medicaments at a reasonable cost for both the domestic and export markets. Its most promising pharmaceutical companies have received technical assistance, most notably from the Government of Germany and the United Nations Industrial Development Organization (UNIDO), and the wider industry has benefited from multilateral capacity-building efforts, including from UNCTAD. As a culmination of various reform efforts in the pharmaceutical sector that have been taking place since 2007, the Ethiopian Government has now included the pharmaceutical manufacturing sector as a priority sector for industrial development and investment for the first time in its August 2010 Growth and Transformation Plan. This categorization will make it easier for local firms in the sector to receive priority treatment for access to credit, tax holidays, upgrades of infrastructure and availability of technical support and technology transfer.*
> Source: UNCTAD (2011), *Investment in Pharmaceutical Production in the Least Developed Countries:*

Why produce this product in Mekelle?

- **Proximity to major ports and good transport**

Mekelle is strategically located at the cross road of Middle East and European markets. It is the nearest Ethiopian city to Djibouti port which is only 680 km from Mekelle. In the future when the relationship between Ethiopia and Eritrea improves, Mekelle will be the nearest city to reach Massawa port at only 420 km. Mekelle is to be connected with the major economic centers of the country and Djibouti port by the national railway network, the construction of which has already started and is expected to be completed by late 2013. This would further improve the connection and reduce transportation costs. A dry port has been established in Mekelle to simplify customs clearance for importation of the raw materials and export of products.

- **Lower factor costs**

Manufacturing pharmaceuticals in Mekelle would be cheaper than in/around Addis Ababa. Land lease for a pharmaceutical factory and other costs are cheaper than Addis Ababa and many other parts of Ethiopia.

- **Availability of skilled personnel**

Education has been a priority in Mekelle over the past two decades. There are now five public institutions of higher education and 10 private ones in Mekelle. Currently, more than 27,000 students are enrolled in different higher education institutions in Mekelle. The colleges of health science and veterinary medicine of Mekelle University have a good reputation and produce approximatelly 300 graduate personnel for the health sector each year. In 2011, Mekelle University and Aksum University (200km north west of Mekelle) had 161 and 79 graduates respectively. In its university – industry linkages program, Mekelle University closely works with the private sector in various research areas.

- **Existence of relatively better industrial base**

Mekelle has a well-established and growing industrial base. Addis Pharmaceutical Factory, one of the biggest drug producers in Ethiopia, is located in Adigrat, 120 km of north of Mekelle. Another medical supply factory, Fanus Meditech PLC, is established in Mekelle and now looking for further expansion. Existence of such factories would create a synergy and cluster for pharmaceutical investments.

Mekelle industrial zone

- Mekelle municipal industrial was established in 2000 and furnished with basic utilities. The zone is delineated for manufacturing sector and is leased to investors at a low fixed lease price, i.e. Birr 1.25/m^2/ year. Leases are granted for up to 70 years.
- Its total area was recently expanded from the original 40 hectares to 247 hectares. An area of approximatelly 100 ha is immediatelly available for new investment projects.
- At present some 230 manufacturing plants are located in the industrial zone, of which 60 projects have started production while the rest are under construction.Their activities range from heavy engineering to agro-processing, plastic and metalwork, sanitary products, pharmaceutical factories, and packaging materials (producing carton boxes).

Support provided by Mekelle City Administration and Tigray Investment Office

The Regional Government and City Administration will assist investors interested in investing in the sector by providing land at very reasonable lease price in the industrial zone.

The Regional and City Investment offices offer the following support:

- Handling investor inquires by appointing a single client executive to provide accurate information and data.
- Organize and facilitate site visit for an investor.
- Provide investors with up to date check list of all clearances and approvals required by different authorities for the project.
- Work with investors to get the necessary permits and licenses and to make the right contacts with service providers at both national and city level.
- Ensure fast access to land in the industrial zone.
- Assistance in applying for investment incentives.
- Post-investment ‘aftercare’ in resolving issues and supporting requests.
- Periodic surveys of investors, followed by public-private dialogue to discuss factors affecting business operation and competitiveness.
- Serve as an advocate for business concerns by engaging with relevant officials, legislators and other necessary to seek to resolve constraints.

Investment incentives

Custom duty exemption:

- 100% exemption from the payment of customs duty on imported capital goods, construction materials and spare parts worth up to 15% of the total value of the capital goods to be imported

Income tax exemptions:

- 2 up to 7 years for manufacturing or agro-industrial, agricultural and ICT investments
- 2 years for expansion or upgrading of existing manufacturing or agro-industrial and agricultural investments
- Loss carry forward for half of the tax holiday period

Export incentives

- With the exception of few products (e.g. Semi-processed hides and skins-150%), no export tax is levied on export products of Ethiopia;
- Duty Draw-back Scheme: Duty paid at the port of entry and locally, on raw materials used in the production of commodities is refunded, 100 percent, upon exportation of the commodity processed.
- Voucher Scheme: A voucher book 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 enables them to operate such Warehouse.

Non Fiscal Incentives

- Investors who invest in areas of agriculture, manufacturing and agro-industry will be eligible to obtain loan up to 70 percent of their investment capital from the Development Bank of Ethiopia (DBE) if their investment is sound to be feasible

Further information available

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