

National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025)



Developing the pharmaceutical industry and improving access

Abridged version
July 2015

Federal Democratic Republic of Ethiopia
Ministry of Health and Ministry of Industry

National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025)




Developing the pharmaceutical industry and improving access

Abridged version
July 2015

Federal Democratic Republic of Ethiopia
Ministry of Health and Ministry of Industry





National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025).

© Government of Ethiopia 2015. All rights reserved.

Requests for permission to reproduce or translate this publication – whether for sale or for noncommercial distribution – should be addressed to the Public Relations and Documentation Service (pr@mcit.gov.et).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Government of Ethiopia. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the Government of Ethiopia in preference to others of a similar nature that are not mentioned.

All reasonable precautions have been taken to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the Government of Ethiopia be liable for damages arising from its use.

Printed in Thailand

Editing and design by Inís Communication – www.iniscommunication.com

Photo (left to right): Warren Zelman Photography, Associated Press/PA

Contents

Acknowledgements	iv
Abbreviations and acronyms	iv
Preface	v
1. Introduction	1
1.1 <i>The Ethiopian pharmaceutical market and industry</i>	1
1.2 <i>Health sector development and access to medicines in Ethiopia</i>	2
1.3 <i>Government support to the national pharmaceutical industry</i>	3
1.4 <i>National policies and institutions relevant to the pharmaceutical industry</i>	3
2. The pharmaceutical value chain	5
2.1 <i>Mapping the Ethiopian pharmaceutical industry on the value chain</i>	5
2.2 <i>Good manufacturing practice roadmap for Ethiopia</i>	6
3. National strategy for pharmaceutical manufacturing development in Ethiopia, 2015–2025	8
Strategic objective 1 → <i>Improve access to medicines through quality local production – implement the GMP Roadmap</i>	8
Strategic objective 2 → <i>Strengthen the national medicine regulatory system</i>	9
Strategic objective 3 → <i>Create incentives designed to move companies along the value chain</i>	9
Strategic objective 4 → <i>Develop human resources through relevant education and training</i>	11
Strategic objective 5 → <i>Encourage cluster development and production of active pharmaceutical ingredients</i>	12
Strategic objective 6 → <i>Create a research and development platform</i>	14
Strategic objective 7 → <i>Attract foreign direct investment in the pharmaceutical sector</i>	17
4. Five-year action plan, 2015–2020	19
5. Government support for the implementation of the strategy and action plan	23
5.1 <i>Strengthening of FMHACA</i>	23
5.2 <i>Institutional development of FBPIDI</i>	23
5.3 <i>Financing of incentives</i>	23
5.4 <i>Facilitating international and public–private partnerships</i>	23
5.5 <i>Development of biotechnology parks</i>	24
5.6 <i>Government adoption of the strategy and action plan and its dissemination</i>	24
6. Expected additional positive benefits of implementation of the strategic plan	25

Acknowledgements

This National Strategy document has been developed jointly by the Government of Ethiopia (Ministry of Health and Ministry of Industry) and the World Health Organization, with the technical support of many individuals and organizations. Without the direct support and guidance of Dr Kesetebirhan Admasu, Minister of Health, Dr Kebede Worku, State Minister of Health, Dr Mebrahtu Meles, State Minister of Industry and Dr Pierre M'Pele, the WHO representative in Ethiopia, development of this vision would not have been possible. The contribution of three WHO consultants is highly acknowledged, namely Dr Giorgio Roscigno, Dr Skhumbuzo Ngozwana and Professor Tsige Gebremariam. WHO provided technical and financial support through its European Commission project on improving access to medicines in developing countries through technology transfer and local production, as well as through a strategic grant supported by the Bill and Melinda Gates Foundation to promote and support local production in developing countries to improve access. The WHO project team was led by Dr Zafar Mirza with technical and logistical support of Dr Jicui Dong, Dr Moredreck Chibi, Mr Abraham Gebregiorgis, Dr Abayneh Tamir Desta and two focal points nominated by the Government of Ethiopia, Mr Yehulu Denkew, Director General of Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA) and Dr Shimelis Admasu, Deputy Director General, Food, Beverage and Pharmaceutical Industry Development Institute. A number of WHO experts provided their review comments, which has enriched the document.

Abbreviations and acronyms

API	active pharmaceutical ingredient
FBPIDI	Food, Beverage and Pharmaceuticals Industry Development Institute
FMHACA	Food, Medicines, Healthcare Administration and Control Authority
GMP	good manufacturing practice
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
PEPFAR	US President's Emergency Plan for AIDS Relief
PFSA	Pharmaceuticals Fund and Supplies Agency
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PMS	post-marketing surveillance
UNIDO	United Nations International Development Organization
WHO	World Health Organization

Preface

Ethiopia is one of the fastest growing economies in the world, with an average growth of around 10.9% for the past decade. There is a national aspiration to graduate to middle-income country status by 2020–2025.

The development of the Ethiopian local pharmaceuticals manufacturing sub-sector has been very much limited in terms of production capacity, technology acquisition, creation of employment opportunity and investment. Most of the local manufacturers are not compliant with international good manufacturing practice (GMP), and no single product has been prequalified by WHO.

Many factors have contributed to the under-development of the local pharmaceutical manufacturing sector. One of the most significant gaps has been a lack of sectoral long-term vision that is in line with the country's ambitious goal of economic and social development.

The growth and development of the Ethiopian pharmaceutical manufacturing sector will be based on the 'value chain' approach, which is a spectrum of progress from the exclusive import of finished pharmaceutical products to a research-based pharmaceutical industry.

The approach contributes towards a knowledge economy with local skilled professionals, regulatory institutional development, business and market development, science and technology advancement, interdisciplinary confluence and local R&D, including development of traditional medicine. Anchored on this philosophy, the strategy and plan of action are expected to pave the way for the existing manufacturers to progress along the value chain and attract new foreign direct investment (FDI) by R&D-based multinational pharmaceutical companies.

Ethiopia is best suited to attract FDI in the pharmaceutical industry due to the presence of a conducive environment in the country including: political stability; economic growth and development; accessibility to local and opportunity for regional market; clear development plan (GTP); policy on local preference and protection of local manufacturing; and an effective regulatory system that strives to ensure safety, efficacy and quality of medicines. Moreover, a government incentive policy – that has played a determinant role in sustaining and developing the local manufacturers to date – shall be strengthened and will apply new incentive packages to increase the number of international GMP-certified manufacturers with WHO prequalified products, diversify exportation, encourage the development of new formulations and utilization of indigenous traditional medicines.

The Government would also adopt some initiatives, as outlined in this document, that deliver significant returns and help local companies become competitive. For example, pooled procurement to minimize the cost of importation of active pharmaceutical ingredients for the pharmaceutical manufacturing industry.

At this juncture, the Government of Ethiopia would like to express its gratitude to the World Health Organization for the technical and financial support provided in the development of this critical strategy and plan of action.

We understand and are committed to the envisaged development of the sector in the next ten years, which needs serious engagement of the ministries of health, industry, science and technology in providing leadership, the participation of the private sector, academic and research institutions, as well as the professionals and support of WHO and other development partners in the implementation of the strategy and plan of action.



H.E. Dr Kesetebirhan Admasu
Minister of Health
Federal Democratic Republic of Ethiopia



H.E. Mr Ahmed Abitew
Minister of Industry
Federal Democratic Republic of Ethiopia

1. Introduction

The Federal Democratic Republic of Ethiopia is the second most populous country in Africa, with a population of 90 million people. Ethiopia is one of the fastest growing economies in the world, with an average growth of around 10.9% for the past decade. There is a national aspiration to graduate to middle-income country status by 2020–2025 and to completely eradicate poverty. The Ethiopian Government's national growth vision is enshrined in the *Growth Transformation Plan I (GTP-I)*,¹ 2010–2015.

Industrial development was an important component of GTP-I. With an emphasis on agricultural and rural development, industry, infrastructure, social and human development, good governance and democratization, GTP-I targets for the pharmaceutical industry included the following:

- Achieve full utilization of the existing capacity of local pharmaceutical and medical supplies manufacturers.
- Raise the share of the domestic market held by local pharmaceutical and medical supplies manufacturers to 50%.
- Increase the export earnings of pharmaceutical and medical supplies manufacturers to US\$ 20 million per year.

The Ethiopian Government took a number of steps to incentivize development of the local pharmaceutical industry during the past five years, with an observable positive impact. GTP-I has played an important role, including laying the groundwork for the development of the Ethiopian pharmaceutical industry. There is now a trend for new foreign and local investments in the sector, resulting in new business ventures. Parallel investments in expanding effective health coverage have improved health indices and have resulted in growing demand for health commodities.

The Government is about to introduce a new five-year national development plan (GTP-II, 2015–2020). The World Health Organization (WHO) was requested to assist in developing a long-term vision and plan for the pharmaceutical industry that explicitly combines the objectives of industrial development policy and health policy so the sector can develop, the economy can grow and people's access to good-quality affordable medicines can improve. Partly, this request was influenced by the *Pharmaceutical Manufacturing Plan for Africa* business plan developed under the auspices of the African Union Commission (AUC), with the support of the United Nations Industrial Development Organization (UNIDO) and endorsed by the Heads of States of Africa, including Ethiopia.

1.1 The Ethiopian pharmaceutical market and industry

The annual pharmaceutical market in Ethiopia is estimated to be worth US\$ 400 to US\$ 500 million² and growing at an impressive rate of 25% per annum. A 2012 estimate by Frost & Sullivan suggests the Ethiopian pharmaceutical market could witness growth

1 *Federal Democratic Republic of Ethiopia poverty reduction strategy paper: growth and transformation plan 2010/11–2014/15*. IMF country Report No. 11/304. Washington, DC: International Monetary Fund; 2011.

2 Personal communication. Pharmaceuticals Fund and Supplies Agency, February 2015.

rates of “slightly over 14%”³ to reach an approximate value of just under US\$ 1 billion by 2018.

Steady economic growth, improvements in the delivery of health care, and introduction of social health insurance coverage across the country in July 2015 all lead to growing demand. These developments are encouraging international pharmaceutical companies to invest in Ethiopia, as evidenced by activities of Cadila, Julphar, GlaxoSmithKline, Sandoz and Hikma Pharmaceuticals.

There are approximately 200 importers of pharmaceutical products and medical consumables in Ethiopia. The local industry comprises 22 pharmaceutical and medical suppliers and manufacturers, with 9 involved directly in the manufacture of pharmaceutical products. Most of the manufacturers operate below their capacities and supply only about 20% of the local market. In 2014, local pharmaceutical companies supplied products to the value of US\$ 44.2 million. Local manufacturers have limited product portfolios and are thought to be able to supply only 90 of the more than 380 products on the national essential medicines list. Around 35–40% of their total output is supplied to the private sector at a price premium of 10%. The annual private pharmaceutical market in Ethiopia is estimated to be worth US\$ 100 million. In 2014, the Ethiopian industry exported pharmaceutical products worth almost US\$ 2 million, which was far below the GTP-I target of US\$ 20 million. The bulk of the exports were accounted for by Sino-Ethiopia, which exported empty gelatine capsules. The ownership of the companies is diverse and ranges from two large companies to smaller entities that are joint ventures between Ethiopian entrepreneurs and foreign investors from China, India, Jordan, Saudi Arabia, Sudan and the United Arab Emirates.

1.2 Health sector development and access to medicines in Ethiopia

Ethiopia is consistently investing in its health sector. The health service coverage has increased from 30% to 89% in 2010. The numbers of health posts and health centres have increased from 4211 and 600 in 2004–2005 to 14 416 and 2999, respectively, by 2012. Significant progress has been seen in other key health indicators, such as a drop in HIV prevalence from 3.5% in 2004–2005 to 1.3% in 2012; a decrease in the maternal mortality ratio from 871 per 100 000 in 2005 to 420 per 100 000 in 2014. Ethiopia achieved the Millennium Development Goal 4 to cut the mortality rate for children under the age of five years ahead of the 2015 deadline, which is seen as a great achievement. The child mortality rate stands at 64/1000 live births (2013/14). Ethiopia has also achieved most of the MDG 6 targets on AIDS, tuberculosis (TB) and malaria.

The public sector, through the Pharmaceuticals Fund and Supplies Agency (PFSA), procures almost 70% of all the medicines consumed in Ethiopia, but there is still significant out-of-pocket expenditure on health, estimated at 46% by the Ethiopian Food, Medicines, Healthcare Administration and Control Authority (FMHACA). PFSA procurement increased from US\$ 27 million in 2007 to US\$ 310 million in 2014.

3 Naidoo, S. *High growth rates expected for the Ethiopian pharmaceutical market, but it's not all smooth sailing – Unpacking the challenges*. Mountain View: Frost & Sullivan Market Insight; 2012 (<http://www.frost.com/prod/servlet/market-insight-print.pag?docid=267359592>, accessed 26 June 2015).

1.3 Government support to the national pharmaceutical industry

Government support is important in the short to medium term to encourage growing pharmaceutical industries in developing countries to become competitive and to channel their growth in accordance with the objectives of health policy. The Ethiopian Government provided various kinds of support to the local pharmaceutical industry during the GTP-I period to promote import substitution, export growth, transfer of technology and job creation and to increase the production of essential medicines to improve access. The Ethiopian Government believes its support and encouragement to produce value-added products for the export market will increase foreign exchange and lay the basis for more rapid industrial development. Ethiopian Government procurement systems give preference to local pharmaceutical companies and offer advanced payment of up to 30% of the value of orders. In some cases, technical assistance and consultancy support are also given to help companies comply with international drug manufacturing standards. Indirect governmental support includes strengthening of FMHACA, establishing the Food, Beverage and Pharmaceuticals Industry Development Institute (FBPIDI), and laying the groundwork for policies and incentives designed to encourage investment in and development of the sector.

Current incentives by the Ethiopian Government for local production include tax-free loans of up to 70% for new investments (so the investor needs to invest only 30% of the project capital at inception) and up to 60% for upgrading projects during the first five years. These loans are granted by the Development Bank of Ethiopia. There is also a 100% custom duty exemption on the import of all granted capital goods, such as manufacturing plant, machinery, equipment and construction materials. Spare parts at up to 15% of the total value of imported investment capital goods are exempted from customs duty. Companies exporting 50% of their products or services, or supplying 75% of their products or services as production or services input to an exporter, are exempted from income tax for five years. Companies exporting less than 50% of their products or services or supplying only to the domestic market are exempted from income tax for two years. Investors that invest in high-priority areas to produce mainly export products are given land necessary for their investment at reduced lease rates. PFSA grants local manufacturers a 25% price preference and also pre-pays 30% of the tender value on awarding the contract; the 70% balance can be accessed through the Development Bank of Ethiopia if the local company requires additional capital and is willing to cede the tender to the bank. Product registration for local manufacturers is reduced to an average of one month. On their own, however, these incentives are not enough to spur development of the industry.

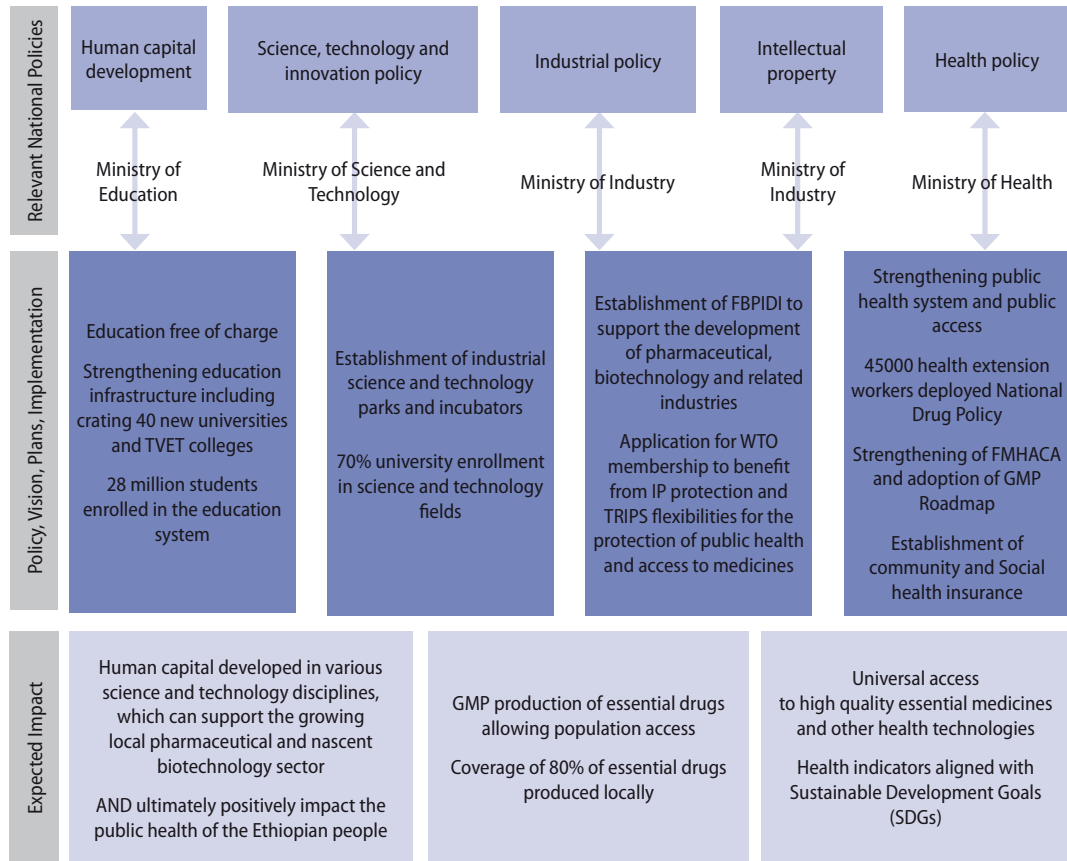
Despite support from the Ethiopian Government, the Ethiopian pharmaceutical industry faces significant challenges, including human resource capacity constraints, limited access to foreign currency, and raw material procurement difficulties. Until now, there has been no coherent national vision, strategy or plan to develop the pharmaceutical industry in the long term.

1.4 National policies and institutions relevant to the pharmaceutical industry

A recent detailed analysis of all national policies relevant to the pharmaceutical sector in Ethiopia was conducted by the United Nations Conference on Trade and Development (UNCTAD). The analysis suggests that Ethiopia's overall policy framework exhibits

a remarkable level of coherence and complementarity of policies between sectors. Figure 1 provides an overview of Ethiopian Government policies, responsible ministries, the vision and plans of implementation of these policies, and their impact.

Figure 1 Relevant national policies and their expected impact



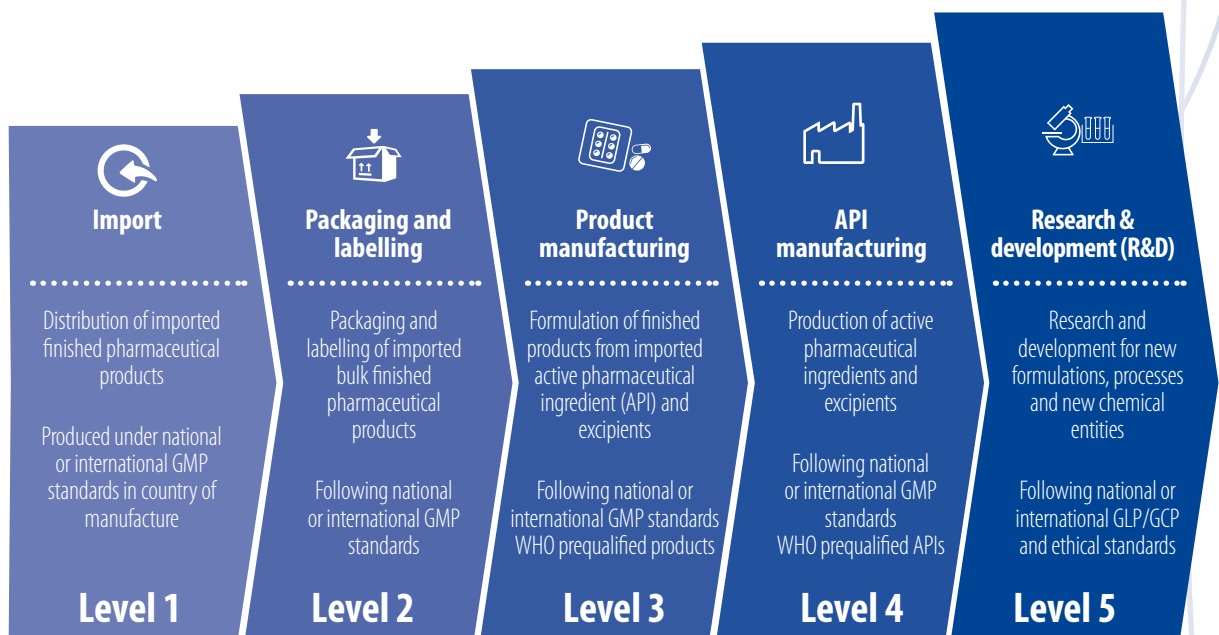
The *National Medicine Policy* was established in 1993 with the aim to provide universal access to good-quality essential medicines. FMHACA was established in 2009 with the mandate to regulate food, medicines and health care services, and with PFSA to reform and restructure the pharmaceutical supply and regulatory functions. The *Industrial Development Strategy (2013–2025)* is designed to mobilize resources and allocate them to the manufacturing sector. It calls for the upgrading and promotion of the pharmaceutical sector and has technology transfer and technology diffusion among its objectives. The Ethiopian Government is actively facilitating foreign direct investment through its investment policy. Ethiopia has not yet acceded to the World Trade Organization.

Of particular importance is the FBPIDI, established by the Ethiopian Government in 2013 with the objective to transform the development of food, beverage and pharmaceutical industries through accelerated technological development and transfer by providing these industries comprehensive, knowledge-based, innovative, and accessible support and to make them internationally competitive so that they have a significant contribution towards import substitution as well as exports in terms of variety of goods and volume.

2. The pharmaceutical value chain

The pharmaceutical value chain is a spectrum of progressive pharmaceutical operations with increased technological complexity. At one end of the chain is exclusive import of finished pharmaceutical products and at the other end is a research-based pharmaceutical industry. In between are various levels of pharmaceutical manufacturing, including production of active pharmaceutical ingredients (API). Each step potentially leads to the next, with added value, complexity, investment and regulatory requirements. It is critical that an acceptable level of international quality standards is followed at every level. A company at the far end of the chain may incorporate all the earlier levels – that is, integrated production, which can be the most cost-efficient and competitive operation. In most cases, however, companies practise various kinds of forward or backward integration. From a policy perspective, it is important that the pharmaceutical manufacturing sector in a country is appreciated and facilitated for its progressive development along the value chain. This approach has huge benefits and positive externalities for a number of other sectors and industries. It contributes to creating a knowledge economy with local skilled professionals, regulatory institutional development, business and market development, science and technology advancement, interdisciplinary confluence and local research and development, including development of traditional medicine. A simple representation of the pharmaceutical value chain is given in Figure 2.

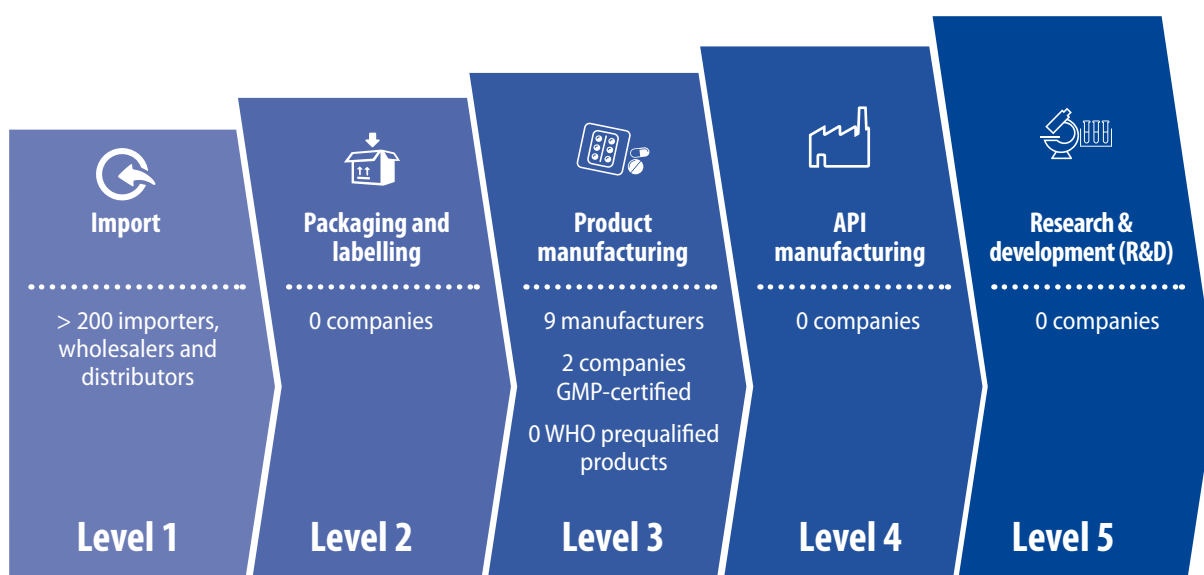
Figure 2 Progressive pharmaceutical value chain



2.1 Mapping the Ethiopian pharmaceutical industry on the value chain

As shown in Figure 3, the majority of the players in the Ethiopian pharmaceutical sector are at Level 1 – they import finished formulations. It is critical to reflect on the potential for developing the industry among the current importers. Three of the major local companies were created by entrepreneurs who started as importers and moved along the value chain.

Figure 3 Pharmaceutical value chain: current situation in Ethiopia



None of the 200 importers and wholesalers have moved to Level 2, which through the addition of a small degree of local content could potentially ensure savings of 10–15% of foreign exchange. There are nine manufacturing companies licensed by FMHACA. Four companies are being assisted by the German Corporation for International Development (GIZ) to apply for good manufacturing practice (GMP) certification by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), with two companies already having been approved. There is evidence of significant investments and progress by most companies towards this end. No pharmaceutical products manufactured in Ethiopia have achieved WHO prequalification status, although one company is actively pursuing this. No companies have yet reached Level 4 – local production of APIs. A Chinese-Ethiopian joint venture company is producing hard gelatine capsules, the only manufacturer in Africa that exports to a number of African and Middle Eastern countries. No company is at Level 5 – active research and development.

2.2 Good manufacturing practice roadmap for Ethiopia

With the establishment of FMHACA, Ethiopia moved to adopt WHO GMP standards. Consequently, after working with the United States Pharmacopeia/Promoting the Quality of Medicines (USP/PQM), WHO and local manufacturers in 2012, Ethiopia adopted the five-year *GMP Roadmap (2013–2018)*. The roadmap was initiated with the aim of improving public access to sustainable, affordable, safe, efficacious and good-quality medicines produced in Ethiopia. An assessment of eight companies was conducted, which grouped them at three levels:

- Level I: manufacturers with up to 50% GMP compliance.
- Level II: manufacturers with 60–80% GMP compliance.
- Level III: manufacturers with more than 80% GMP compliance.

Table 1 presents the findings of this assessment.

Table 1 Ethiopian pharmaceutical manufacturers' good manufacturing practice (GMP) scores and compliance levels

Company	GMP scores (%)	GMP level
1	35.5	I
2	52.5	II
3	89	III
4	44.5	I
5	35	I
6	4	I
7	48	I
8	17.5	I

The findings in Table 1 indicate that six of the manufacturers were at Level I. The roadmap, in consideration of the challenges that the industry faces, adopted a pragmatic three-phased approach to ensuring all companies become compliant with WHO GMP standards by 2018.

3. National strategy for pharmaceutical manufacturing development in Ethiopia, 2015–2025

The aim of this strategy is to assist local pharmaceutical companies and other sector actors to move along the value chain and to increase the number of players at every step. Achievement of this requires the implementation of several measures and creation of an environment conducive for the growth of the pharmaceutical industry. The timing of this strategy is also critical. Once adopted by the Ethiopian Government, it can directly influence GTP-II (2015–2020) and GTP-III (2020–2025). The strategy sets out the details of how to transform the pharmaceutical sector in Ethiopia. Seven strategic objectives of the strategy are as follows:

- Strategic objective 1: Improve access to medicines through quality local production – implement the GMP Roadmap.
- Strategic objective 2: Strengthen the national medicine regulatory system.
- Strategic objective 3: Create incentives designed to move companies along the value chain.
- Strategic objective 4: Develop human resources through relevant education and training.
- Strategic objective 5: Encourage cluster development and production of active pharmaceutical ingredients.
- Strategic objective 6: Create a research and development platform.
- Strategic objective 7: Attract foreign direct investment in the pharmaceutical sector.

Strategic objective 1

Improve access to medicines through quality local production – implement the GMP Roadmap

The mission of the *Fourth Health Sector Development Plan (2010–2015)* is to address morbidity, mortality and disability and improve the health status of the Ethiopian people by providing and regulating a comprehensive package of promotive, preventive, curative and rehabilitative health services via a decentralized and democratized health system. The imperative to address the needs of the people and ensure universal access is also captured by the *National Drug Policy*, which has among its core objectives the need to meet Ethiopia's demand for essential medicines and to strengthen the supply, distribution and use of these medicines.

In order to ensure local companies comply fully with international GMP standards, a *GMP Roadmap (2013–2018)* was adopted and is being implemented by the Ethiopian pharmaceutical industry and FMHACA. A committed and complete implementation of this roadmap by 2018 is an essential condition to improve access to good-quality medicines.

Strategic objective 2

Strengthen the national medicine regulatory system

A well-resourced, effectively functioning national medicine regulatory authority is a prerequisite for building a competitive pharmaceutical industry capable of ensuring the safety, quality and efficacy of all medicines on the market. The regulatory authority should be able to ensure all pharmaceutical value chain players involved in clinical research, laboratory work, manufacturing, importation and exportation, wholesaling, distribution and retail sale of products conform with acceptable international standards available for all these operations. The authority therefore must have the capacity to regulate the entire value chain and to continually assess the safety, efficacy and quality of all marketed medicines through, for example, dossier evaluations, manufacturing plant inspections and post-marketing surveillance. The FMHACA needs ongoing strengthening through recruitment and retention of qualified personnel by offering competitive remuneration; establishment of twinning programmes with stringent regulatory authorities, and staff rotation programmes to expose FMHACA staff to international best practice; strengthening its quality control and inspection capacity by putting in place state-of-the-art laboratories, working guidelines, standard operating procedures; integration with regional regulatory bodies; modernizing its information and data processing system; developing internal and external education and training programmes with international partners such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), WHO and local academia to upgrade local regulators, including formal education in regulatory affairs; and participation in regional regulatory harmonization initiatives.

Strategic objective 3

Create incentives designed to move companies along the value chain

In addition to the existing support, this strategy proposes new time-bound, tailored incentives with the aim of moving companies up the value chain. The incentives include import-product restrictive policies to create a window of opportunity for local pharmaceutical companies to improve and replace imported products with locally produced products by complying with international GMP standards. The newly proposed incentives are intended to facilitate investments to set up new factories and to upgrade and enhance the competitiveness of existing companies and related industries, such as the packaging industry.

The incentives will be time-bound as firms should require less governmental support as they gain increased technological capabilities and gain more business. The strategy proposes a package to facilitate foreign direct investment and its attendant technology transfer, skills transfer, expertise and capital inflow. The incentive package is geared towards indigenization of foreign technologies, creation of jobs and promotion of exports. We describe below the proposed incentives and their rationale.

Pooled procurement of raw materials

In order to overcome the problem of high costs being paid by Ethiopian local manufacturers due to low-volume purchases of APIs, excipients and packaging materials, and to address the problems of variable quality, foreign exchange challenges,

long lead times, high shipping costs, port charges and administrative hurdles of dealing with port authorities:

- FBPIDI to facilitate consolidated bulk purchase and consignment stocking of critical imported raw materials and to sell to the local industry at cost plus a minor handling fee.

Technology acquisition grants

Many companies currently have old and obsolete equipment and machinery. In order to adopt state-of-the-art plant, machinery and equipment to facilitate GMP compliance:

- Ethiopian Government to provide a capital goods acquisition loan (e.g. 80%) payable in five years;
- FBPIDI to negotiate preferred supplier status with three to five leading suppliers of pharmaceutical manufacturing technology.

Human resource development facilitation

Non-availability of skilled experts for the pharmaceutical industry is a huge constraint in Ethiopia. To deal with this:

- FBPIDI to initiate a grant/soft loan (up to a maximum of 5% of a company's annual turnover) with the aim of training and retaining skilled staff;
- FBPIDI to collaborate with academia to launch a pharmaceutical management and production management programme such as MBA or other postgraduate diplomas;
- 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.

Enhancing productivity

Current manufacturing suffers from operational inefficiencies. To improve production and hence competitiveness:

- FBPIDI to collaborate with academia to introduce lean manufacturing.

Leveraging PFSA procurement

In order to align and plan national production and procurement:

- PFSA to offer long-term fixed supply contracts (e.g. five years) to local producers to facilitate better planning and attract foreign direct investment.

Incentivizing local investment in new products and equipment

Currently it is difficult for locally produced products to compete with imported equivalents from countries where companies enjoy significant export incentives. In order to achieve competitiveness through optimal capacity use, a number of interventions are required, such as creating toll manufacturing opportunities that also facilitate technology transfer and training opportunities, product portfolio widening

and diversification, as local manufactures will either invest more aggressively in new formulation and dossier development or procure dossiers on the international market:

- Ethiopian Government to restrict the importation of 20–30 Essential Medicines List products so these can only be locally produced and procured by PFSA and the private sector. The list should be a mix of low- and high-margin products and prices should be controlled for three years to create competition and enhance efficiencies.

Phase IV clinical trials in local population for new chemical entities after registration

In order to build capacity to conduct clinical trials in the country:

- FMHACA to register and approve for sale any new chemical entities, on the condition that the originator company conducts Phase IV studies in Ethiopia to confirm efficacy and lack of toxicity in the local population.

Once the Ethiopian Government has finalized these incentives, in order to attract and incentivize foreign direct investment, an investment memorandum would be circulated widely explaining the incentives.

Strategic objective 4

Develop human resources through relevant education and training

Systematically and sustainably investing in human resource development is the key to pharmaceutical manufacturing development. A comprehensive programme is needed to organize and ensure relevant education, on-the-job training, continuing education programmes and distance learning opportunities for staff. A continuum of skills is required that stretches from the tertiary and postgraduate skills needed in research and development and general management, to professional managerial and technical skills required to run manufacturing plants, to trained factory technicians to operate and maintain the plant and equipment.

The Ethiopian Government has already taken some appropriate measures in this regard; for example, Addis Ababa University is starting an MSc degree programme in regulatory affairs, increasing enrolment of students in science and technology, and improving the capacity of science and technology institutions to produce qualified technicians, engineers and scientists; and providing managers and professionals with short-term training programmes in business management, leadership, GMP and entrepreneurship. The Ministry of Science and Technology has recently issued directives for the establishment of university–industry partnerships for promoting technology innovation, transfer and diffusion in line with its *Science, Technology and Innovation Policy (2012)*.

The strategic plan aims to address the shortage of skills through the provision of a wide variety of training programmes and to address core competencies required in the pharmaceutical industry, including product innovation and drug development; quality control and quality assurance; drug approval, supply chain management and regulation; good agriculture practice; GMP; good wholesaling practice; good distribution practice; good laboratory practice; good clinical practice; drug manufacturing; and

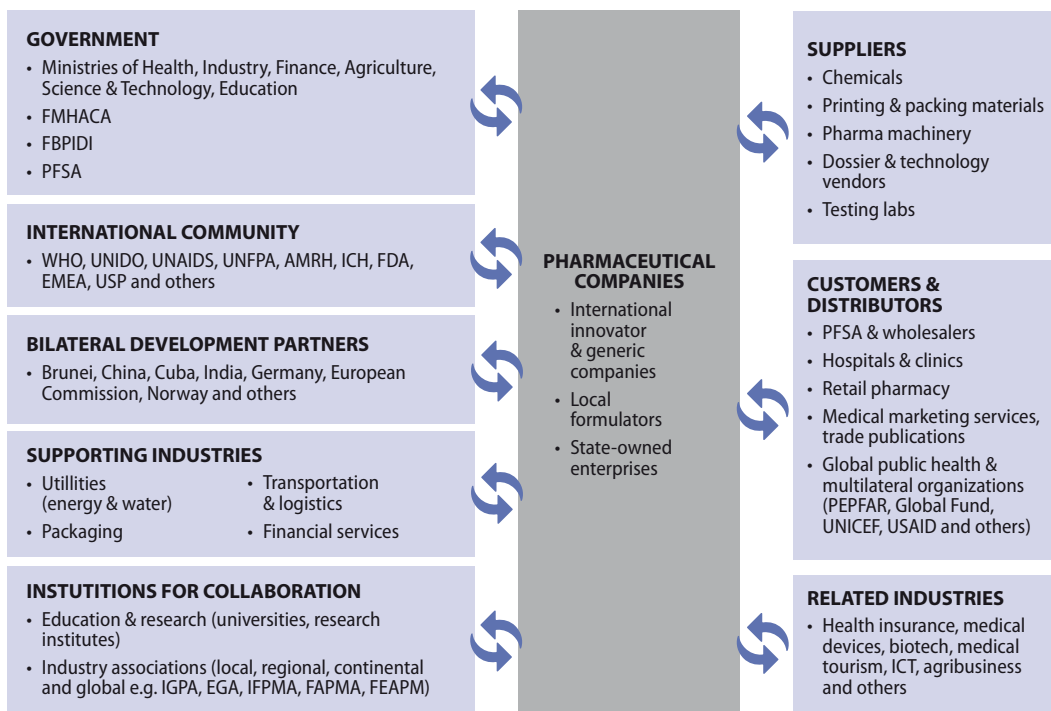
pharmaceutical management. The plan also provides an indicative list of potential partners and providers of training and technical assistance.

Strategic objective 5

Encourage cluster development and production of active pharmaceutical ingredients

The strategic plan proposes a pharmaceutical cluster development approach rather than focusing only on manufacturing. Research conducted in South Africa has demonstrated that for every one job created in the local pharmaceutical manufacturing sector, about seven jobs are created in associated industries. The study also showed that if the Government of South Africa paid a premium of up to 32.5% for locally manufactured products, then the overall benefits would still be greater for the South African economy than buying the cheaper imported medicines.⁴ Figure 4 shows the pharmaceutical cluster approach.

Figure 4 Pharmaceutical cluster



Production of active pharmaceutical ingredients in Ethiopia

There is hardly any production of APIs in Africa – almost all APIs used in Africa are imported from China and India. Some 40–60% of the final retail price of the pharmaceutical product is made up of APIs. Producing APIs is a technically complex and expensive undertaking, requiring expertise in chemistry and availability of raw materials. API production in Africa is generally considered unfeasible – but this strategic plan proposes otherwise. For African pharmaceutical manufacturing to become competitive, it is important that Africa produces APIs; this is possible by using advanced and efficient technologies rather than relying on old methods of API production. With pooled procurement of APIs and the right incentive packages, local

⁴ An unpublished study by Research and Information Department Industrial Development Corporation of South Africa in February 2008 entitled: *Cost-benefit analysis of procuring anti-retrovirals from South African manufacturers as opposed to foreign producers*. Personal Communication.

pharmaceutical businesses could become interested in investing in API production to gain a competitive edge.

The decisions on which technologies to invest in, and which products to make with these technologies, need careful consideration and should take into account the availability of suitable human resources, technology (including transfer of know-how and reagents), capital investments, the time required to establish production and approval of the products, the cost of production and real market opportunities.

There are many potential technologies and product classes that could be considered. It is not the objective of this strategy to identify which technologies Ethiopia should invest in, but rather to provide a framework on how such decisions should be made. For example, biocatalysis is being used as a method to catalyse chemical reactions in selected API production and, in some cases, is replacing some of the traditional chemical synthetic steps, which can be inefficient and require significant purification. Examples of molecules that can be produced using biocatalysis include atorvastatin, levetiracetam, ibuprofen, pregabalin, artemisinin and eplerenone. Biocatalytic synthesis can be cleaner, greener, faster and higher-yielding, and it could have the potential to make Ethiopia an important competitor in the API space.

Biocatalysis technology is currently limited to only a few approved drugs, and to only a few of the synthetic steps for the production of those drugs, meaning that the cost–benefit analysis needs to be considered on a case-by-case basis. In addition, the recombinant expression systems and enzymes needed for the efficient conduct of such biocatalysis are proprietary, and establishing the processes requires access to the reagents and know-how or a lengthy re-engineering of suitable enzymes. The decision to invest in the development of new synthetic routes for APIs needs a careful evaluation of what drugs could be made, where the technology and know-how will come from, and whether the project will yield a long-term return on investment.

As another example, many countries pay significant prices for imported biotherapeutics, including monoclonal antibodies for the treatment of cancers and autoimmune disorders, currently sold at prices 100 to 1000 times the cost of production. Establishing a tissue-culture platform for the production of high-value biologicals appears attractive, but careful consideration needs to be given to the time required to establish the technology and the predicted market space at that time.

There are therefore many options available to Ethiopia, including the option of importing semi-finished APIs and processing the final steps. Overall, trying to compete with large existing API producers using existing platforms is unlikely to be sustainable. Investing in cutting-edge technologies to be a step ahead of these producers, or benefiting from the window of opportunity to produce drugs that are patented elsewhere, may provide a competitive edge. The decision of which technologies to invest in or which APIs to make should be evidence-based.

The Ethiopian Government has mandated of the Ethiopian Public Health Institute to manufacture vaccines. This fits well within the vision of this strategy and action plan. Currently the Ethiopian Public Health Institute is renovating its vaccine production facility to make it suitable for production of polysaccharide vaccines and cell culture-based anti-rabies vaccines for humans. The new facility has state-of-the-art equipment

and can house the relevant technology platform for biotechnology products, including future production of monoclonal antibodies. WHO is currently assessing the capacity needs in this regard.

Strategic objective 6

Create a research and development platform

In order to create a knowledge economy in Ethiopia, it is critical that a national system of health technology innovation is developed in line with the *National Science, Technology and Innovation Policy (2012)*.

Ethiopia has recently established a National Science, Technology Innovation Council, chaired by the Deputy Prime Minister. Under the Council, a National Research Council has been established with the objectives to promote, coordinate and support research and development and innovation in line with the technological, economic and social needs of the country by fostering high-quality research; establishing a research culture, promoting human resources development and building the research workforce; ensuring dissemination of scientific knowledge; and facilitating technology transfer and promoting commercialization of research and development and innovation outputs into products and services. It requires a strong collaboration between the stakeholders in the state, public research institutes and universities, and the private sector.

This plan stresses the importance for the Ethiopian Government to adopt a more intensified and highly coordinated approach to establish a national innovation system by focusing on the ideas discussed below.

Promoting research and development

Ethiopia is well positioned due to its strong governmental institutions and a clear set of priorities, including development of the biopharmaceutical industry. There are a number of Ethiopian Government agencies that directly and indirectly impact on research and the research-based industries: the Ministry of Science and Technology, the Ministry of Health, the Ministry of Education and the Ministry of Industry. The strategy for the development of a research and development-based pharmaceutical sector should rest on the following principles:

- encouragement and support of basic research;
- domestic industry modernization;
- development of biopharmaceutical technologies and industry
- export orientation;
- improved-quality generics;
- investment in the modernization of research into natural products and traditional medicine.

Developing, attracting and retaining experts

Development of research and development-based pharmaceutical manufacturing is not possible without highly skilled scientists, technologists, engineers and technicians working together with administrators and managers. Ethiopia has suffered from a 'brain drain' of qualified people. The Ethiopian Government needs to provide strong incentives and put in place schemes to retain talent and lure scientists back home. A development

strategy that encourages the participation of emigrants in the economic and scientific development of their countries can mitigate the effect of the brain drain.

Establishing science and technology parks and incubators

Incubators⁵ address the most challenging aspects of building a successful new technology platform when access to early capital and expert mentoring might turn ideas into viable products. A university research park or science and technology park is an area designed to promote innovation. It is a physical place that supports university–industry–government collaboration with the intent of creating high-technology economic development and advancing knowledge. The parks offer a number of shared resources, such as incubators, programmes and collaboration activities, uninterrupted power supplies, telecommunications hubs, reception and security, and management offices. Science parks are sources of entrepreneurship, talent and economic competitiveness, and they are key elements of the infrastructure supporting the growth of today’s global economy.

The Ethiopian Government is planning the creation of various independent science parks hosted in universities. It is proposed to create within these science parks the following three types of incubator around various technological platforms:

- **University incubators:** These are set up by academic and technical institutions with the task of turning home-grown projects into spin-off companies in which the parent organization retains some equity. Companies launched in such incubators could attract academic staff with prospects of higher salaries.
- **Returned overseas students/professional incubators:** Many Ethiopian professionals are employed in international pharmaceutical companies, some at very senior positions. These professionals may be attracted by the opportunity of founding their own company as a start-up or using incubator resources to run research projects.
- **Industry incubators:** These should be built inside technology parks as pilot plants and provide in-house laboratory equipment for scientists from pharmaceutical companies.

Establishing strategic technology platforms

The national science base must be built strategically to compete in the world market by allocating funds highly selectively in technology platforms that have the potential to impact widely in multiple fields. When selecting which technologies to invest in for API production, the identification of which strategic technology platforms to establish should be evidence-based, taking into account access to expertise and know-how, market opportunities and competitive advantages. As an example, the establishment of a fermentation platform could lead to manufacture of certain APIs to supply the local industry; it could also lead to development of by-products such as antigens for use in the development of the biotechnology sector and enzymes for biocatalysis.

5 “Technology incubators are a specific type of business incubator: property-based ventures which provide a range of services to entrepreneurs and start-ups, including physical infrastructure (office space, laboratories), management support (business planning, training, marketing), technical support (researchers, databases), access to financing (venture capital funds, business angel networks), legal assistance (licensing, intellectual property) and networking (with other incubators and government services).” From OECD report (1997), *Technology Incubators; Nurturing Small Firms*. OCDE/GD(97)202.

Other platforms for consideration could include plant-based production of proteins, downstream process development, assay development and diagnostics.

As an agricultural country, Ethiopia has a number of raw materials that can be developed as part of its agroindustrial development into excipients. Examples are starch, lactose, sugar, cellulose, and their derivatives.

Such technological platforms are vast, covering a huge array of know-how, equipment requirements and building space. Careful and strategic prioritization is required in the selection of appropriate technology platforms, and this would be part of the implementation process of this strategy.

Integrating Ethiopian research-based companies

Ethiopia is in the process of building many of the individual elements required to create a fully integrated pharmaceutical industry. These elements are in some cases fledgling and in many ways still disconnected. A clear governmental vision, strong commitment and sustained action can bring these individual elements into a robust national innovation system for health technologies and a well integrated pharmaceutical sector in Ethiopia that possesses all the critical industrial and research capabilities to move from packaging, to GMP formulation, to API manufacturing and to technological platforms capable of producing innovative products.

The research and development value chain is long and complex, and yet value can be created along it by 'back-integrating'. There is an opportunity for Ethiopia to develop a strong capacity for managing international clinical trials. The Ethiopian Government can develop the appropriate legal framework and a conducive environment, and invite international innovator companies to build the capacity, skills and competencies needed to move Ethiopia along the chain. Participation by leading hospital centres and research institutes in global clinical trials provides the opportunity to work on cutting-edge medicines.

National companies able to supply Ethiopia, the rest of Africa and the world with low-cost GMP-standard generic products in high volumes should be the aim. This strategy has been shown to serve the public health needs in developing countries well. The national policy framework and incentives should be such that Ethiopian companies are able to immediately start producing generic versions of innovator products as soon as they go off patent, but also to produce in Ethiopia more recently approved drugs that are not patented in Ethiopia but are patented in the major generic-producing countries and are unavailable at affordable prices in Ethiopia and the surrounding region.

In order to support the establishment of national research-based companies, Ethiopia should consider establishing technology incubators that enable translational research on candidate technologies and products to be conducted and that could feed into local industry. As indicated earlier, there are numerous technological sectors that Ethiopia should explore as foundations for building local capacity. The decision on which sectors to focus on needs to take into account many factors, including human resources, access to technology and the market opportunity.

For example, establishing a fermentation-based incubator could permit industrial research on the production of some generic APIs, enzymes and bacterial antigens;

a bioreactor-based incubator could permit industrial research on the production of monoclonal antibodies and some viral vaccines; a formulation-based incubator could permit the development of novel formulations and delivery systems for drugs and vaccines, making these more applicable to local needs; and a diagnostics-based incubator could develop diagnostics for local and regional needs. Other platforms that could be considered include blood-derived products, medical devices and assistive devices. In addition, depending on the generic APIs being produced, the country may find that certain classes of chemical reagent are difficult to source and local production of these would free up bottlenecks in the supply chain. Incubators to establish intermediate active ingredients would support both generic manufacturing and the production of innovator drugs.

Such incubators require significant investment in terms of both capital and human resources, and it will not be feasible to create all at the same time. Therefore, a detailed analysis of each of these will be conducted and evidence-based prioritization developed.

Researching traditional medicines and natural products

Traditional medicine has been identified as one of the eight important components of the *National Health Policy of Ethiopia*. Although traditional medicine and herbal remedies play a significant role in the health care systems of the larger population of Ethiopia, little has been done to integrate them into the country's health care system. Research institutes such as the Ethiopian Public Health Institute and universities in Ethiopia have investigated the safety and efficacy of hundreds of herbal extracts. Research activities and documentation of the traditional practices and constituents of herbal remedies have been fragmented and uncoordinated. Furthermore, traditional medicine practice in Ethiopia is at present largely unregulated.

The strategic plan calls for research activities of traditional medicine and herbal remedies to be prioritized based on the health needs of the country. Research on traditional medicine and herbal remedies should be coordinated and integrated. Priorities should be given to those traditional medicines in wide use in Ethiopia and elsewhere.

Strategic objective 7

Attract foreign direct investment in the pharmaceutical sector

Ethiopia is one of the fastest growing economies in the world, and it is projected by Ernst & Young to grow into the third largest economy in sub-Saharan Africa by 2023, with a gross domestic product of US\$ 472 billion.⁶ In order to fast-track the development of the Ethiopian pharmaceutical industry, it will be critically important to attract foreign direct investment from international pharmaceutical companies, private equity and venture capital firms. Foreign direct investment plays a very important role in facilitating the transfer of technology, expertise and relevant capacity-building initiatives. Foreign direct investment catalyses quicker access to international markets by promoting adherence to international standards.

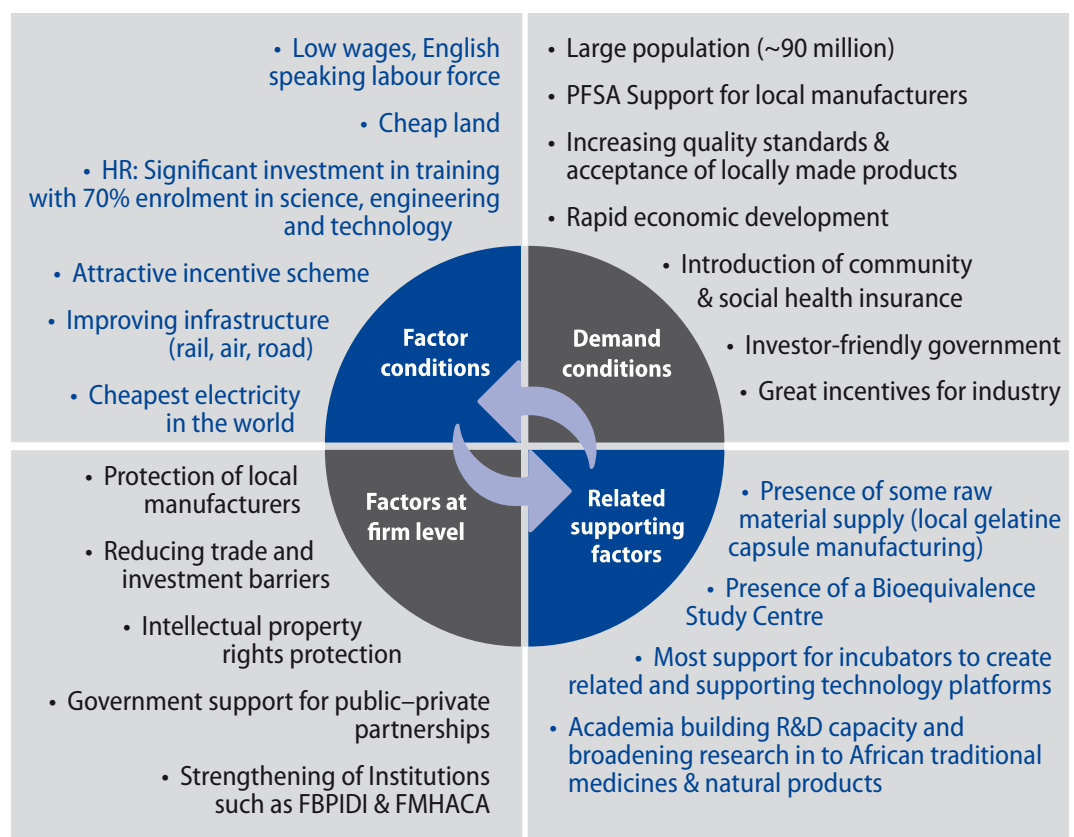
⁶ Negatu, Z. *Investing in Ethiopia: The Global Business Advisors' Perspective*. Corporate Council on Africa: 7th bi-annual business summit. Washington, D.C.: Ernst & Young; 2009.

According to the International Federation of Pharmaceutical Manufacturers & Associations, the ability to attract foreign direct investment in the pharmaceutical industry is determined by eight factors:

- viable and accessible local regional market;
- political stability and good economic governance;
- clear development priorities, and local preference for and protection of local manufacturing;
- effective regulatory authorities;
- availability of skilled workers;
- adequate capital markets;
- strong intellectual property rights and effective enforcement;
- quality of the relationship between industry and government, and the extent to which they are able to work together effectively for long periods of time.

Figure 5 explains Ethiopia’s attractiveness as an investment destination for pharmaceuticals.

Figure 5 Positive partners investment in pharmaceutical sector in Ethiopia



4. Five-year action plan, 2015–2020

The rationale for this strategy and action plan is to set a vision and direction for the growth and development of the pharmaceutical manufacturing sector in Ethiopia and an action plan for the next five years with clear milestones and indicators. The action plan coincides with the next five-year GTP-II (2015–2020).

The strategy and action plan are developed to facilitate progressive and dynamic advancement of existing and new pharmaceutical companies on a value chain.

The vision is to see the pharmaceutical industry systematically expanding, diversifying, integrating and innovating, and lifting with it associated industries, science and technology, human resource development and health sector development, all contributing to the establishment of a robust knowledge economy in Ethiopia. If implemented sustainably over a period of time, this strategy could transform the pharmaceutical sector in Ethiopia, which can then serve as an engine of growth and development. Such development, however, has to be guided and supported strongly by the Ethiopian Government, led by the private sector, and facilitated by foreign direct investment and international cooperation.

Table 2 shows the targets that can be achieved in the next 5 to 10 years (by 2020 and 2025) if this strategy is implemented effectively. Figure 6 presents succinctly what progress is envisaged until 2020 and 2025.

Table 2 Selected indicators of progress and targets

Indicator	Current	2020	2025
Pharmaceutical manufacturers with international GMP compliance (<i>n</i>)	2	5	20
Essential medicines purchased by PFSA from local manufacturers (%)	20	50	60
Number of WHO prequalified products produced locally	0	4	15
New manufacturing companies and local capital invested (<i>n</i>)	0	5	11
Joint ventures with international GMP compliant companies (<i>n</i>)	3	8	15
API manufacturers (<i>n</i>)	0	1	3
Export of locally produced medicines by GMP-complaint producers (US\$ million)	2	30	80
Phase IV clinical trials and post-marketing studies conducted in Ethiopia (<i>n</i>)	0	10	30
Phase II and III clinical trials conducted in Ethiopia (<i>n</i>)	0	3	10
Bioequivalence studies conducted by Bioequivalence Centre (<i>n</i>)	0	10	25
Studies on bioavailability of available essential medicines (<i>n</i>)	0	18	30
Locally developed traditional medicines on the market (<i>n</i>)	0	5	20
Natural products with identified active ingredients (<i>n</i>)	–	80	160
Clinical trials conducted on traditional medicines (<i>n</i>)	0	3	20
Incubators (detailed indicators will be developed) (<i>n</i>)	0	1	3
Number of graduates in industrial pharmacy and regulatory sciences	0	200	1500
Courses established in quality assurance/control, GMP, management and entrepreneurship (<i>n</i>)	0	10	50

Figure 6 Projected pharmaceutical value chain in Ethiopia in 2020 and 2025

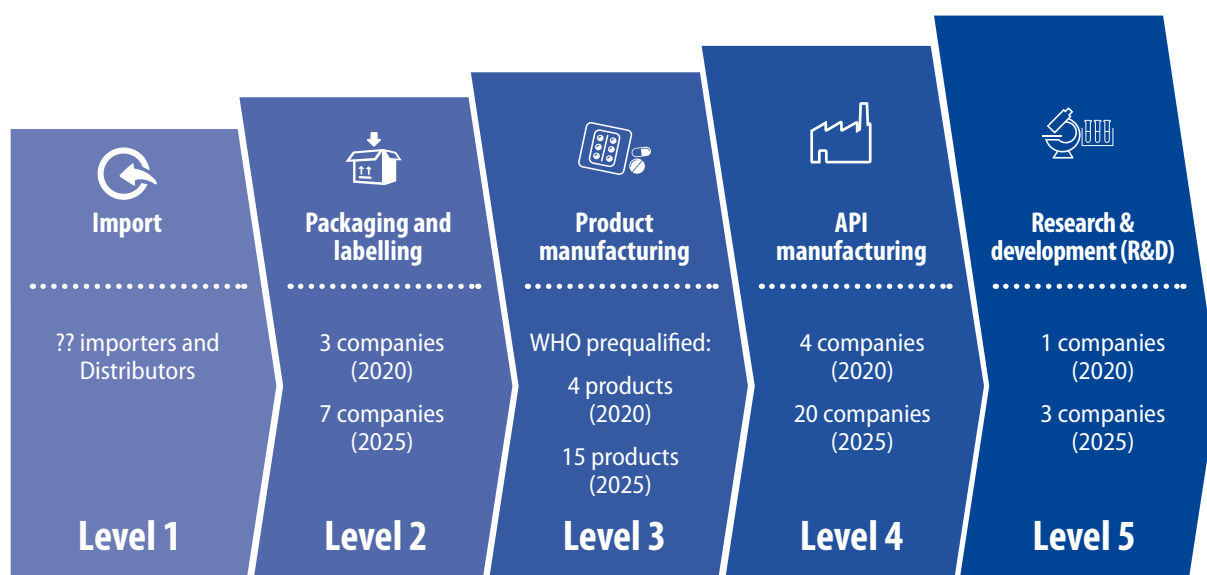


Table 3 Summary of five-year action plan necessary to achieve targets

Strategic objectives and action plan	2015	2016	2017	2018	2019
Strategic objective 1: Improve access to medicines through good-quality local production – implement the GMP Roadmap					
Pharmaceutical quality management implementation	X	X	X		
Premises renovation, reconstruction, re-design	X	X	X		
Production and quality control equipment location, adaptation and maintenance to suit operations	X	X	X		
Water plant installation and qualification	X	X			
Heating, ventilation and air-conditioning installation	X	X			
Validation and qualification of critical processes, key equipment			X		
Implementation of good documentation practice that meets cGMP	X	X			
All manufacturing companies are GMP-compliant				X	
Strategic objective 2: Strengthen the national medicines regulatory system					
Recruitment, retention of qualified personnel through offering competitive remuneration and other staff retention schemes	X	X	X	X	X
Establishing twinning programmes with stringent regulatory authorities, and staff rotation programmes to expose FMHACA staff to international best practices		X	X	X	X
Putting in place internal and external training programmes with international partners such as WHO, USFDA, EMEA, ICH, and local academia, to upscale the regulators	X	X	X	X	X
Supporting attendance in local and international training programmes for regulators to adopt international best practices and form linkages	X	X	X	X	X

Strategic objectives and action plan	2015	2016	2017	2018	2019
Strategic objective 3: Create incentives designed to move companies along the value chain and strengthen their operations					
Importing new products and moving to production: registration waiver for PMS plan, 5% preference and 5% prepayment by PFSA	X	X	X	X	X
Importing products for local packaging: 70% loan for GMP setup costs, 10% preference and 10% prepayment by PFSA, export incentives		X	X	X	X
Production under local GMP: 70% loan for GMP setup costs, 25% preference and 30% prepayment by PFSA, technology acquisition grant, 3 years income tax exemption, participation in pool procurement	X	X	X	X	X
Production under WHO GMP: 70% loan for GMP setup costs, 25% preference and 30% prepayment with PFSA, technology acquisition grant, 3 years income tax exemption, export incentives (voucher with Ethiopian Airlines for discounts, zero tax from export income for 5 years)	X	X	X	X	X
Production of WHO-prequalified medicines: 70% loan for GMP setup costs, 25% preference and 30% prepayment by PFSA, technology acquisition grant, 3 years income tax exemption, export incentives (voucher with Ethiopian Airlines for discounts, zero tax from export income for 5 years), support for international bids (e.g. Global Fund, PEPFAR), support for voluntary licensing and Medicines Patent Pool processes	X	X	X	X	X
Production of API and research and development: 70% loan for GMP setup costs, 25% preference and 30% prepayment by PFSA, technology acquisition grant, 3 years income tax exemption, export incentives (voucher with Ethiopian Airlines for discounts, zero tax from export income for 5 years), support for international bids (e.g. Global Fund, PEPFAR), support for voluntary licensing and Medicines Patent Pool process, research grants				X	X
Strategic objective 4: Develop human resources through relevant education and training					
HRD policy being implemented to develop competent skilled technicians, competent engineers, and scientists for pharmaceutical technology and production processes through national education and training systems	X	X	X	X	X
Curricula drafted/revised (e.g. industrial pharmacy, production management, regulatory science, supply chain management, industrial chemistry, synthetic medicinal chemistry) and offering both short- and long-term training programmes to support manufacturing sector with steady flow of skilled manpower	X	X	X	X	X
Enrolling sufficient number of students in science and technology disciplines		X	X	X	X

Strategic objectives and action plan	2015	2016	2017	2018	2019
Capacity-building of science and technology institutions to produce qualified technicians, engineers and scientists	X	X	X	X	X
Creating and maintaining workforce in manufacturing and service providing enterprises with knowledge and skills necessary to learn, adapt and use technology	X	X	X	X	X
In collaboration with technical vocational education and training institutions and universities, put exerted efforts to implement short-term and bridging courses to train students to bridge skills gap in manufacturing sector	X	X	X		
Providing managers and professionals with short-term training programmes in business management, leadership and GMP	X	X	X	X	X
Fostering university–industry linkages to enable students to get practical exposure in the industry and promote collaborative research	X	X	X	X	X
Strategic objective 5: Cluster development and production of active pharmaceutical ingredients					
Establishment of GMP-compliant packaging factories		X	X	X	X
Establishment of gelatine raw material production			X	X	X
Initiation of API production					X
Strategic objective 6: Create a research and development platform					
Vibrant R&D units developed (for APIs, synthetic, natural and herbal products, lead compounds, biologicals and excipients)					X
Strategic objective 7: Attract foreign direct investment in the pharmaceutical sector					
Promote Ethiopia and the sector to attract foreign direct investment	X	X	X	X	X

5. Government support for the implementation of the strategy and action plan

Government support is critical for the implementation of this strategy and action plan. More specifically, sustained support from the Ethiopian Government is needed in the following areas:

5.1 Strengthening of FMHACA

A strong, well-funded, well-resourced independent regulatory system is critical for the development of the Ethiopian pharmaceutical sector. The Ethiopian Government needs to make additional funding available for FMHACA to enable the organization to recruit and retain highly qualified staff and ensure continued capacity- and skills-building. Closer collaboration with WHO and other international partners is needed. FMHACA should be supported for full participation in the African Medicines Regulatory Harmonization processes.

5.2 Institutional development of FBPIDI

FBPIDI has to play a key role in the implementation of the strategy and action plan. An institutional development plan needs to be developed by FBPIDI. Its appropriate funding and staffing should be major priorities for the Ethiopian Government. FBPIDI needs to provide investment and financial advisory services to local and foreign investors, initiate relevant human resource development programmes, establish market intelligence, promote the Ethiopian pharmaceutical industry, facilitate technology transfer and product and technology acquisition, promote research and development, and facilitate implementation of GMP roadmap and advancement of companies on the value chain.

5.3 Financing of incentives

In the long term, it would be appropriate for the industry to access the FBPIDI services on a cost-sharing or reimbursable basis. In the short term, given the substantial challenges that the Ethiopian industry faces, and the competing demands for capital, it is proposed that the Ethiopian Government covers the costs of the early interventions. It is proposed that the Ethiopian Government and FBPIDI engage a team of experts to determine the costs of the investment needs to enable FBPIDI to carry out its mandate, and to work out the impact of the new proposed incentive scheme on the Ethiopian Government's budget.

5.4 Facilitating international and public–private partnerships

To realize the policy objectives of attracting foreign direct investment and associated transfer of technology, FBPIDI needs to undertake mapping of all potential local and international partners and investors and systematically reach out to them. Partners for international cooperation include agencies such as WHO, UNIDO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). For foreign direct investment, joint ventures, technology transfer and technical cooperation partnership with international pharmaceutical companies and investors (private equity/venture capital firms) would

be required. The assistance of technical agencies such as the International Society for Pharmaceutical Engineering, ICH and PIC/S is required. Cooperation needs to be strengthened with the New Partnership for Africa's Development and its African Medicines Regulatory Harmonization initiative and associated Africa-based regulatory centres of excellence for regulatory harmonization. Close partnerships are needed with local universities and research institutes. Experts in new API production technologies such as micro-reactor technology (continuous flow manufacturing) and biocatalysis are required for API production. Partnerships need to be forged with providers of international-standard and best-in-class pharmaceutical manufacturing and related equipment and services. Collaboration with IMS Health would permit the gathering of market data.

5.5 Development of biotechnology parks

The Government of Ethiopia has already embarked on a programme of action that will culminate in the creation of biotechnology parks, with research and development facilities, pilot manufacturing facilities and technology incubators. The Ethiopian Government needs to sustain this investment to root research and development culture in the pharmaceutical sector, including encouraging establishment of start-up biotechnology companies and assisting with commercialization of their innovative technologies.

5.6 Government adoption of the strategy and action plan and its dissemination

We believe a process should be led by the Ethiopian Government for eventual adoption of this strategy and action plan. This process involves taking on board all stakeholders, including the pharmaceutical industry and other private-sector actors, relevant government ministries and agencies, and development partners. There should be discussions with all stakeholders. After appropriate refinements, the Ethiopian Government should announce the strategy and action plan and use this as a basis for all its actions to develop the pharmaceutical industry in Ethiopia, with explicit benefits for the industry, economy and health.

6. Expected additional positive benefits of implementation of the strategic plan

As well as the positive outcomes described above, the implementation of this strategic plan by 2025 will also produce the following critical benefits:

- A strengthened, internationally recognized regulatory authority.
- FBPIDI as a strong and resourceful institute to oversee the implementation of this strategic plan.
- A bioequivalence study centre as a regional contract research organization.
- Development of a packaging cluster with potential for export of pharmaceutical, food, cosmetics and related packaging materials.
- Creation of a gelatine platform competitively supplying gelatine capsules in Africa and beyond, with a positive impact on farming and veterinary practices.
- Development of incubators leading to the production of antibodies for the production of diagnostics and monoclonal antibodies (by 2030).
- Expansion of the vaccine institute's product portfolio to include human vaccines for the local population.

This *National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025)* is a visionary programme of action. If implemented from a value chain perspective, and in a committed and sustained manner, by making the required investments and by forging strategic partnerships, it could transform the pharmaceutical sector in the country over the next 10 years. It can contribute to improving access of the Ethiopian people to locally produced, good quality essential medicines, and result in the creation of a research and development-based industry that would effectively contribute to skilled human resource development and to the growing knowledge economy. It has the potential to lift the whole sector and a number of associated industries and businesses along with it.

Federal Democratic Republic of Ethiopia

Ministry of Health

P.O. Box 1234

Addis Ababa, Ethiopia

Telephone: +251-11-551-7011

Fax: +251-11-551-9366

Email: moh@ethionet.et

<http://www.moh.gov.et>

Federal Democratic Republic of Ethiopia

Ministry of Industry

P.O. Box 6945

Addis Ababa, Ethiopia

Telephone: +251-11-553-4942, 515-8054, 550-7542

Fax: +251-11-553-4932, 553-4968, 553-4969

<http://www.moin.gov.et>