Launch of Ethiopian National Strategy and Plan of Action for Pharmaceutical Manufacturing Development and Improving Access

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Introduction

Currently around 2.2 billion people around the world live on less than US$2 each day\(^1\). Poverty is a major obstacle in the acquisition of health products and medical devices, especially in low- and middle-income countries (LMICs). While efforts have been made in recent years by the LMICs governments, international development agencies, non-governmental organizations and by the pharmaceutical industry, to increase access to medicines and health technologies, much more still needs to be done to reduce preventable morbidity and mortality. According to the World Health Organization (WHO) report *The world medicines situation*\(^2\), up to half of the population of African nations still lack access to essential medicines and health services.

Strengthening access is an essential prerequisite for achieving universal health coverage and other cross-cutting health indicators embedded within the Sustainable Development Goals (SDGs). Developing national capacities to develop and manufacture quality essential medicines is an important step, among many others, towards improving access in LMICs.

Local production can improve affordability of quality medicines. It has the potential to offer other advantages over imports. For example, by shortening related supply chains it can help reduce stock outs; and by expanding and diversifying the supply chain, it allows developing countries to secure access in response to growing demands. There is also some evidence to suggest that locally manufactured products are more successful in reaching rural populations than imported ones\(^3\).

Moreover, a competitive pharmaceutical sector can substantially contribute to social and economic growth in LMICs by spurring business and market development, human resource development and strengthening local research and development capacity.

Recognizing the advantages of local production for both public health and economic development, many LMICs have identified strengthening of local production as a priority, and are actively pursuing capacity strengthening in this area. *The Pharmaceutical Manufacturing Plan for Africa – Business Plan (PMPA-BP)* was endorsed by the heads of states in the African Union in 2012 and sets out a vision to strengthen the ability of Member States to produce high quality, affordable pharmaceuticals across all essential medicines.

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2 http://www.who.int/medicines/areas/policy/world_medicines_situation/en/
3 Mujinja et al, “Local production of pharmaceuticals in Africa and access to essential medicines: ‘urban bias’ in access to imported medicines in Tanzania and its policy implications”, Globalization and Health, 10:12, 2014
However, most African countries face significant challenges in developing pharmaceutical production capacity. These include: human resource capacity constraints; limited access to foreign currency; difficulties in raw material procurement; achieving good manufacturing practice (GMP) compliance; and achieving economic feasibility.

The local manufacturing initiative, implemented by the WHO and its partners in collaboration with the EU Commission and Bill and Melinda Gates Foundation (BMGF), explores, promotes and supports the feasibility of quality local production in developing countries. The initiative has been developed in the context of the WHO Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (GSPA-PHI) and aims to increase access to essential medicines, vaccines, medical devices, in-vitro diagnostic tests and blood products.

Under the auspices of the initiative, WHO is providing crucial technical assistance to the determined Government of Ethiopia to develop and implement a long-term vision for local pharmaceutical production that combines the concurrent goals of ensuring access to essential medicines and economic growth through a thriving pharmaceutical sector. The 10-year National strategy and 5-year plan of action for pharmaceutical manufacturing development in Ethiopia, developed by the Government of Ethiopia with WHO support, was launched in Addis Ababa on 14 July 2015.

4 http://www.who.int/phi/publications/gspa-phi/en/
The Strategy was launched by the Deputy Prime Minister of Ethiopia and participated by a large number of UN agency heads, development partners and high-level dignitaries.

“The plan will be a flagship program of the Ethiopian Second Growth and Transformation Plan…and it will contribute significantly to the country’s economic growth and social development.”

His Excellency Mr Demelke Mekonnen, Deputy Prime Minister of Ethiopia

“This national strategy and plan of action is a breakthrough for Ethiopia and a beacon of hope for Africa…I am excited to see countries in Africa improve their pharmaceutical industry, to improve access [and] to make pharmaceutical products affordable and of the quality that they deserve to have.”

Dr Margaret Chan, WHO Director General

“This is initiative is not just good for Ethiopia, but for Africa. [Ethiopia] should aim to be one of the Centres of Excellence on pharmaceutical manufacturing for the continent.”

Dr Nkosazana Dlamini-Zuma, African Union Chairperson

“I am very happy that UNIDO is one of the organizations [that] works together with WHO, UNAIDS and Global Fund, who have provided financing for distribution and also other [areas] related to the pharmaceutical industry in this continent.”

Mr Li Yong, UNIDO Director General
“This plan is not just for Ethiopia. There are 300 million people in East Africa, an incredibly big market out there for you. So you need to think about bigger markets…about regional markets and regional strategies moving ahead.”

Mr Steve Kayizi Mugerwa, African Development Bank Vice President

“Congratulations on a tripartite effort of the African Union, the WHO and the Government of Ethiopia who have put together an ambitious, intrepid and thorough plan for establishing an incredible manufacturing capacity in this country which is clearly long overdue but which has tremendous potential moving forward.”

Dr Tim Evans, Senior Director of Health Nutrition and Population Global Practice at the World Bank

“I think the idea of working to strengthen regulatory systems, pharmacovigilence is critical…I have no doubt that with the entrepreneurship and intelligence that [Ethiopia] will be able to build a strong pharmaceutical industry.”

Dr Seth Berkley, Gavi Alliance CEO

“We are committed to supporting the availability of markets…not just [to] 93 million people in Ethiopia, we [also] need a global market [and] we are committed to supporting you.”

Mr Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria

“I am very impressed with the strategy from a development perspective. Ethiopia’s plan certainly has the potential to provide drugs at an affordable price.”

Mrs Helen Clark, UNDP Administrator
On 14 July 2015, on the side-lines of the 3rd UN Financing for Development Conference in Addis Ababa, Ethiopia, the National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia was launched by the Deputy Prime Minister of Ethiopia, His Excellency, Demeke Mekonnen. The high-level launch event was attended by a number of global, regional and national development leaders, including WHO Director General Dr Margaret Chan, Chairperson of the African Union Commission Dr Nkosazana Dlamini-Zuma, United Nations Development Programme (UNDP) Administrator Mrs Helen Clark, African Development Bank Vice President Mr Steve Kayizi Mugerwa, GAVI CEO Dr Seth Berkley, Global Fund Executive Director Mr Mark Dybul, Senior Director of Health Nutrition and Population Global Practice at the World Bank Dr Tim Evans, United Nations Industrial Development Organization (UNIDO) Director General Mr Li Yong and United Nations Office for Project Services (UNOPS) Executive Director Ms Grete Faremo, among others.

The ambitious 10-year strategy aligns the objectives of health policy with those of industrial development policy. It aims to expand the pharmaceutical output of local manufacturers from 20% to 60% and to meet 50% of the local needs for essential medicines by 2020. It also aims to enhance export of locally produced medicines by GMP-complaint from current $ 2 million to $30 million by 2020 and $ 80 million by 2025.

In his remarks, Deputy Prime Minister Demeke emphasized: “This national strategy and plan of action will contribute significantly to the country’s economic growth and social development.” He also said that this strategy is going to be a flagship program of the next 5-year national development plan (GTP-II, 2015–2020). His sentiment was echoed by Ethiopia’s Minister of Health, Dr Kesetebirhan Admassu, who pointed out that the strategic plan will have far-reaching impact beyond access to essential medicine,
including development of a knowledge economy and enhanced national research and development capacity.

The strategic plan sets out detailed, time-bound goals for a range of inter-connected, complimentary activities aimed at transforming the pharmaceutical sector. Areas of focus include improving the quality of local pharmaceutical production to meet GMP standards, strengthening the national medicine regulatory system, developing human resources, creating a research and development platform, manufacturing of active pharmaceutical ingredients (API) and attracting foreign direct investments (FDIs) in the pharmaceutical sector.

African Union Chairperson, Dr Nkosazana Dlamini-Zuma and WHO Director General Dr Margaret Chan both commended the Ethiopia Government for launching the strategy, which is the inaugural translation of the vision of the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA) at the country level. Dr Chan further stressed the importance of the strategic plan by pointing out: “Access to medicines is an integral component of universal health coverage.” She invited representatives of other international and bilateral agencies to lend their support to the Government of Ethiopia in implementing the strategy.

Guest speakers at the launch event applauded the vision and comprehensive approach of the strategic plan. Dr Seth Berkley, CEO of GAVI, praised the focus on quality assurance and GMP compliance, an area that many developing country manufacturers struggle with. Mark Dybul, Executive Director of the Global Fund, added that sustainability of quality medical products depends on their access to adequate markets; he expressed commitment on behalf of the Global Fund to support the availability of national and global markets for Ethiopian manufacturers.

Dr Tim Evans, the World Bank’s Senior Director of Health, Nutrition and Population Global Practice, lauded the focus on the health workforce, which is often a blind-spot in public health. A highly trained health workforce is essential to all components of pharmaceutical production, such as maintaining the regulatory process, procurement systems, supply and distribution systems.

Helen Clark, Administrator of UNDP, commended the strategic plan to improve access to essential medicines, which is a key priority for UNDP. She emphasized the potential of the strategic plan to positively impact the future of Ethiopia and remarked that the national strategy and plan of action is very impressive from a development perspective.

All the speakers pledged commitment on behalf of their institutions to support the Government of Ethiopia in the implementation of the national strategy and plan of action on pharmaceutical manufacturing development in the coming years.
An overview of Ethiopia’s strategic plan

In recent years, the Government of Ethiopia has made significant investments in the country’s health sector. The health service coverage has increased from 30% to 89% in 2010 and 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 combating diseases such as HIV, tuberculosis and malaria, with Ethiopia achieving most of the Millennium Development Goal (MDG) 6 target on these diseases. Ethiopia has also achieved the MDG 4 goal to reduce the mortality rate for children under the age of five and has made significant progress in reducing maternal mortality rates.

The Ethiopian Government took a number of steps to incentivize development of the local pharmaceutical industry during the past five years that have resulted in positive impacts on foreign and local investments in the sector. However, despite a conducive policy environment and support from the government, the Ethiopian pharmaceutical industry still faces significant challenges. These include human resource capacity constraints, limited access to foreign currency, and difficulties in raw material procurement, among others.

WHO was requested by the government to provide assistance in developing a long-term vision and plan for the pharmaceutical industry that helps to overcome these challenges and ensure that the development of the industry is aligned with the public health goal of improving people’s access to quality assured, affordable medicines.

Seven key strategic objectives

In order to help transform the pharmaceutical sector in Ethiopia, seven key strategic objectives have been adopted. These are as follows:

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

The national strategic plan stipulates that the growth and development of the Ethiopian pharmaceutical manufacturing sector will be based on the ‘value chain’ approach. The pharmaceutical value chain is a spectrum of progressive pharmaceutical operations with increased technological complexity. At one end of the chain is the 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.

Currently, the vast majority of Ethiopian manufacturers are located at Level 1 of the value chain. The aim of this strategy is to assist local pharmaceutical companies and other crucial sectoral actors to move along the value chain and to increase the number of players at every step.

In 2012 Ethiopia adopted a Roadmap for a pragmatic, three-phased approach to improving the GMP-compliance status of pharmaceutical manufacturers in the country. Under this Roadmap all manufacturers in Ethiopia are expected to become compliant with WHO GMP standards by 2018.

The crucial role of government support

Ethiopia’s national strategy and plan of action is envisioned as being guided and supported by the Ethiopian Government, led by the private sector, and facilitated by foreign direct investment and international cooperation. Ethiopia’s national strategic plan envisions sustained support from the Government in the following areas:

- Maintaining a well-funded, well-resourced, independent regulatory system.
- Ensure continued development of the Food, Beverage and Pharmaceuticals Industry Development Institute (FBPIDI), which is tasked with overseeing and coordinating the implementation of the national strategy and action plan.
- Financial support to the FBPIDI in the early years.
- Facilitating international and public–private partnerships.
- Catalysing research and development in the Ethiopian pharmaceutical sector, including encouraging establishment of start-up biotechnology companies and assisting with commercialization of their innovative technologies.
- Leadership in adopting the strategy and action plan and its dissemination through continued dialogue with all stakeholders, including the pharmaceutical industry and other private-sector actors, relevant government ministries and agencies, and development partners.
WHO’s approach to supporting pharmaceutical manufacturing development

The WHO local manufacturing initiative aims to increase access to essential medicines, vaccines, medical devices, in-vitro diagnostics and blood products in developing countries. It is implemented with support from the European Commission (EC) and BMGF and in collaboration with a broad range of partners.

Developed in context of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), the local manufacturing initiative supports the development of local production of medical products in developing countries, with a particular focus on Africa. In doing so, the project supports local initiatives in developing countries and implementation of regional frameworks such as the Pharmaceutical Manufacturing Plan Africa – Business Plan (PMPA-BP). Crucially, the initiative provides targeted technical assistance in areas where developing countries face particular challenges, such as GMP compliance, multi-sectoral policy coherence and economic feasibility of the pharmaceutical industry.

A framework for policy coherence for local production to improve access

Phase I of the project (2009–2012) focused on identifying the main challenges and obstacles to local production of medical products relevant to public health needs of developing countries and related transfer of technology.
A framework for local production for access to essential medical products developed during Phase I of the project highlights the objectives of a typical national health policy/national medicines policy and national industrial policy.

**Industrial policy**

**Main objective:** To develop a viable local industry that is competitive, reliable, innovative, productive and responsible.

**Key factors from medical products development perspective:**
- **Competitive:** offers better prices.
- **Reliable:** complies with quality standards; ensures steady supply.
- **Innovative:** aims for technological change and invests in research and development.
- **Productive:** contributes to national economy through employment generation; human resource development; and supporting associated industries and suppliers.
- **Responsible:** shows corporate responsibility towards social conditions and environment.
- **Strategic:** balances current and future demands.

**Health policy**

**Main objective:** To promote health for all through universal health coverage in terms of prevention, treatment and rehabilitation.

**Key factors from access to medical products perspective:**
- **Universal access to medical products:** through public sector supply system and/or social protection programmes.
- **Availability of essential medicines and diagnostics:** in appropriate formulations suitable for local use.
- **Affordable prices:** for government procurement agencies and for out-of-pocket expenditures by people.
- **Quality assurance:** through effective regulation.
- **Uninterrupted supply:** of essential medical products.
- **Rational selection and use:** by health managers and clinicians.

**Government support of local production for access to medical products**

**Direct support to reduce the cost of manufacture:** Grants, subsidies, soft loans, provision of land, tax and duty exemptions for imported inputs for local production of essential medical products.

**Indirect support of local production for improving access:** Invest in strengthening regulation of national medical products; develop national priority lists of medical products; improve the financing of health services for expanding the domestic market; facilitate access to foreign markets; facilitate development of regional pooled procurement mechanisms; encourage regulatory harmonization; introduce appropriate pricing policies; facilitate relevant transfer of technology; support incremental innovation and production; develop appropriate intellectual property regimes; develop appropriate investment policies and facilitate joint ventures; facilitate international cooperation for local production.

**Shared goals of health and industrial policies relating to local production for improvement in access to medical products**

- Strategic selection of essential medical products for local production.
- Pricing of locally-produced products that governments and people can afford.
- Strict compliance to quality standards by the manufacturers and effective national regulatory authorities.
- Health security – an uninterrupted supply of essential medicines.
- Innovation for development of products that are more suitable for local conditions.
Phase II of the project (2012–2015) aimed at building capacity and developing learning resources in a wide variety of areas. These include: development of a capacity-building manual on policy coherence between various ministries; development of a web-based information and knowledge repository on local production and technology transfer; methodology to measure the impact of local production on access to medicines; assistance for local production of selected essential medicines, vaccines, bio-therapeutics, in-vitro diagnostics and blood products; and advocacy for quality local production for improving access in developing countries.

During this phase, WHO has worked in close collaboration and dialogue with the Joint United Nations Programme on HIV/AIDS (UNAIDS) and UNIDO to undertake a strategically important joint study on forecasting future demand for health technologies in Africa, and the role of local manufacturing to ensure future commodity security.

The launch of the Ethiopia National Strategy and Plan of Action for Pharmaceutical Manufacturing marks a significant achievement for WHO, and it will continue to assist the government of Ethiopia, in collaboration with bilateral and international partners, to implement this strategy over the coming years.

Future directions

As Africa grows economically, more and more African governments are showing political commitment towards strengthening pharmaceutical manufacturing as way to fulfil their dual mandates of achieving universal health coverage and robust economic development. Local manufacturing of medicines and health technologies is a complex undertaking and high-level government requests to WHO for technical assistance in strengthening local production are increasing. WHO is seen as an organization that can not only help national governments formulate a clear, holistic and long-term vision, but it also brings the added value of methodically linking local production to improvements in access to essential medicines and health technologies.

1. Assisting governments to develop long-term coherent national strategies for pharmaceutical manufacturing development using the value-chain approach.
2. Assisting governments in developing and implementing time-bound national GMP roadmaps for upgrading national pharmaceutical and health technology industries to ensure quality manufacturing.
3. Assisting governments in developing time-bound incentives for local pharmaceutical companies to develop and compete, and meet the local medicine needs.
4. Facilitating north–south and south–south transfer of technology between companies for important essential medicines and other health products that address priority public health needs in developing countries.
5. Support governments in their efforts to develop appropriately educated, trained and skilled human resources for pharmaceutical and health technology manufacturing, including in the area of regulatory sciences.
6. Supporting reliable collation of market data and monitoring the impact of local production on access to medicines and other health technologies.
The 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, 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.

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