



SUPPORTING PHARMACEUTICAL PRODUCTION IN AFRICA

Global UNIDO Project: Strengthening the local production of essential medicines in developing countries through advisory and capacity building support




UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION





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THE PROJECT AT A GLANCE

Goal:	Increase the capacity of the local pharmaceutical sector in developing countries to supply safe, efficacious and affordable medicines
MDG:	6. Combat HIV/Aids, Malaria and other Diseases 8. Develop a Global Partnership for Development
Theme:	Advancing economic competitiveness
Donor:	Government of Germany, UNIDO
Partners:	Ministries of Health and/or Ministries of Industry/Trade, pharmaceutical sector
Budget:	Phase 5: EUR 2,340,000 Total: EUR 10,377,000
Status:	Phase 5: 2015-2016
Duration:	2006-2016
Project outreach:	AFRICA Burundi, Democratic Republic of Congo, Ethiopia, Ghana, Kenya, Lesotho, Nigeria, Senegal, South Africa South Sudan, Tanzania, Uganda, Zambia, Zimbabwe ASIA Myanmar, Viet Nam

BACKGROUND

Many people die because they do not have access to safe and efficacious medicines

Many deaths could be prevented if safe and efficacious medicines were readily available to treat patients especially in Africa. Not only the lack of access to affordable medicines is a problem also sub-standard and counterfeit medicines on the market pose a major threat to public health.

The pharmaceutical sector has a special role as its products, safe and efficacious medicines, are important in providing effective health care for the population. Many countries therefore see a need to enhance the capabilities of this industry locally. The pharmaceutical sector, for example, is a priority sector in the Accelerated Industrial Development Agenda (AIDA) for Africa that has the objective to lift Africans out of poverty.

73% of the estimated 1.6 million people dying each year from AIDS are Africans. With reliable access to the right medication people living with HIV can lead productive lives.

A study by USP and FDA in Ghana has shown that up to 70% of medicines needed to save the lives of young mothers are sub-standard. With safe and effective medicines readily available many maternal deaths can be prevented.

Local pharmaceutical production can have many benefits

Local production can be a source of quality assured medicines and supplant substandard & counterfeit medicines that presently enter the international supply chains and are hard to control for resource strapped regulators.	Local production can contribute to preventing discontinuities of medicines supplies (stockouts) that can be regularly observed in many developing countries.	Local production promotes local value addition and generates income.	Local production can create jobs and as a knowledge intensive industry lead to technology spill overs.	Local production can service the expanding markets that are brought about by a growing population and the advance of non-communicable diseases in many developing countries.	Local production can be a step towards sustainability of treatment programs and prepare the grounds for maintaining access to medicines beyond the current era of drug donations.
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“*The time for Africa to break its dependency on foreign imports is now. The local manufacture of pharmaceuticals in Africa is an opportunity to develop a broader manufacturing and knowledge-based economy.*”

Michel Sidibé, UNAIDS Executive Director (at the Seventh Joint African Union (AU) Conference of Ministers of Economy and Finance and the Economic Commission for Africa (ECA) Conference of African Ministers of Finance, Planning and Economic Development, Abuja, Nigeria, 25-30 March 2014)

The many challenges facing the local pharmaceutical industry require a holistic approach.






The challenges, however, the local pharmaceutical industry faces in upgrading facilities and production practices in Africa towards international standards include the requirement for large capital investments and the need for highly specific expertise, specially trained workers, increased regulatory oversight and an overall business environment that allows for the industry to develop.

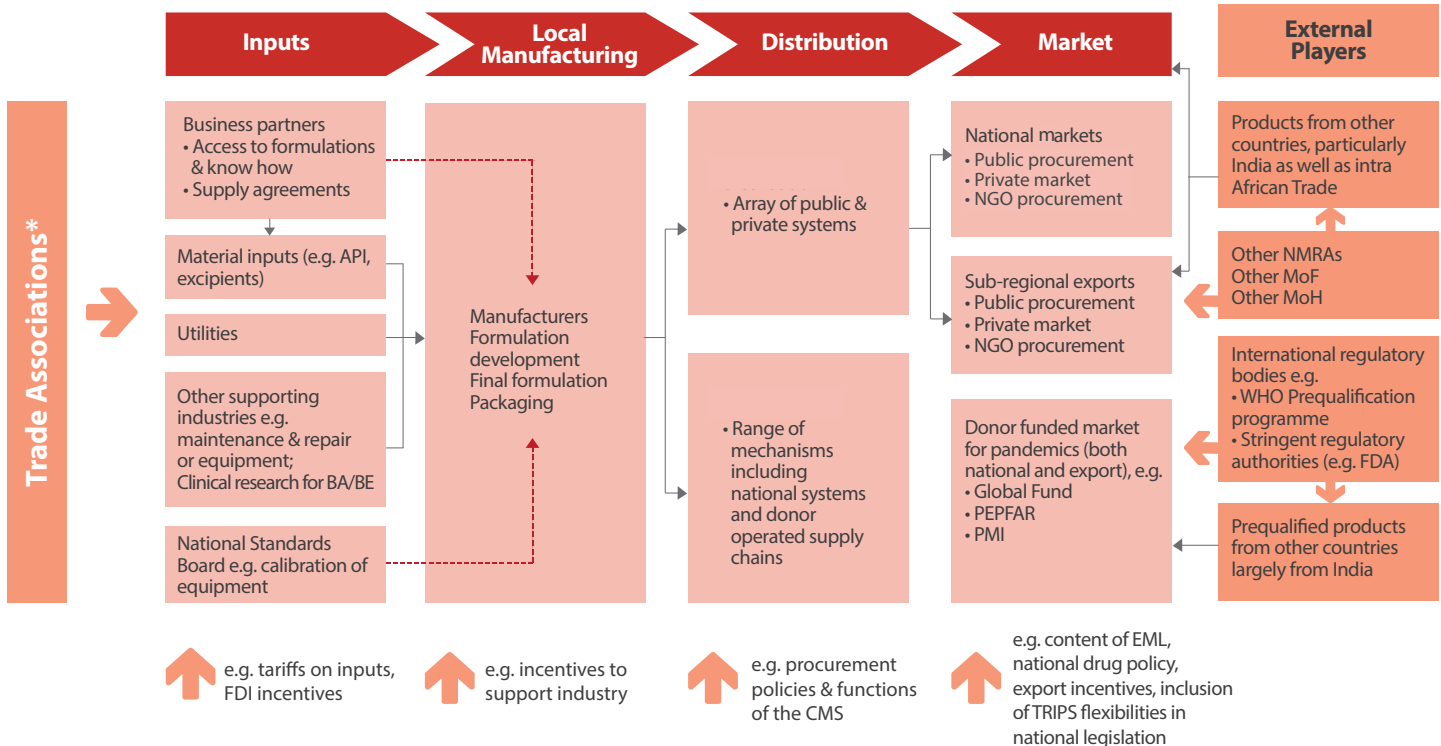
Due to this complex set of challenges UNIDO adopts a holistic approach working towards an enabling environment and suitable institutional capacities so that the private sector can reach its potential.

UNIDO aims at increasing the capacity for local production of essential medicines to supply safe, efficacious and affordable medicines.

PHARMACEUTICAL MANUFACTURING SYSTEM

National Medicines Regulatory Authorities

- 
 e.g. oversight of clinical trials and GLP
- 
 e.g. dossier review, plant inspection, GMP certification & monitoring
- 
 e.g. oversight and enforcement of GDP and GWP
- 
 e.g. pharmacovigilance and adverse events reporting system
- 
 e.g. dossier review, plant inspection & GMP certification and monitoring



* = Note trade associations can perform a range of functions on behalf of their members to influence the business environment, such as dissemination of best practice, partnership brokering, lobbying

Key: → = Material flows
 - - - → = supply of services/access to knowledge
 → = influence, including through regulatory oversight, policy, lobbying

PROJECT APPROACH

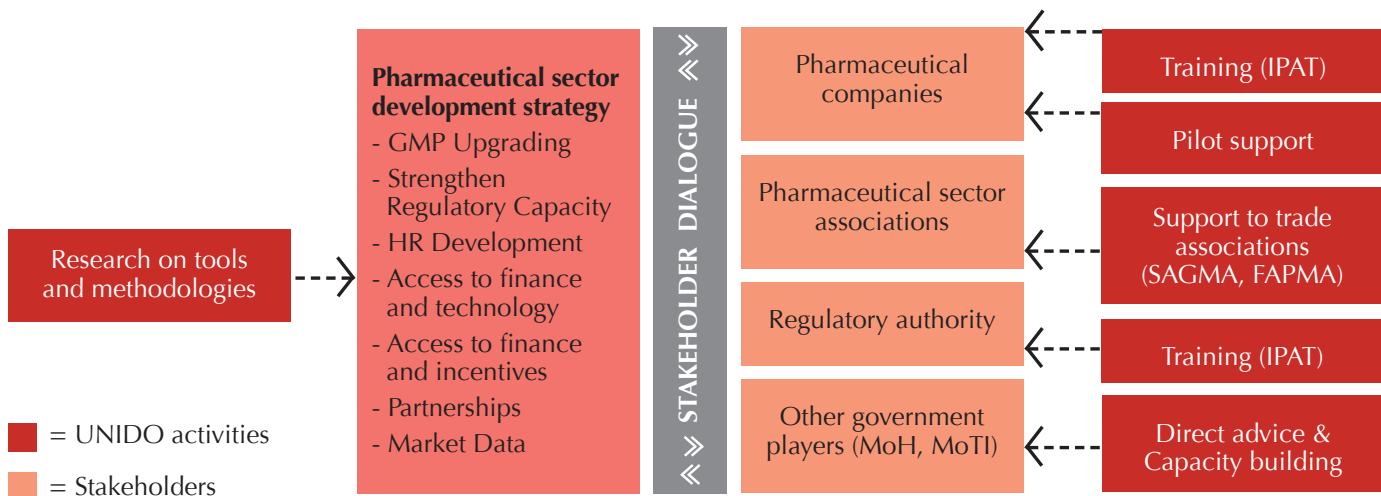
UNIDO believes that real progress in as complex a sector as the pharmaceutical industry can only be achieved if the main actors work together.

Therefore working with the main stakeholders towards a shared development strategy is the core of UNIDO's work. UNIDO uses a consultative mechanism to arrive at a shared vision and elaborate together with the key stakeholders a strategy to move towards that goal and take the sector forward. The strategy touches on many areas and issues that need to be addressed in a coordinated manner in order to improve the operating environment for pharmaceutical manufacturers.

To support this process UNIDO is working on tools that can be adapted further to the specific situation like the GMP Roadmap, a methodology to diagnose in- efficiencies of production and is conducting research on incentives. This research also involves work at the plant-level where experts have offered bespoke advice to companies on topics like GMP and production efficiency.

To enable the pharmaceutical industry to constructively engage with the public sector beyond the project's duration, UNIDO is strengthening pharmaceutical manufacturer associations to fulfil an advocacy function and deliver services to their members. As a contribution to developing personnel specialized in industrial pharmacy, UNIDO is supporting the Kilimanjaro School of Pharmacy in Moshi, Tanzania to offer the Industrial Pharmacy Advanced Training which now even forms the basis for a Master's degree.

UNIDO's approach



PHARMACEUTICAL SECTOR DEVELOPMENT STRATEGIES

Strategies for pharmaceutical industry development – Getting the industry and the public sector to push together

UNIDO has been working in Ghana and Kenya to assist in the formulation of multi-stakeholder strategies to develop the local pharmaceutical industries. In parallel UNIDO is conducting technical work to develop solutions that support and substantiate the implementation of these strategies.

Pharmaceutical Sector Development Strategy Ghana

The Ministry of Trade and Industry (MoTI) in Ghana has identified the domestic pharmaceutical industry as a priority sector. Supported by UNIDO, the Ministry engaged a broad range of stakeholders, including the private sector, other government ministries such as the Ministry of Health and the Ministry of Finance and Economic Planning, the Food and Drugs Authority (the national regulator), the Pharmaceutical Society of Ghana, international partners and universities in a consultative process to discuss the future direction of the industry in 2009. The stakeholders in Ghana articulated a shared ambition for the industry:

“Through working together we will build a center of excellence in Africa, delivering high-quality affordable medicines for all.”

This stated ambition was developed through a multi-stakeholder consultative process that included an initial roundtable, chaired by the Honorable Minister for Trade and Industry, and the subsequent formation of a number of sub-committees to deliberate on specific issues. These sub-committees identified critical challenges facing the industry, and also suggested potential approaches to address these.

A conceptual strategy document, building on the work of these groups as well as contributions from individual stakeholders, put forward a holistic approach for the development of the pharmaceutical sector in Ghana.

This conceptual strategy was reviewed and approved by the Ministry of Trade and Industry and the Ministry of Health in late 2010. Further work to flesh out the details of the conceptual strategy was undertaken, in order to produce an operational strategy which includes strategy components.

This groundwork has put Ghana in the position of a pilot country for the Business Plan to implement the Pharmaceutical Manufacturing Plan for Africa (PMPA). Following the invitation by President Mahama a taskforce composed of UNAIDS, UNIDO, WHO and other international agencies under the auspices of the African Union Commission laid the foundations for the implementation of the PMPA Business Plan.

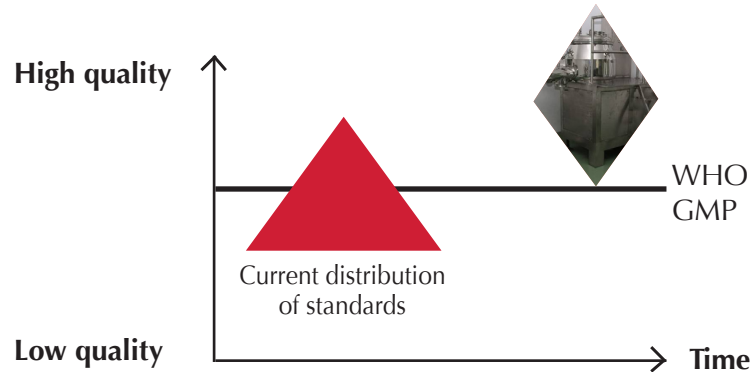


Kenya GMP Roadmap

UNIDO together with stakeholders in Kenya has developed the Kenya GMP Roadmap. It was launched in December 2014.

The Roadmap sets out a multiyear path leading to the implementation of higher quality requirements, based on WHO GMP standards. This will lead to the strengthening and upgrading of the pharmaceutical industry, positioning it to deliver higher quality medicines meeting both the higher local, and wider international quality standards. Implementation of the Kenya GMP Roadmap will involve continued collaboration between the local regulator, the PPB, and industry. The Roadmap was designed and developed through a consultative process involving both the local manufacturing industry and the Government of Kenya. Key local groups which participated in the process include the Pharmacy and Poisons Board (PPB), the Ministries of Health (MOH) and of Industrialization and Economic Development (MOIED), the National Quality Control Laboratory (NQCL) and the manufacturers themselves, including their representation through the Federation of Kenyan Pharmaceutical Manufacturers (FKPM) as well as individual non – FKPM members.

The plan recognizes the need for capacity building and acknowledges the challenges which will be faced during the upgrading process. The Kenya GMP Roadmap is a central component in the wider strategy for the improvement of the local manufacturing industry, as laid out in the Kenya Pharmaceutical Sector Development Strategy (KPSDS) document which was published by UNIDO in 2012.



Supporting the revitalization of Zimbabwe's pharmaceutical industry

The pharmaceutical industry in Zimbabwe has suffered in recent years due to market reverses and reduced investment. To put the industry on a more positive trajectory, UNIDO has recently started to assist the government in spearheading a bold revitalization program building on the findings of a Pharmaceutical Sector Profile published in 2011 and supplemented by expert assessments in 2014.

The pharmaceutical sector has been earmarked as a priority sector for development in the country's Industrial Development Policy (IDP 2012-2016) as well as in the Zimbabwe Agenda for Sustainable Socio-Economic Transformation (ZIM ASSET, Oct. 2013-Dec 2018). This is viewed as one meaningful way to address the access-to-medicines challenge.

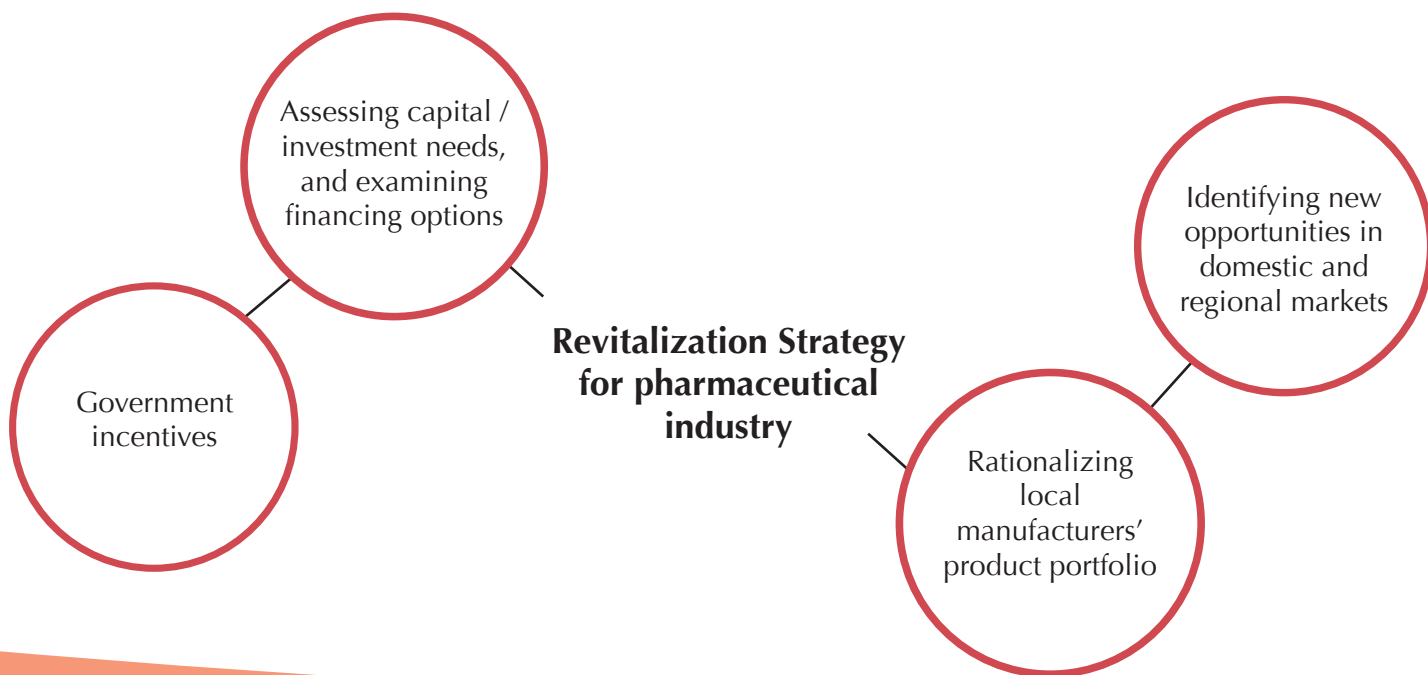
Priority measures to revitalize the pharmaceutical industry include:

- Redress duties on imported raw materials used in pharmaceutical manufacturing
- Expedite market access for local medicines
- Encourage/incentivize public procurers to source locally
- Assist industry to tap into procurement of medicines by private medical insurers

Defined goals for a comprehensive longer-term strategy are to:

- Enable the private sector to produce more of the country's requirement of essential medicines
- Improve the sector's contribution to Zimbabwe, in terms of social and economic benefits.

This Sector Development Strategy will encompass the key elements shown below:





PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA

In 2011, the AUC Commissioner for Social Affairs invited UNIDO to form a partnership to accelerate the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA) – an initiative initially endorsed by AU Heads of State and Government of the AU at the 2007 Accra summit.

From Plan to Action – the PMPA Business Plan

The AUC’s PMPA Business Plan, which was developed with UNIDO assistance, was endorsed by AU Heads of State and Government at their 2012 summit.

The AUC has invited UNIDO to take the lead in developing the consortium to implement the PMPA Business Plan; UNAIDS and WHO leaders are strongly behind the plan and UNIDO is now collaborating closely with these organizations and others.

Pharmaceutical Manufacturing Plan for Africa (PMPA) initially endorsed by AU Heads of State and Government at the Accra summit

2007

PMPA Business Plan, which was developed with UNIDO assistance, was endorsed by AU Heads of State and Government at the Addis Ababa summit

2012

With executive heads of 3 heads UN agencies commit to work together on PMPA BP implementation in a joint editorial in the WHO Bulletin

2014

2011
The AUC Commissioner for Social Affairs invited UNIDO to form a partnership to accelerate the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA)

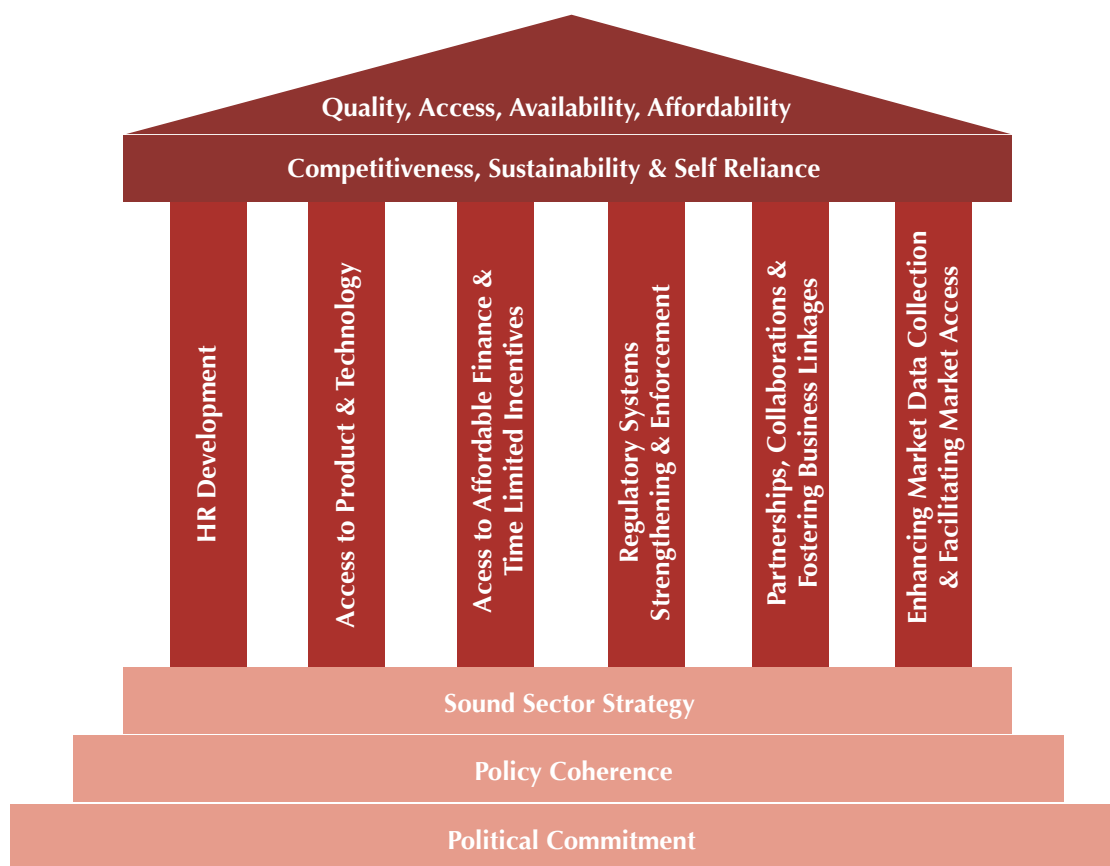
2013
Consortium mission to Ghana as a pilot country for PMPA BP implementation following an invitation from President Mahama

Vision

To develop a competitive and enduring integrated manufacturing pharmaceutical industry in Africa, able to respond to the continent's need for a secure and reliable supply of quality, affordable, accessible, safe and efficacious medicines.

The PMPA BP offers an approach and a framework for African countries to develop their pharmaceutical industry. It is based on the principle that there is no one size fits all solution and the individual country's strategy will be tailored by drawing on a comprehensive package of solutions.

The intervention logic of the PMPA BP – Key PMPA BP Success Factors



The PMPA Business Plan represents a historic opportunity: the topic of promoting local pharmaceutical production is now a top priority for many donors and multilateral organizations; UNIDO is well positioned to play a lead role in this high profile area and will continue to build strong relationships, further develop technical solutions and seek to expand its focus to include other life science products. An estimated US\$50 million is required for the first five years of the PMPA BP implementation.

Through the work with the AUC on the PMPA Business Plan, UNIDO has demonstrated that it is a thought leader in the realm of local pharmaceutical production; furthermore, through its recommendations and follow-up activities, it has displayed a willingness to work with partner organizations that have complementary skills and mandates both within the UN system and beyond. The need to work in partnership with other organizations is central to UNIDO's approach and reflects the complexity of the sector and recognition that multiple dimensions that transcend mandates need to be addressed in a coordinated manner for high quality essential medicines to be produced and for the industry to be sustainable. To that end UNIDO is working closely with WHO, UNAIDS and the African Union Commission to implement the AU's PMPA Business Plan.

“*Together, we can develop the pharmaceutical industry in Africa; this will contribute to improved public health and will help alleviate human suffering. In line with our mandate to promote inclusive and sustainable industrial development, we will support efforts to enhance public health and enable populations to be increasingly economically productive through the development of viable high-quality industries in this important knowledge-intensive sector in Africa.*”

LI Yong, Director General of UNIDO

TRAINING

Skills for a stronger industry - Industrial Pharmacy Advanced Training

By March 2014, 70 graduates from 8 African countries completed the Industrial Pharmacy Advanced Training (IPAT) at the Kilimanjaro School of Pharmacy in Moshi, Tanzania. It provides state of the art knowledge on pharmaceutical manufacturing and regulatory affairs to professionals from the pharmaceutical manufacturing sector, regulatory agencies and universities. The modular nature of the course, which includes a laboratory practical, is particularly well suited to reach the relevant people for a training on the job.

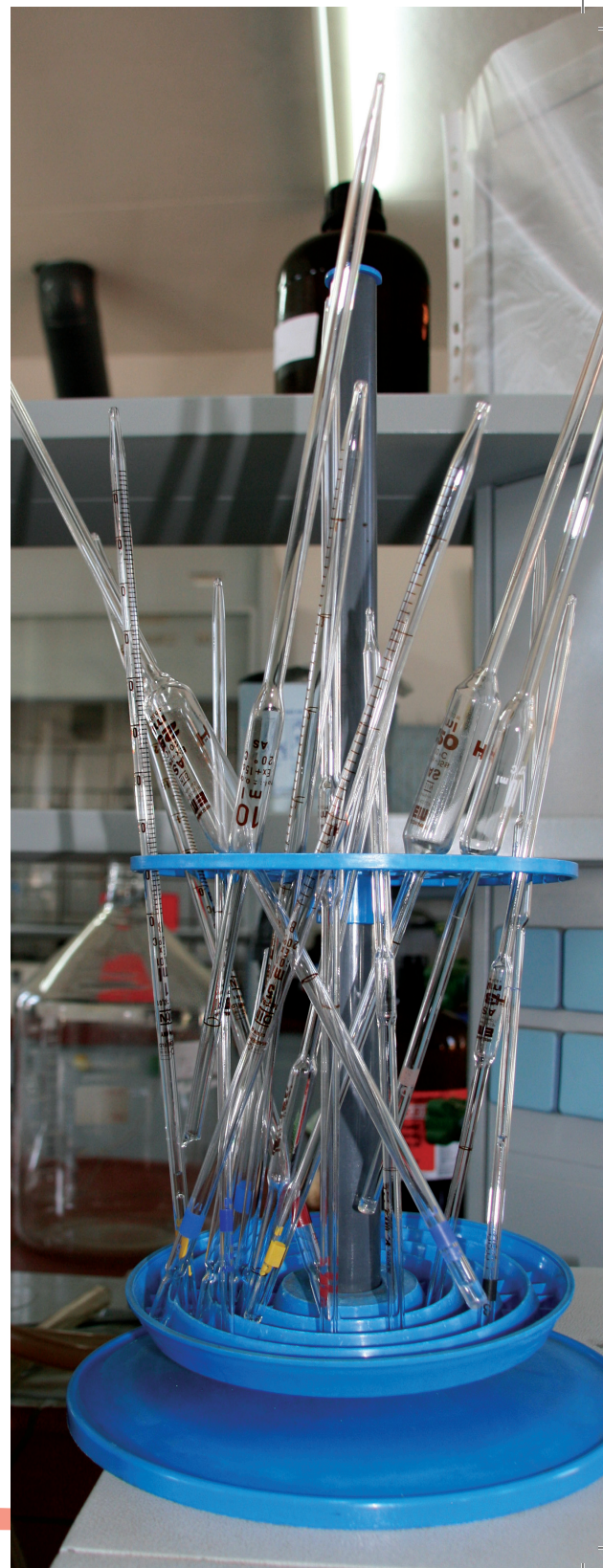
“*The entire course was interesting and insightful; Gives me an edge in my practice as industrial pharmacist.*”

IPAT Participant 2012-2014

The course is an important building block in improving the professional skills available in the pharmaceutical sector in Africa to allow for the development of the sector.

“*Uganda National Drug Authority would wish to acknowledge UNIDO's noble cause of improving knowledge and skills in industrial pharmacy amongst Ugandan professionals and Africa at large (through facilitating the Industrial Pharmacy Advanced Training that takes place at Kilimanjaro School of Pharmacy in Moshi, Tanzania). The few modules so far taken by our officers have been very beneficial to them and the organization and a great deal of value has been added to their work outputs.*”

Gordon K. Semantiko, Executive Secretary, National Drug Authority, Uganda





Taking training to the next level – the Master's program

In 2014 Kilimanjaro School of Pharmacy, Purdue University, Merck Foundation and UNIDO teamed up to take training for the pharmaceutical sector in Africa to the next level. During the next two years 25 students from pharmaceutical manufacturers, regulatory agencies and universities have the opportunity to obtain a Master's in Biotechnology, Innovation and Regulatory Science from Purdue University. The mix of 11 live and on-line courses is a unique opportunity to get a professional qualification of international renown and further specialize in industrial pharmacy.

Master's Courses

Industrial Pharmacy Advanced Training (IPAT)

1. Drug Development
2. Good Regulatory Practice
3. Molecular Basis of Manufacturing
4. Quality Management Audits and Inspections
5. Documents and Dialogues of Drug Development and Regulation
6. Measurement and Evaluation in Industry and Technology
7. Quality and Productivity in Industry and Technology
8. Project Management in Industry and Technology
9. Analysis of Research in Industry and Technology
10. Technology from a Global Perspective
11. Global Supply Chain Management

PHARMACEUTICAL SECTOR ASSOCIATIONS

Helping industries to make themselves heard – supporting the formation of trade associations

In the Southern African Region UNIDO has assisted the formation of the Southern African Generic Medicines Association (SAGMA).

The association's role is two-fold:

- to engage in advocacy for the sector in the region and
- to provide services to its members

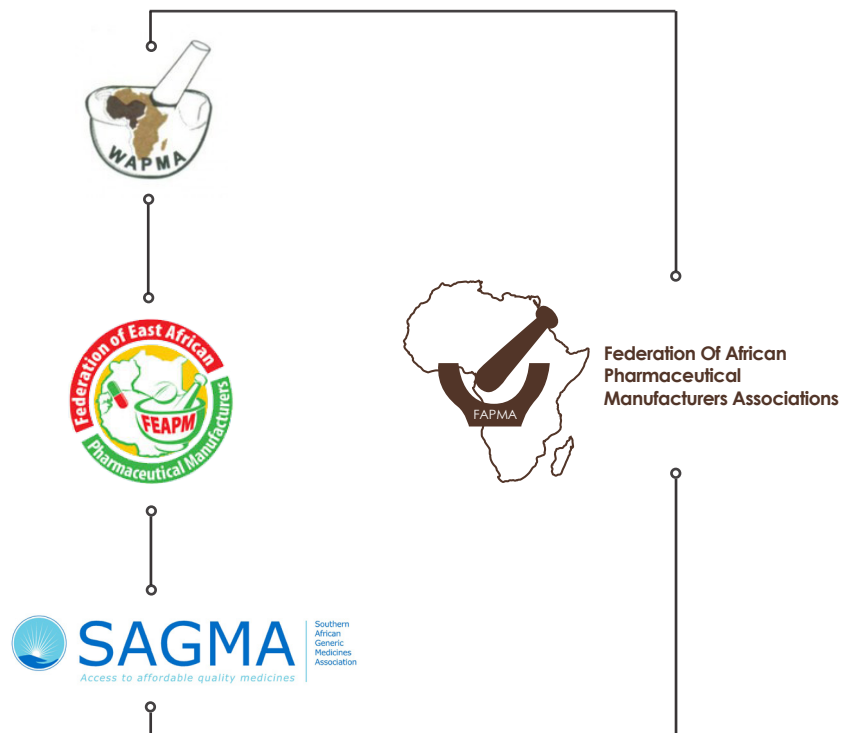
UNIDO continues to support the development of this association towards self-sufficiency.

Speaking for the industry at the continental level – FAPMA

In 2012 the three regional pharmaceutical manufacturers associations came together to form the Federation of African Pharmaceutical Manufacturers Associations (FAPMA). The umbrella association, which represents the pharmaceutical industry on the African continent, was launched with UNIDO support in 2013. FAPMA represented the industry at 4 high-level events in 2013. FAPMA is the voice of the pharmaceutical industry in Africa and is highly regarded as a private sector partner.

“*We are united behind the common goal of developing a self-sustaining pharmaceutical manufacturing industry in Africa that, not only contributes to the reduction of disease, but also drives economic development on the continent.*”

Paul Lartey, Chairman of FAPMA in his inauguration speech January 2013



IN FOCUS 2015

At the continental level UNIDO will continue to support the AUC in the implementation of the Business Plan to operationalize the Pharmaceutical Manufacturing Plan for Africa (PMPA). UNIDO is leading a core group of agencies, whose Chief Executives have explicitly committed to the cause.

“*The task of ensuring reliable and sustainable manufacturing of medicines and other health technologies is a complex undertaking that requires highly accountable and strategic partnerships. UNAIDS, UNIDO and WHO are working closely with the AUC to better coordinate inter-agency efforts to support African governments.*”

Michel Sidibé, Executive Director of UNAIDS, Li Yong, Director General of UNIDO, Margaret Chan, Director General of WHO; Joint Editorial, Bulletin of the World Health Organization, June 2014

At the country level work will move ahead in Ghana, Kenya and Zimbabwe

In Ghana early implementation of the AUC's PMPA BP will progress based on the strategy developed through a multi-stakeholder consultative process escorted by UNIDO. As part of the broader workplan UNIDO will advise on priority areas such as mobilizing investment capital for the sector, business linkages, licensing, access to technology and know-how and appropriate incentives for the pharma industry. UNIDO will coordinate with international and national partners to accelerate this work.

In Kenya efforts in 2015 will focus on kicking-off the Kenya GMP Roadmap, a five-year plan to

bring the pharmaceutical manufacturing industry to WHO GMP standards. Baseline assessments at all active manufacturers will set the scene and quantify upgrading requirements and inform further work. To support companies in their upgrading efforts trainings will address key bottlenecks and incentives will be defined.

“*It is envisaged that at the end of the implementation of this plan the local pharmaceutical manufacturing industry will be able to meet local demands as well as increase its presence on the international market, provide more employment and contribute to availability of foreign exchange through reduced imports. Importantly, the Kenyan population will be healthier as a result of accessing high quality medicines produced according to WHO standards of production.*”

Adan Mohamed, EBS, Cabinet Secretary, Ministry of Industrialization and Enterprise Development, Republic of Kenya

A Training to prepare pharmacy students in the EAC for their mandatory internship with a pharmaceutical manufacturer will promote skills in industrial pharmacy. This activity will be carried out together with the Federation of East African Pharmaceutical Manufacturers (FEAPM).

UNIDO will embark on exploratory work to define the possible contours of broadening UNIDO's local production support from medicines to the area of vaccines.

UNIDO IN BRIEF

UNIDO is the specialized agency of the United Nations that promotes industrial development for poverty reduction, inclusive globalization and environmental sustainability.

The mandate of the United Nations Industrial Development Organization (UNIDO) is to promote and accelerate inclusive and sustainable industrial development (ISID) in developing countries and economies in transition.

The Organization draws on four mutually reinforcing categories of services: technical cooperation, analytical and policy advisory services, standard setting and compliance, and a convening function for knowledge transfer and networking.

UNIDO's vision is a world where economic development is inclusive and sustainable and economic progress is equitable.



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