



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



BOOSTING PHARMACEUTICAL PRODUCTION

A close-up photograph showing a person's hands in blue nitrile gloves. The right hand is holding a clear plastic jar tilted to the left, pouring a mixture of blue and white capsules into the left hand. The capsules are of various shapes and sizes, some appearing to be coated or multi-layered. The background is a plain, light-colored surface, possibly a lab bench. The overall lighting is bright and clinical.

“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...”

- *LI Yong, UNIDO Director General*



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INTRODUCTION

Since 2006, UNIDO has provided technical cooperation and advisory services to advance local pharmaceutical production (LPP) in developing countries with a wide range of public and private sector partners. Under a global project, UNIDO contributed to improving the operational environment and technical capacities of local manufacturers, and helped “mainstreaming” LPP as a global development theme. This engagement has established UNIDO as a leading organization on the LPP agenda, with a strong and vibrant network of partners. The success of the global LPP project - funded by Germany as a basis to attract additional resources for scale-up and transformational impact - has increased demand for UNIDO’s services and allowed it to expand its engagement beyond essential medicines into the local production of biologicals and vaccines.

THE IMPORTANCE OF LPP

- » More than **two billion people worldwide cannot get the medicines** they need.
- » LPP can help vulnerable populations, especially those in remote rural areas, to access quality medicines, thus contributing to **“leaving no one behind, and reaching the furthest behind first”**, the overarching principle of the 2030 Agenda for Sustainable Development.
- » LPP can **reduce the dependency on international donations** and a shrinking number of overseas companies who dominate the global market.
- » LPP is easier to control and **can help curb the vast influx of sub-standard medicines** into developing countries.
- » While LPP is wide-spread, most companies operate much below international standards. **Helping to upgrade their production contributes directly to people’s health**, as well as to inclusive and sustainable industrial development (ISID).

UNIDO STRATEGY

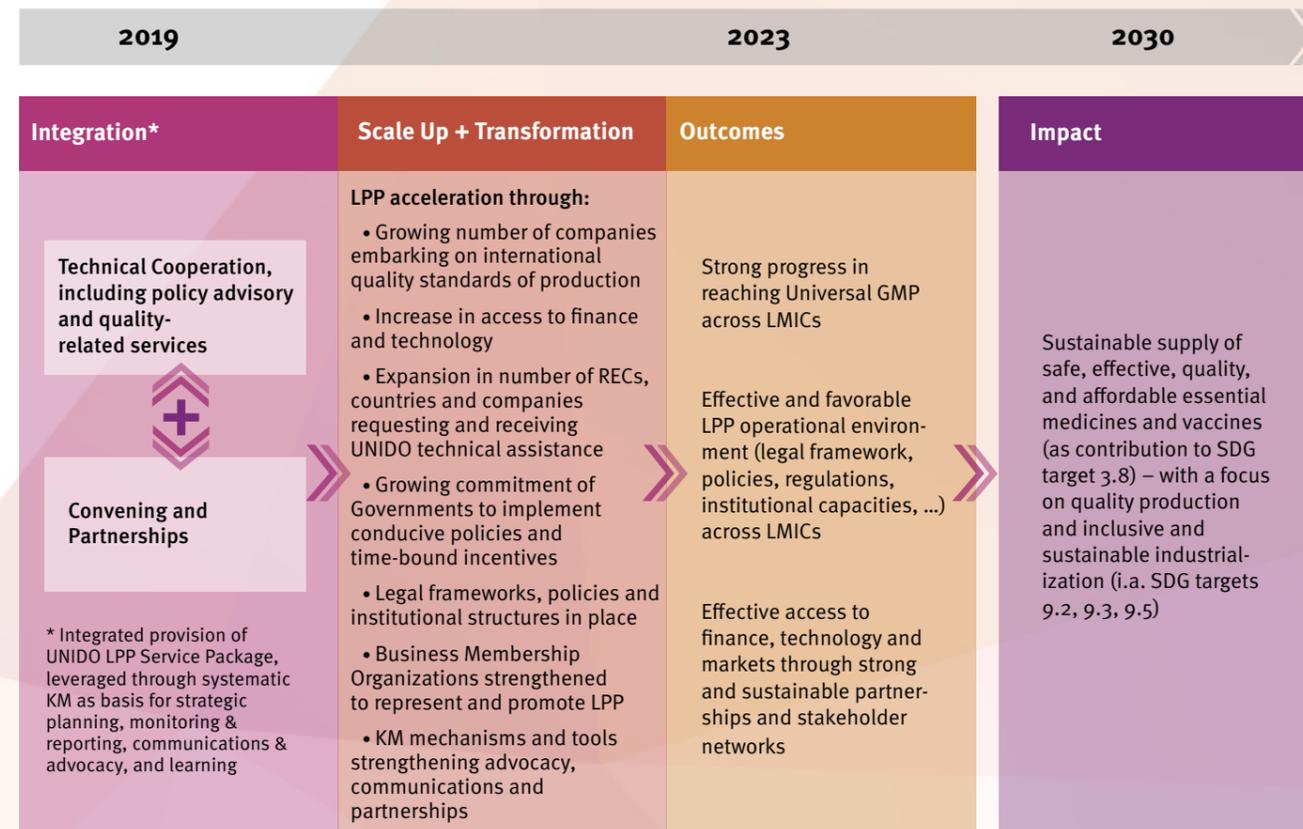
Against this background, UNIDO is taking its assistance to the next level by using a programmatic approach. In line with the Theory of Change of UNIDO’s Medium Term Programme Framework, a multi-disciplinary team of UNIDO technical experts ensures effective and coherent delivery of the organization’s key LPP services. Proactive knowledge management and communications provide the basis for strategic operational planning and coordination which integrate technical cooperation, policy advice and quality-related services with priority partnerships for scale up and transformational change. A particular focus is given to removing key systemic constraints such as lack of finance, technology and access to markets. As such, UNIDO’s support to LPP contributes effectively to strengthening the health security of LMICs and attaining SDG target 3.8 on “access to safe, effective, quality, and affordable essential medicines and vaccines for all”, while, at the same time, contributing to ISID as enshrined in SDG9.

UNIDO SERVICES

UNIDO’s global LPP project (2006-2018) confirmed the need for continued delivery and further expansion of a tested package of LPP services under a programmatic approach. In particular, these include:

- » **Policy advice** to formulate and implement pharmaceutical sector strategies, policies and programmes
- » **Technical guidance to companies** to achieve international production standards such as Good Manufacturing Practices (GMP)
- » **Business mentoring** to increase production efficiencies and cost savings, and to improve business planning
- » **Promotion of investment and technology transfer through** 1) working with local companies and partners, and 2) matchmaking platforms and activities between both North-South and South-South, brokering win-win arrangements, including through Public-Private Partnerships
- » **Human resources development** to ensure further expansion and long-term sustainability of local production
- » **Analysis and research** for developing sector policies and strategies, including on the economics of production and on market data, as a basis for rational decision making by companies, investors and policymakers
- » **Strengthening regional and continental pharmaceutical manufacturers associations** who represent and promote the industry, provide services to its members and engage with decision makers to address remaining challenges to LPP

UNIDO LPP PROGRAMME - THEORY OF CHANGE:



PHARMACEUTICAL SECTOR STRATEGIES, POLICIES AND PROGRAMMES

Boosting local pharmaceutical manufacturing requires implementation of a holistic set of complementary initiatives. Following this vision, UNIDO supported the formulation of the Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPA-BP) which provides an integrated framework of vital “solutions” to establish a vibrant and sustainable pharmaceutical industry across African countries.

In addition, UNIDO is helping individual countries to develop and implement holistic pharmaceutical sector strategies which combine and tailor generic LPP “solutions” to different national contexts. At regional level, UNIDO is working with the West Africa Health Organization (WAHO) on a strategic programme to operationalize the ECOWAS Regional Pharmaceutical Plan.

MAIN APPROACH

At the outset, a pharmaceutical sector analysis looks at the national health budget, medicines expenditures, relevant policies and legislation, tax regime, regulatory capacity and quality assurance, medicines produced, imports and exports, as well as access to finance conditions.

Based on the analysis, UNIDO supports the development and operationalization of pharmaceutical sector strategies to advance the industry. By engaging all key stakeholders, developing the sector strategy can result in quick and important policy and legislative changes, as well as improved cross-sectoral commitment and collaboration.

RESULTS AND IMPACT

Pharmaceutical sector analyses and development strategies in Ghana, Kenya and Zimbabwe, with a focus on:

- » Policy framework, including time-limited incentives
- » Regulatory framework and capacities
- » Quality standards of production, in particular Good Manufacturing Practices and WHO pre-qualification
- » Industry structure
- » Market diagnostics: Market shares of imported (donated), (re)exported, and locally-produced medicines
- » Local industry product portfolios
- » Competitiveness of domestic companies
- » Quality assurance in the distribution chain
- » Public procurement of medicines
- » Access to finance for investment in the sector

Implementation of national sector strategies, resulting in:

- » Development of Kenya GMP Roadmap
- » Faster market authorization and reduced registration times for local products
- » Tariff rationalization
- » Temporary incentives/preferential treatment for local manufacturers

FACTS AND FIGURES

- » **6** out of **7** companies assessed in 2012 achieved noticeable improvements in GMP compliance in 2015, 3 of them achieved a higher GMP compliance rating (Kenya)
- » Import duties / VAT rolled back on a list of **234** raw materials used in pharmaceutical manufacturing (Zimbabwe)
- » Import restrictions, including special licensing to import **23** molecules that are also produced locally by more than one company (Zimbabwe)
- » Total pharmaceutical sector strategy delivered, with complete costs for quality upgrading and revamping of company product portfolios (Zimbabwe)



INTERNATIONAL QUALITY STANDARDS AND EFFICIENT PRODUCTION

The ultimate objective of the global LPP agenda is that pharmaceutical manufacturing in all developing countries adheres to international Good Manufacturing Practices (GMP) standards to ensure consistent quality of medicines. In accordance with the PMPA Business Plan, UNIDO supports WHO-GMP as the target to which all countries should aspire.

In order to counterbalance the higher costs associated with producing medicines in line with international quality standards and to ensure the competitiveness and sustainability of LPP, UNIDO also supports initiatives to increase the efficiency of pharmaceutical production. As part of the global LPP project, UNIDO worked with companies in applying Lean Six Sigma, OPEX and similar methods to maximize the use of available resources, minimize waste (physical, down-time, etc.) and assure overall efficiency in organizational processes.

MAIN APPROACH

GMP Roadmap:

Compliance with WHO-GMP requires implementation of an array of production measures to ensure that medicines are of consistent quality, as well as safe and efficacious. As such, moving towards internationally recognized GMP is a complex and costly multi-year process which - due to lack of financial resources, as well as technical and human resource capacities - the majority of manufacturers in developing countries are unable to pursue on their own. To address this challenge, UNIDO has developed the GMP Roadmap approach. In close collaboration with key national stakeholders, the GMP Roadmap process first compares existing manufacturing practices with international WHO-GMP and identifies those technical challenges posing the greatest risks to the quality of medicines, and thus to the health of patients. Subsequently, the GMP Roadmap establishes a gradual pathway to address these priority risks with clearly defined milestones and targets towards WHO-GMP compliance within a defined timeframe.

Production efficiency and competitiveness:

To make pharmaceutical production more efficient and competitive, UNIDO has been working directly with companies to optimize the cost of manufacturing through methods such as Lean Six Sigma (LSS). LSS helps companies to reduce wastage and variation in the production process. By increasing profitability, it contributes to making LPP more sustainable and allows companies to invest more in upgrading production towards international GMP quality standards.

RESULTS AND IMPACT

- » As part of the GMP Roadmap approach, UNIDO has conducted over 100 baseline assessments across Africa
- » Successful piloting of the UNIDO GMP Roadmap in Kenya has led to its adoption and broad-based application by GIZ in the EAC region
- » The West African Health Organization (WAHO) decided to collaborate with UNIDO in applying a Regional GMP Roadmap Framework as a central component for developing the pharmaceutical industry
- » An LSS Programme in Kenya enabled participating companies to increase productivity and output, leading to plans for the execution of additional LSS projects

FACTS AND FIGURES

- » Total of **107** GMP baseline assessments conducted, incl. **34** in Kenya, **26** in Ghana, and **18** in Nigeria
- » **6** of **7** companies participating in GMP Roadmap process improved their overall rating, or their score in either site or quality management system (Kenya)
- » Implementation of GMP Roadmap Framework for West Africa involves all **15** countries in the ECOWAS region, providing foundation for comprehensive WAHO/UNIDO LPP Programme
- » LSS Programme in Kenya increased annual profits or savings per company by more than **USD 100.000**



Affordable finance and technology are fundamental requirements for pharmaceutical manufacturers in developing countries to upgrade their production to international quality standards, such as Good Manufacturing Practices (GMP), and to gain access to markets. As part of UNIDO's services to promote investment as well as technology transfers in the sector, UNIDO conducted a Partnership Mentoring Programme to help African pharmaceutical manufacturers to best prepare themselves for partnerships with international pharmaceutical firms, finance institutions and development partners.

MAIN APPROACH

The objective of the Partnership Mentoring Programme was to stimulate growth of local pharmaceutical manufacturing in Africa through partnerships with European firms, and to assist a cohort of promising African manufacturers in finding a European technology or finance partner.

To identify these companies, UNIDO reached out to pharmaceutical manufacturers in 19 countries in sub-Saharan Africa. From a total of 30 received applications, 10 companies were selected for the programme, based on criteria including adequate commercial and manufacturing capabilities as well as a sound growth strategy as presented in the application.

The selected African companies were then mentored in developing a highly focused prospectus with clear and concise growth and partnership strategies. The companies were invited to meet face-to-face with European firms and investors at the UNIDO International Business and Investment Forum in Bonn, Germany, March 1-2, 2018. The Forum, organized by the UNIDO Pharma Team and the Investment and Technology Promotion Office (ITPO) in Bonn, not only served to discuss the key topics of access to finance, technology and markets, but introduced European companies and investors to African pharma markets and business environments, and to the investment opportunities of a rapidly growing middle class with increased purchasing power.

RESULTS AND IMPACT

The African companies that went through the Partnership Mentoring Programme are able to use the acquired knowledge and skills, and a revised prospectus that incorporates feedback from the Bonn Forum, to find

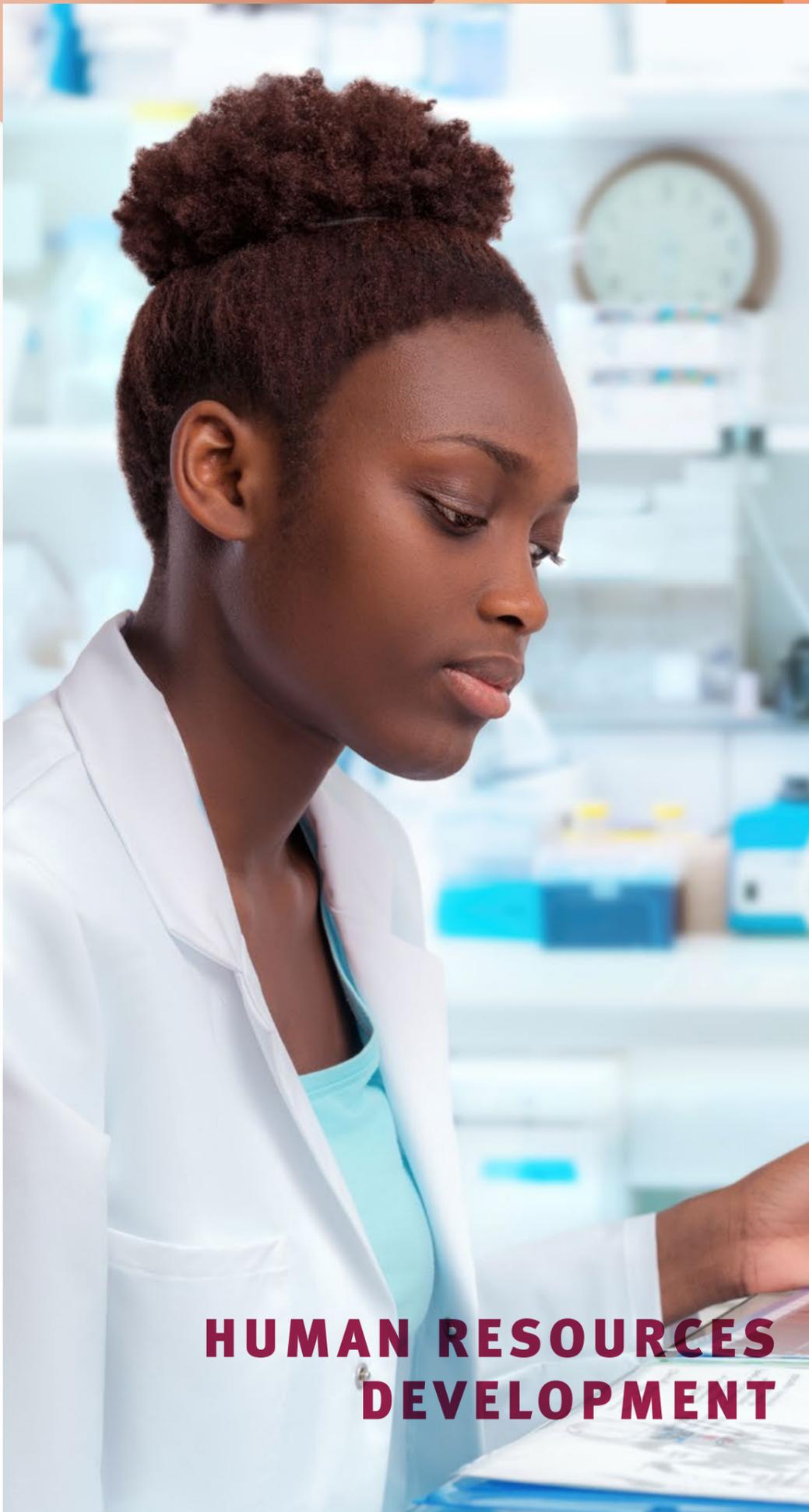
their next partner. Just weeks after the face-to-face event, a number of African companies already had follow up discussions and meetings with European firms and investors who participated in the Forum.

The majority of participants commented that the Forum offered a chance to gain valuable insights and market intelligence. For African companies it served as their first opportunity to compare themselves with other manufacturers within and outside Africa. Some African companies explored how to do business together. The presence of the Global Fund to Fight AIDS, Tuberculosis and Malaria provided new perspectives and orientations to African companies on the value of attaining WHO Prequalification (WHO-PQ) for their products. Many participants expressed their wish to attend a similar event in the future.

FACTS & FIGURES

- » **10** African companies mentored to present clear and focused growth and partnership strategies to potential partners
- » **5** companies confirmed to have learned concrete lessons from the mentoring process that will help in their partnership efforts. **3** followed up with engaging further experts to expand work in the field
- » More than **100** B2B conversations between pharmaceutical manufacturers from Africa and Germany/Europe served to explore options for future business partnerships
- » **3** African companies are in talks with finance institutions and **3** on technology-transfer; **4** intra-African linkages have been established and will be further explored

INVESTMENT AND TECHNOLOGY TRANSFER



HUMAN RESOURCES DEVELOPMENT

The pharmaceutical industry requires highly skilled university graduates in a wide range of disciplines including sciences, engineering, technology, as well as management, law and ICT. Apart from academic qualifications, the work force in the pharma sector needs practical industry-specific training to be productive. In this context, shortages of qualified human resources in many developing countries constitute a major constraint for advancing pharmaceutical production.

In response, UNIDO has consistently prioritized support to developing human resources as a key component of its global LPP project.

MAIN APPROACH

Since 2008, UNIDO supported a partnership between Saint Luke Foundation/Kilimanjaro School of Pharmacy in Tanzania and the US universities Howard and Purdue to conduct an Industrial Pharmacy Advanced Training (IPAT) Programme which provided state-of-the-art knowledge and skills on pharmaceutical production, regulatory affairs and research. The curriculum, which consists of four modules plus lab training - and has been expanded to 11 modules for a Master's program in 2014 - is particularly well suited for obtaining practical skills and insights into the operational environment and processes of the pharmaceutical industry.

Another key initiative has been UNIDO's assistance to business membership organizations (BMOs) in assessing training needs of the pharmaceutical industry, and in helping pharmacy students to acquire on-the-job experience so that they can benefit more from mandatory placements in the industry.

RESULTS AND IMPACT

Between 2008 and 2018, participants from 11 African countries graduated from the IPAT course and its Master's Program. The course received very high satisfaction ratings from participants who highlighted its value in providing them with hands-on knowledge and skills to succeed in their professional careers.

In supporting the Federation of East African Pharmaceutical Manufacturers (FEAPM) to set up a training program for pharmacy students, UNIDO enabled pharmacy students in the EAC region to acquire the necessary knowledge and skills for mandatory placement in the pharmaceutical industry. This contributed to the wider goals of embedding industrial pharmacy into the pharmacy education in the EAC and to strengthen the linkages between academia and the industry.

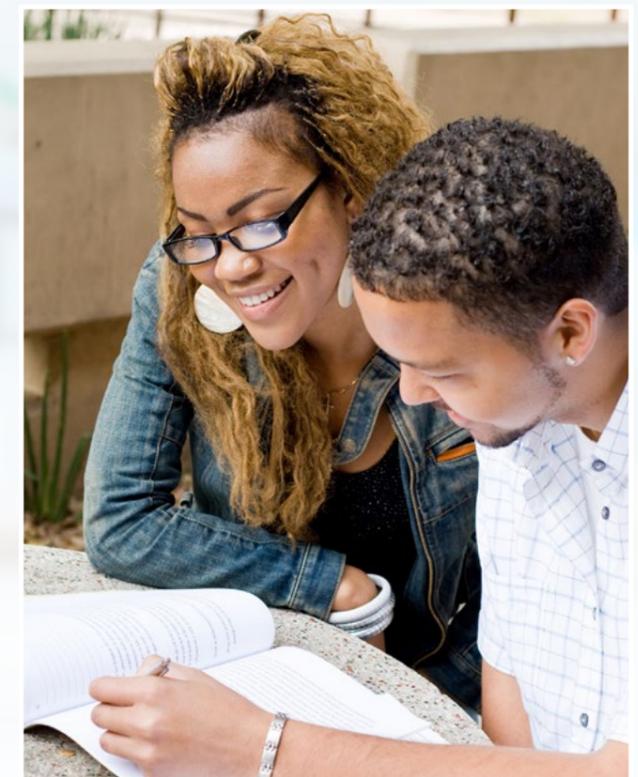
FACTS AND FIGURES

IPAT Program 2008-2018:

- » Total number of graduates: **106** (female: **41**, male: **65**)
- » Master's Programme graduates: **41**

FEAPM pre-internship course:

- » Number of pharmacy students trained: **32**



Conducting studies and assessments on key LPP issues, as well as close collaboration and exchanges with experts from academia and the private sector, has been central to UNIDO's LPP work.

Analyses and regular consultations with a wide range of LPP experts have further substantiated the technical and economic viability of LPP, and provided new insights into its potential for advancing ISID and public health. While this has helped "mainstream" the LPP agenda, analysis and research continue to be constrained by a lack of access to pharmaceutical market data in developing countries. To address this challenge, UNIDO is supporting the creation of pharmaceutical market information systems.

MAIN APPROACH

Analysis and research has not only strengthened the case for LPP but also contributed to the relevance and quality of UNIDO's technical cooperation. More recently, studies on manufacturing and commercializing vaccines in Africa have contributed to further consultations and advocacy to expand the scope of LPP beyond generic medicines.

In addition to supporting studies and assessments on key aspects of LPP, UNIDO has used its convening function to bring together academic experts and private sector representatives to present and discuss approaches for strengthening LPP. In 2017, UNIDO organized an Expert Group Meeting focusing on practical approaches towards satisfying three key requirements for effective pharmaceutical sector development: Access to affordable finance, access to technology and appropriate policies/incentives.

To improve access to pharmaceutical market information, UNIDO supported a project in four countries of the East African Community (EAC) which included a comprehensive assessment of the sources and quality of existing primary pharmaceutical data for commercially imported, donated and locally produced medicines.

RESULTS AND IMPACT

The findings and recommendations of the 2017 Expert Group Meeting on affordable finance, technology transfer and a favorable policy environment for LPP have been summarized in a guidance document so as to provide policymakers, pharmaceutical companies, development partners and investors with practical insights on how these fundamental requirements could be met.

The pharmaceutical market information project helped develop and operationalize a market information software solution (iPMIS) hosted by Medicines Regulatory Authorities (MRAs) to deliver up-to-date information on the main medicines market components. Personnel in MRAs and pharmaceutical companies have been trained in medicines classification and use of iPMIS.

In 2017 and 2018, UNIDO supported further exploration of the local production of vaccines, through studies on vaccine manufacturing and procurement in Africa, establishing manufacturing capabilities for human vaccines, and a case study in South Africa on commercializing vaccines.

FACTS AND FIGURES

Global mainstreaming of LPP Agenda:

- » Increased ownership and commitment to global LPP agenda by key stakeholders such as Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Interagency Pharmaceutical Coordination Group
- » UN General Assembly Declarations on:
 - » Third Industrial Decade for Africa (IDDA III) 2016-25, June 2016 (pharma sector is included as priority theme)
 - » Industrial Development Cooperation, Dec 2016 (welcomes UNIDO's assistance to LPP)

Pharmaceutical Market Information Systems:

- » Over **20,000** regionally registered medicines classified, and compiled into a database by Medicines Regulatory Authorities in the EAC

ANALYSIS AND RESEARCH



PHARMACEUTICAL MANUFACTURING ASSOCIATIONS

In response to strong demand from African pharmaceutical manufacturers and a number of national business associations, UNIDO has prioritized support to setting up and strengthening regional and continental business membership organizations (BMOs) for the pharma sector in Africa. Through promoting and supporting the interests of local pharmaceutical companies, these BMOs contribute to the establishment of a vibrant and self-sustaining pharmaceutical industry that is able to provide affordable and efficacious quality medicines, thus advancing public health and economic development across the continent.

MAIN APPROACH

Starting with support to the formation of the Southern African Generic Medicines Association (SAGMA) in 2009, UNIDO has been instrumental in establishing the Federation of African Pharmaceutical Manufacturer Associations (FAPMA) which was launched in 2013. As a federation of regional pharmaceutical BMOs, FAPMA gives pharmaceutical manufacturers a unified voice across the African continent. FAPMA's members comprise the Federation of East African Pharmaceutical Manufacturers (FEAPM) and the West African Pharmaceutical Manufacturers Association (WAPMA), in addition to SAGMA.

Both the regional BMOs and FAPMA engage with a wide range of stakeholders to boost the pharmaceutical industry on the continent. Through their participation in high-level advisory groups and committees they play an important advocacy function vis-à-vis policy makers and international procurement entities. In addition, they provide essential services to their members by offering

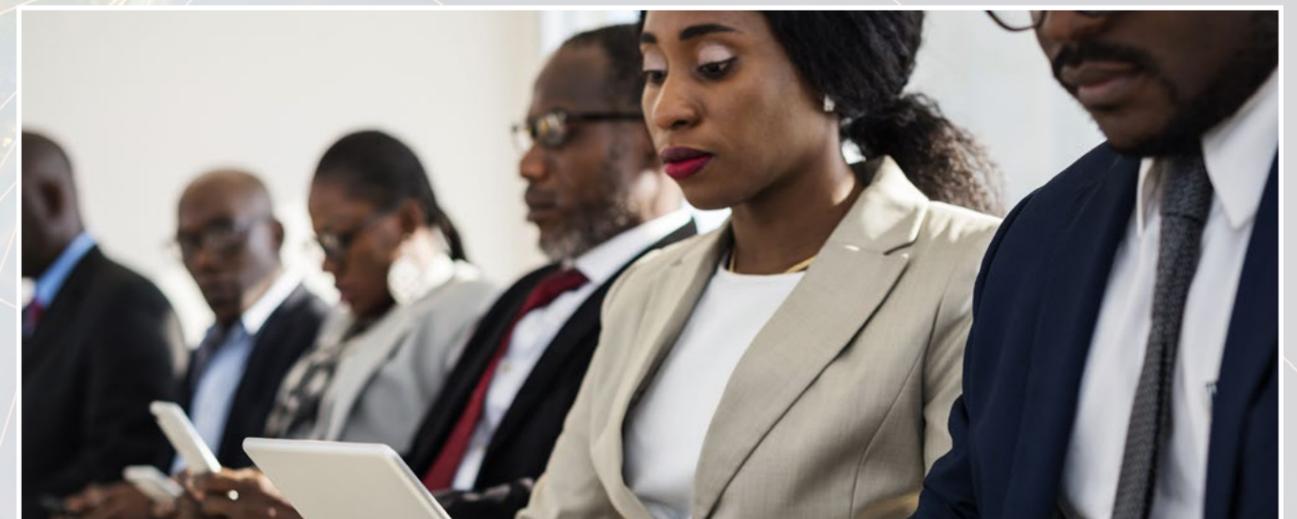
trainings, as well as conducting research and surveys on key issues to further develop the pharma sector.

Through their activities and services which also include support to setting up and strengthening national-level BMOs, as well as facilitating access to markets and finance, FAPMA and the regional BMOs are increasingly recognized as valued and effective representative bodies of the African pharma sector.

RESULTS AND IMPACT

FAPMA/Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Conference (June 2017): A first-of-its-kind event, it brought together 52 Africa-based pharmaceutical companies with close to 30 eminent technical partners and others involved in large-scale procurement of medicines using donor-funding. The conference agreed on a roadmap for collaboration with African manufacturers, linking technical support and investments in Africa-based manufacturing with business opportunities. Key steps of the roadmap include a comprehensive assessment of Africa-based companies to identify potential suppliers to the Global Fund, as well as the launch of an essential medicines strategy and a global tender.

FEAPM Academia Internship Program - with 32 pharmacy graduates and students to close the gap between formal pharmacist education and basic knowledge on industrial pharmacy - required for effective participation in the compulsory internship program in EAC countries. The program further enhanced the dialogue between academia and industry on required skills for the pharmaceutical sector in EAC countries.





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