UNIDO Global Project: Strengthening the Local Production of Essential Medicines in Developing Countries (DCs)

...can increase access to medicines and contribute to economic growth

In Perspective

Health is a major challenge for Africa where HIV/AIDS, TB and malaria, and a myriad of other diseases, kill millions of people each year. This terrible human cost is a major factor that impeded the continent’s efforts to escape poverty. Many deaths could be prevented with timely access to appropriate and affordable medicines.

While the overall pharmaceutical market in sub-Saharan Africa (SSA) is worth USD 3.8 billion annually, the pharmaceutical manufacturing sector in Africa contributes only 25-30 per cent of the continent’s needs. The production of life-saving drugs is furthermore concentrated in very few countries: 70 per cent of pharmaceutical manufacturing takes place in South Africa and an additional 20 per cent in Nigeria, Ghana and Kenya combined. The continent depends largely on imports from Asia, frequently with long lead times.

Health is a very important prerequisite to achieving the Millennium Development Goals (MDGs). Since the year 2000 substantive amounts of money have become available through international organizations such as The Global Fund to increase access to life-saving drugs. Very few of these drugs are currently procured from African producers. In a globalizing world this might seem appropriate, but the specific realities in pharmaceuticals mean that further development of local manufacturing has the potential to positively impact the health outcomes in developing countries, as well as adding to economic growth. The pharmaceutical sector can be seen as a strategic sector, and complete dependence on imports of essential medicines in quite substantial regions of the world have raised concern about the continuity of supply. The need for tight regulation and quality control can arguably be enforced more easily if the suppliers are in closer proximity to the end-user. Considerations such as these have sparked a growing interest in the local manufacturing of pharmaceuticals especially in Africa from players such as the African Union, national governments in the region, and some international development partners.

In Focus

The project aims at the expansion and upgrading of small and medium sized enterprises in selected developing countries, mainly in Africa, for the local manufacturing of essential generic drugs, with the objective of enhancing access of the poor to these drugs at affordable prices. This objective is pursued through a combination of advisory, promotional, institutional capacity-building and enterprise level activities to address the complex set of challenges that the local production of essential medicines in developing countries faces.

Challenges

The local manufacture of essential drugs meets with manifold challenges related to company level dimensions of manufacturing, but also originating from the wider operating environment. Weaknesses at plant level in reaching and maintaining quality standards in line with established international – e.g. WHO – Good Manufacturing Practices (GMP) stem from the lack of capital, but also the lack of human resources with the high specialized skill levels typically required for the manufacture of medicines and the maintenance of facilities. Beyond the plant, the small size of domestic markets diminishes the prospects for achieving optimal production efficiency against the background of high production costs. These result from the need to import all major raw materials as well as high utility and transportation costs. Furthermore, the business environment in developing countries in general has deficits, and in particular the pharmaceutical sector lacks effective support services among others from regulatory authorities and quality control labs.

Joining Forces with the African Union

These formidable challenges call for a comprehensive approach that addresses constraints at the enterprise, institutional and policy level at the same time. To address these challenges, in July 2011, UNIDO joined forces with the African Union Commission (AUC) on the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA). This continent-wide plan was endorsed by African Heads of State in 2007. AU Ministers of Industry reiterated the importance of developing the sector under the auspices of the PMPA in March 2011 by including it as a priority in the AIDA Framework.

The UNIDO-AUC collaboration will initially focus on the formulation of a PMPA ‘operational plan’, which will be endorsed by AU policy makers in mid-2012, with the objective of moving rapidly to implementation of the approach over an extended period of time. The plan will include a technical cooperation component to support individual countries and regions in developing their pharmaceutical industries to positively influence access to medicines as well as to add to economic growth. The approach
will build on the 6-year experience of the ongoing UNIDO Project in the field to tailor support measures to the varying needs of the different regions in Africa. UNIDO will continue to apply a comprehensive approach that combines simultaneous support measures at the enterprise, institutional and policy level to move the whole sector towards international Good Manufacturing Practices (GMP) in a competitive manner.

To achieve this objective the industry will need support. Therefore the PMPA will be implemented as a technical assistance program to those countries willing to actively support the sector by providing incentives, but also strengthen Medicines Regulatory Authorities. The structure of the industry needs to be developed so that in the medium term it is competitive without depending on subsidies.

The range of issues to be addressed covers an array of different disciplines including industrial development, technical production and regulatory aspects. No one entity has the full range of expertise necessary to resolve all the challenges. Consequently, UNIDO is working to build partnerships with other key organizations such as WHO, UNAIDS and the United States Pharmacopoeia.

**Institutional Level**

**Southern African Generic Medicines Association (SAGMA)**

During a UNIDO/BMZ-GIZ/SADC workshop in Lusaka, Zambia, in November 2008, companies and business associations from various countries in the Southern African region identified a need for sub-regional advocacy and service provision in the generic medicines manufacturing sector. A private sector-driven initiative emerged for establishing a Southern African Generic Medicines Association (SAGMA). This sub-regional association has now embarked on promoting the interests of the Southern African generics industry. Since its inauguration in December 2009 SAGMA has started to pursue its mission “to achieve self-sufficiency and reliability in the local production and provision of affordable quality generic medicines in SADC”. UNIDO facilitated and supported the formation process of this new regional association and continues to support SAGMA in exercising its main functions in advocacy for, and service provision to, its members.

**Support for advanced training on industrial pharmacy in Africa**

22 participants from six African countries – DR Congo, Kenya, Lesotho, Nigeria, Tanzania, Uganda – have to date successfully completed the Advanced Industrial Pharmacy Training Programme, organized by the Kilimanjaro School of Pharmacy (KSP), St. Luke Foundation, Tanzania. Sponsored by the global UNIDO project, the trainees were being familiarized with drug development, drug manufacturing as well as regulatory & quality compliance issues. Another 24 participants are currently enrolled in the course and will complete the training in 2012.

**Select Project Milestones to date**

**Developing Pharmaceutical Sector Strategies at the National Level**

The pharmaceutical industry is a complex one that involves many stakeholders spanning the fields of health and industry given the role that inexpensive and high quality medicines play in ensuring access to medicines. Since affordability and quality are key considerations, the critical question that policy-makers face is: How can this industry sector improve quality standards whilst maintaining its competitiveness?

To find a shared answer, UNIDO has adopted a consultative process in Ghana and Kenya that engages with the full range of stakeholders including the regulator, the private sector, Ministries of Health, Ministries of Trade and Industry, universities, financiers, and others. Consultations have identified the key challenges that the sector faces, enabled stakeholders to discuss the different perspectives on the industry and to develop a shared strategy that the main entities can support and buy into. As well as facilitating the consultations and advising on strategy, UNIDO is developing specific solutions to help the actors overcome common challenges such as establishing a GMP roadmap for the upgrading of the industry, facilitating technology transfer, incentivizing adequate financing and/or guiding human resource development.

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Participants of the Industrial Pharmacy Advanced Training Course at Kilimanjaro School of Pharmacy in Moshi, Tanzania, sponsored by UNIDO 2010

The Lab session was a good way of relating and performing what was learnt theoretically into actual practice, Participant of the Industrial Pharmacy Advanced Training Course

Coming from private pharmaceutical enterprises, medicines regulatory authorities and research entities, the trainees included staff from companies that the UNIDO project seeks to assist in their upgrading efforts. The training programme is carried out by KSP in close collaboration with renowned lecturers from Purdue and Howard University, USA. It aims at filling a void on the continent: the lack of a well educated and qualified workforce is among the key factors constraining the growth and development of a local pharmaceutical industry.