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Independent Final Evaluation

GLOBAL ACTIVITIES

Strengthening the local production of essential generic drugs in developing countries, Phase 2 (TE/GLO/08/030)

Strengthening the local production of generic drugs in least developed countries (LDCs) through the promotion of SMEs, business partnerships, investment promotion and south-south cooperation (XP/GLO/09/016)

Strengthening the local production of essential medicines in developing countries through advisory and capacity-building support, Phase 3 (TE/GLO/10/023 & XP/GLO/11/007)

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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Vienna, 2015

Distr. GENERAL

ODG/EVA/13/R.25

April 2015

Original: English

This evaluation was managed by the responsible UNIDO project manager with quality control by the Evaluation Group

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Contents

Acronyms and Abbreviations

AIDA	Accelerated Industrial Development of Africa
AIDS	Acquired Immune Deficiency Syndrome
AMFm	Affordable Medicines Facility malaria
AMRH	African Medicines Regulatory Harmonization (initiative)
ANDI	African Network for Drugs and Diagnostics Innovation
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
AU	African Union
AUC	African Union Commission
ART	Antiretroviral therapy
ARV	Antiretroviral medicines
BMI	Business Monitor International
BMZ	Bundesministerium fuer wirtschaftliche Zusammenarbeit und Entwicklung
BP	Business Plan
CAGR	Compund Annual Growth Rate
CEO	Chief Executive Officer
COHRED	Council on Health Research for Development
COMESA	Common Market for Eastern & Southern Africa
DAV	Drug Administration of Viet Nam
DC	Developing Country
DEG	Deutsche Investitions und Entwicklungsgesellschaft mbH
DfID	Department for International Development
DNDi	Drugs for Neglected Diseases initiative
EAC	East African Community
EC	European Commission
ECOWAS	Economic Community of West African States
EML	Essential Medicines List
EU	European Union
FAPMA	Federation of African Pharmaceutical Manufacturers Associations
FDA	Food and Drug Administration (US)
FDA	Food and Durgs Authority (Ghana)
FDB	Food and Drugs Board (Ghana)
FIND	Foundation for Innovative New Diagnostics
FKPM	Federation of Kenya Pharmaceutical Manufacturers

GFATM	Global Fund to fight Aids, Tuberculosis and Malaria
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GPRM	Global Price Reporting Mechanism
GSK	Glaxo Smith Kline
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HAI	Health Action International
HIV	Human Immunodeficiency Virus
HQ	Headquarters
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICTSD	International Centre for Trade and Sustainable Development
IFC	International Finance Corporation
InWEnt	Capacity Building International (Internationale Weiterbildung und Entwicklung gGmbH) (Germany)
IPC	Interagency Pharmaceutical Coordination Group
IP	Intellectual Property
IPR	Intellectual Property Rights
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
LDC	Least Developed Country
LPP	Local Pharmaceutical Production
M&E	Monitoring & Evaluation
MDG	Millennium Development Goal
MNC	Multinational Corporation
MoF	Ministry of Finance
MoH	Ministry of Health
MoI	Ministry of Industry/Industrialisation
MoIT	Ministry of Industry and Trade (Viet Nam)
MoMS	Ministry of Medical Supplies
MoTI	Ministry of Trade and Industry (Ghana)
MPHS	Ministry of Public Health and Sanitation
NEPAD	New Partnership for Africa's Development
NGO	Non-Governmental Organisation
NHIA	National Health Insurance Agency (Ghana)
NHIF	National Health Insurance Fund (Kenya)
NHIS	National Health Insurance Scheme (Ghana)
NMP	National Medicine Policy

NMRA	National Medicines Regulatory Authority
NQCL	National Quality Control Laboratory
NSC	National Steering Committee
OTC	Over-the-Counter
OVI	Objectively Verifiable Indicator
OXFAM	Oxford Committee for Famine Relief
PEPFAR	(The United States) President's Emergency Plan for AIDS Relief
PMAG	Pharmaceutical Manufacturers Association of Ghana
PMPA	Pharmaceutical Manufacturing Plan for Africa
PMTCT	Prevention of Mother to Child Transmission
PPB	Pharmacy and Poisons Board
PQ	Prequalification
PQP	Prequalification Programme
PSMWG	Procurement and Supply Chain Management Working Group
PTC	Programme Development and Technical Cooperation
PSC	Project Steering Committee
PSD	Private Sector Development
QC	Quality Control
QS	Quality Standard
R&D	Research and Development
RBM	Roll Back Malaria Partnership
SADC	Southern African Development Community
SAG	Strategic Advisory Group
SAGMA	Southern African Generics Medicines Association
SARPAM	Southern Africa Regional Programme on Access to Medicines and Diagnostics (*SARPAM)*
SMEs	Small and Medium-Sized Enterprises
SSA	Sub-Saharan Africa
STA	Senior Technical Advisor
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
ToR	Terms of Reference
TRIPS	Trade Related Aspects of Intellectual Property Rights
U4P	UNIDO Pharmaceutical Production Partnership Platform
UN	United Nations
UNAIDS	Joint United Nations programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development

UNDAF	United Nations Development Assistance Framework
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USP	United States Pharmacopeia
VNPCA	Viet Nam Pharmaceutical Companies Association
WB	World Bank
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Glossary of evaluation terms

Term	Definition
Baseline	The situation, prior to an intervention, against which progress can be measured.
Conclusions	Conclusions point out the factors of success and failure of the evaluated intervention, with special attention paid to the intended and unintended results and impacts, and more generally to any other strength or weakness. A conclusion draws on data collection and analyses undertaken, through a transparent chain of arguments.
Effect	Intended or unintended change due directly to an intervention.
Effectiveness	The extent to which the development intervention's objectives were achieved, or are expected to be achieved, taking into account their relative importance.
Efficiency	A measure of how economically inputs (through activities) are converted into outputs.
Impact	Positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended.
Indicator	Quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a development actor.
Lessons learned	Generalisations based on evaluation experiences with projects, programmes, or policies that abstract from the specific circumstances to broader situations. Frequently, lessons highlight strengths or weaknesses in preparation, design, and implementation that affect performance, outcome, and impact.
Outcomes	The likely or achieved short-term and medium-term effects of an intervention's outputs. Related terms: result, outputs, impacts, effect.
Outputs	The products, capital goods and services that result from a development intervention; may also include changes resulting from the intervention that is relevant to the achievement of outcomes.
Recommendations	Proposals aimed at enhancing the effectiveness, quality, or efficiency of a development intervention; at redesigning the objectives; and/or at the reallocation of resources. Recommendations are linked to conclusions.
Relevance	The extent to which the objectives of a development intervention are consistent with beneficiaries' requirements, country needs, global priorities and partner and donors' policies. Note: Retrospectively, the question of relevance often becomes a question as to whether the objectives of an intervention or its design are still appropriate given changed circumstances.
Results	The output, outcome or impact) of a development intervention. Related terms: outcome, effect, impacts.
Sustainability	The continuation of benefits from a development intervention after major development assistance has been completed. The probability of continued long-term benefits. The resilience to risk of the net benefit flows over time.

Executive summary

Introduction

Access to medicines is directly related to income and, despite progress made in the last decade, this access is still a major problem for most developing countries.

The World Health Organization's (WHO) World Medicines Situation Report (2004) estimated that in low-income countries almost 40% of the population had no access to essential medicines. This figure came down to 24% and 0.6% in medium and high income countries respectively. The Report also found that high-income countries dominate in world pharmaceutical production. Their share of production (by value) increased from 89.1% in 1985 to 92.9% in 1999, while the combined share of middle- and low-income countries decreased from 10.9% to 7.1% over the same period. An update of this Report in 2013 found that public sector availability of generic medicines is still less than 60% in the Western Pacific, South-East Asia and Africa regions and at least one-third of the world's population has no regular access to medicines.

The evaluation was carried out between December 2012 and May 2013 by an international consultant, Mr. Joan Rovira, a health economist. Field missions to Kenya (11 to 16 February 2013), Ghana (18 to 22 February 2013), and Viet Nam (25 to 29 March 2013) were carried out.

Project description

This UNIDO global project is concerned with the problems of Local Pharmaceutical Production in Developing Countries (DCs)/Least Developed Countries (LDCs) and the impact goal is to increase the supply of quality affordable essential medicines from producers in those countries. The activity was conceived in 2005 at the instigation of the main donor, the Government of Germany, and the project is managed by UNIDO's Business, Investment and Technology Services Branch in the Programme Development and Technical Cooperation Division.

A holistic approach has been taken and this operates at three levels of intervention: micro, meso, and macro. The micro level refers to enterprises, i.e. local pharmaceutical manufacturers. The meso level refers to the institutions that operate in the sector with regulatory or representative roles or providing specific inputs (e.g. education and training) to the sector and services to the enterprises. Finally, the macro level refers to the national and international policy making domain.

Over time, several adjustments have been made in the logistical framework (logframe) as a result of lessons learned and new opportunities that appeared during implementation.

The project has been built as a successive set of projects, with each one laying the foundations for the following phase. In this way, each phase has benefited from lessons learned during the previous one and this has helped to guide the process of building partnerships with the relevant national stakeholders and United Nations (UN) organisations. The three phases implemented so far have the following basic features:

- Phase 1 (January 2006 to June 2008): A fact finding and stocktaking phase, the initial focus of which was on the production of drugs for pandemic diseases and on LDCs.

- Phase 2 (July 2008 to December 2010) in which the scope of the project broadened beyond pandemic diseases and LDCs to include essential generics and DCs in general. This move reflected the lesson learned in Phase 1 that commercial viability could hardly be expected or derived from the manufacture of a narrow range of medicines.

- Phase 3 (January 2011 to December 2012), in which earlier country interventions were both continued and replicated in other countries. This phase also foresaw the development and implementation of an enhanced UNIDO project. However, the main activity was in response to the African Union Commission's (AUC's) request in June 2011 for the joint elaboration of a Business Plan (BP) for the accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA).

Initially, the stated logic of the project was to approach access to medicines from a production point of view. During the first two phases - and partly also during phase 3 - 'improved access' was stated as one of the two ultimate impact goals with strengthening LPP as the second one.

Evaluation missions and methodology

The evaluation comprised a review of the project documents; a briefing at UNIDO headquarters in Vienna; field missions between February and April 2013 to Kenya, Ghana and Viet Nam to interview national stakeholders; teleconferences with some key international stakeholders; and debriefing in Vienna at the end of April 2013. The purpose of this evaluation is three fold:

1. To determine the extent to which the expected results have been achieved.
2. To identify strengths and weaknesses in project implementation, design - including the logframe.
3. To identify potential options for improvement especially with regard to the start of Phase 4, which was imminent when this evaluation commenced.

The methodology used in the evaluation consisted in a review and analysis of the project documents, complemented by a review of the published academic and institutional literature and interviews with stakeholders in Kenya, Ghana and Viet Nam.

The evaluation faced some limitations due to:

- Changes in objectives and overlapping of project phases.
- Multi-causality of outcomes and impact, making it difficult to assess which part is attributable to the project.
- Limited availability of key information, basically that required to identify the baseline situation.
- Short-term outcomes are mostly intangible and hence difficult to measure. At the same time, it is still too early for long-term objectives and impact (e.g.

increase in LPP) to have materialised.
- Potential biases in information collected by means of interviews with stakeholders who are often the target of project interventions.

Regional background

The original project proposal (now referred to as phase 1) included activities in Africa and Asia. The concentration on Sub-Saharan Africa (SSA) was a decision based on early phase diagnostic work and a joint prioritization between UNIDO and the donor.

Although the project has a global scope and outputs have been produced in 14 countries, the main focus is on Africa and current interventions are concentrated in three countries, Kenya, Ghana and Viet Nam.

These three countries share some common traits. They are all low-income countries and they all have weak health insurance systems. The pharmaceutical industry is relatively small - 42 companies in Kenya, and 22 in Ghana - but less so in Viet Nam, where there are 165 pharmaceutical companies. The industry concentrates on the production of generic medicines. Companies import most raw materials and active pharmaceutical ingredients (APIs) and technological capacity is limited to the formulation phases of the pharmaceutical production cycle. The quality of production is relatively low by international standards although relatively better in Viet Nam than in Kenya and Ghana. This situation precludes companies from taking advantage of the market potential of big international donors, all of whom require prequalification status for their pharmaceutical suppliers.

Collaboration in the PMPA has offered UNIDO the opportunity to think and plan an intervention from a regional perspective since this is the most appropriate approach in a highly globalised sector such as pharmaceuticals.

Key evaluation findings

1. Relevance and ownership

The relevance and appropriateness of UNIDO's global project and its holistic design is positively valued by the majority of stakeholders, who find that the logic of the intervention is sound. The need to upgrade quality to international standards is accepted by most of them.

2. Efficiency and management

Given the ambitious goals of the project and the results attained, the size of the budget - at Euro 3.2 million - is relatively modest. In this respect, the resources invested in the project can be viewed as providing good value for money.

UNIDO has shown its capacity for leading the holistic, multi stakeholder approach required to ensure the development of LPP. The project management team has shown the flexibility required adapting to the lessons learned and to the opportunities that arose in the course of the project. Revisions were introduced in order to improve the project strategy, priorities, and results and required a reallocation of human resources and budget lines as well as donor approval of the proposed changes.

The work of the project team, national consultants and short-term international consultants is positively valued by all national stakeholders. However, many of them find that the transformation of the project into operational strategies and work plans seems to lag behind.

A few companies expressed dissatisfaction at delays in implementation and the limitation of resources. The delays are attributed to lack of sufficient support (from government and UNIDO) and lack of clarity on the amount of resources put into the project. Other causes are the need for learning-by-doing - with a mix of successes and failures - which is inherent in an innovative approach; the realisation that initial project objectives were too ambitious and spread across too many countries in relation to the team's capacity and the budget; the emergence of key opportunities that could not have been foreseen (e.g. the invitation to participate in the PMPA Business Plan); and external factors, such as elections, changes of persons in key positions, etc.

3. Effectiveness

At the end of Phase 3, UNIDO has acquired a good understanding of the specifics of pharmaceutical sector development in DCs/LDCs since the first global project to strengthen the local production of essential generics started in January 2006.

At that time, the international community by and large was rather sceptical about the strategy of improving access to essential drugs via local production. Now, however, there is a general recognition of UNIDO's key pioneering role in raising awareness of the importance of strengthening LPP and of the Organization's potential to play a leading role in coordinating United Nations (UN) organisations in this initiative.

By far the most important achievement of the project to date at macro/continental level is its contribution to the PMPA BP, which it is likely to become the main reference point for the development of any further activities by UNIDO and other organisations in the field of LPP in Africa. The launch of the Business Plan with the technical support of UNIDO opens up new opportunities for a supranational strategy.

UN organisations involved in the pharmaceutical sector are now willing to accept the leadership of UNIDO in the design and implementation of collaborative LPP strategies and this is a position shared by most industry associations and national governments and by most companies.

4. Main country-specific findings

Kenya

The project is considered relevant and appropriate by most stakeholders.

A general impression gained from interviews is that industry in Kenya is aware that it is up to the national stakeholders (both government and industry) to assume ownership and leadership of the project and not to rely exclusively on UNIDO and other external sources of assistance.

Several positive changes in the sector are attributed to the project. For instance, country profiles were considered important in order to establish where the

pharmaceutical industry in Kenya stands. Moreover, UNIDO is seen as having promoted dialogue and collaboration, turning former 'enemies' into 'allies'.

Complaints over slow implementation were frequently raised in the course of interviews. Industry is looking for more leadership from the Ministry of Medical Supplies (MoMS) and the Ministry of Industry (MoI) which are expected to collaborate in the implementation of the project.

Ghana

The main national counterpart, the Ministry of Trade and Industry (MoTI) acknowledged some advances but complained of the lack of a detailed project document. They also mentioned that “so far no single company has been upgraded”. Moreover, the local industry association, the Pharmaceutical Manufacturers Association of Ghana (PMAG), has become a valid and active counterpart for the industry.

On the other hand, national public health organisations seem less involved.

Several key international organisations in Ghana recognise UNIDO's expertise and expect it to lead the initiative to strengthen pharmaceutical production of essential generics while they provide support in their own fields of expertise and mandates.

Several stakeholders expressed strong dissatisfaction at the slow progress of implementation, which has not to date lived up to their expectations. Moreover, there seems to be a widespread lack of clarity among potential stakeholders regarding their expected roles and responsibilities and the project’s aims. They attribute this to the lack of an agreed project work plan, which, at the time the evaluation took place, was still in the making. The MoTI and the MoH are awaiting this work plan in order to obtain a more formal commitment to the project by the Government.

Viet Nam

The UNIDO project in Viet Nam is at a much earlier stage than in Ghana and Kenya. The report entitled 'Pharmaceutical Sector Profile and Policy Review' is the first and main deliverable under the ongoing UNIDO/WHO collaboration. One important outcome is that, as a result of the project, the MoH is preparing an amendment to the existing Drug Law of 2005 and many of the recommendations made by UNIDO's international consultant have been introduced in the draft law.

There is a possibility that problems of ownership and management might appear in Viet Nam. The Drug Administration of Viet Nam (DAV) does not appear to have staff with the requisite technical expertise to lead the project. They have limited managerial and economic experience, a key factor in demonstrating a comprehensive overview of the project. DAV's position as a department of relatively low level within the MoH is an additional limitation when it comes to coordinating the various high level institutions involved in the project.

In addition, the absence of the Ministry of Industry and Trade (MoIT) among government stakeholders – on the grounds that it is responsible for the chemical industry but not for the pharmaceutical industry which is a responsibility of the MoH – is

hard to understand and could become a major handicap in a project aimed at the development of local industry.

Price regulation seems to be a source of uncertainty for the industry in Viet Nam. The cost-of-production approach to fixing maximum prices apparently puts national manufacturers in a disadvantaged position in relation to foreign companies and importers.

The WHO-UNIDO collaboration in Viet Nam has been a pioneering experience for these two organisations who have worked simultaneously with the same objectives in the same country. The aim of the collaboration was to prepare a comprehensive pharmaceutical industry profile and to analyse the pharmaceutical policies in place. All stakeholders judge this partnership positively and note with satisfaction that the project has facilitated new pharmaceutical legislation in Viet Nam.

5. Sustainability

It is too early to make a full assessment of the sustainability of the project. There are, however, some discernible factors that can contribute to the desired sustainability.

The project has been providing support and help in building institutions that ensure the sustainability of the process, such as the Saint Luke Foundation in the area of training, and the launching and strengthening of pharmaceutical manufacturers associations that can become stable and effective counterparts.

Moreover, the project has contributed to widespread recognition by companies, regulators and other parties that attaining international quality standards is a prerequisite for simultaneously achieving both public health and economic objectives. If these standards are actually attained, they will make the industry more competitive and hence sustainable.

6. Crosscutting issues

Recognising that gender topics were not a significant feature of project design and implementation in the initial phases of the project, a specific report was commissioned from an expert at the end of 2012. This resulted in preliminary ideas and recommendations on how gender can be adequately reflected in the project in future interventions at the policy and institutional levels. The findings are also expected to be built into the work plan for phase 4.

With respect to environmental considerations, the project does not seem to pose any significant risks.

7. Recommendations

To UNIDO

The tonning down of the access goal by UNIDO because of lack of evidence on the link between LPP and access seems unnecessary and may have negative consequences. Public health and access-oriented organisations might become less inclined to collaborate with UNIDO if they get the impression that it has become less committed to public health and concentrates on industrial goals. UNIDO should ensure that partner

organisations understand its commitment to both public health and industrial goals of the project.

In order to improve the evaluability of future interventions, the project should set up quasi-experimental evaluations, by comparing the evolution of a selected set of indicators on access, quality and competitiveness between countries that benefit from the project and a control group that does not. This is, of course, a costly activity that would require a substantial increase in the project budget.

In light of the frequent complaints and frustration voiced by national stakeholders in relation to perceived delays in implementation, the project planning should be more realistic in future phases of the project as to the expected outcomes and also to try to define achievable timelines for the outcomes and impact.

One management option to consider for future phases of the project would be to shift resources from headquarters to the countries where interventions are taking place, and to set up National Steering Committees in order to ensure ownership and sustainability.

Future phases of the project should address issues related to price regulation. Many DCs still rely on pricing according to the cost of production criterion, which usually discriminates against LPP because import prices – with their implicit profit margins – are accepted as costs, while locally produced products are controlled by their cost components. Pricing policies are a potential tool to provide incentives to (or at least, not to distort) the goals of LPP strategies. An additional positive effect is that promoting rational pricing policies can be a way of involving ministries with economic portfolios in the project, as this is usually part of their responsibilities.

Future similar interventions should explore the feasibility and convenience of product-oriented approaches, i.e. to focus supply-side policies on specific categories of medicines. This could, for example, be achieved by prioritizing the production of essential medicines that cover important local health needs or pose special problems of availability and affordability for the country.

In case of resource availability, UNIDO should replicate the PMPA initiative at other regional or global levels.

To the donor

The donor should ensure coordination of all organisations funded under its project to promote LPP and access to medicines. For example, stakeholders involved in UNIDO's national strategy building in Kenya and Ghana appear unaware of the important role that appropriate management of Intellectual Property Rights - a topic falling within the mandate of UNCTAD - has in improving opportunities for developing LPP.

Provided that the donor is satisfied with the performance of the UNIDO project and agrees with future plans, it should consider funding an appropriate budget increase to allow for an expansion which would include some key activities such as building the knowledge base to make LPP promoting activities more evidence based and hence more effective and efficient.

1. Introduction and background

1.1. Introduction

This evaluation was carried out between December 2012 and May 2013 by one consultant, Joan Rovira, a health economist. The Terms of Reference (ToR) of the evaluation are provided in Annex A. The evaluator had not been involved in the design or implementation of the project and this was his first professional assignment for the United Nations Industrial Development Organization (UNIDO).

The evaluation exercise consisted in:

a) A review of the project documents, mainly progress reports covering the period from December 2008 to December 2012 and additional documents provided by the project team, complemented by a review of the published academic and institutional literature (Annex C).

b) Production of an inception report.

c) A two day visit to UNIDO headquarters in Vienna from 30 to 31 January 2013 to hold personal interviews with members of the project team to obtain a briefing on the state of the project, to present and discuss the inception report of the evaluation, and to collect additional documentation.

d) Field missions to Kenya (11 to 16 February 2013), Ghana (18 to 22 February 2013), and Viet Nam (25 to 29 March 2013) to interview national stakeholders.

e) A debriefing session in Vienna (29 to 30 April 2013) for a presentation of the preliminary findings.

f) Teleconferences with some key international stakeholders: WHO headquarters and donor representatives.

The main findings are based on the analysis of qualitative and quantitative information obtained through document review, key informants' semi-structured interviews, and observations in the field.

In the field work, information was gathered during 40 interviews with a total of 63 individuals (18/36 in Kenya, 16/18 in Ghana and 6/9 in Viet Nam). The affiliation of interviewees was government and the public sector (11/20), companies and industry associations (17/22), international organisations (4/4), non-governmental organisations (NGOs) (1/1), academics and independent experts (3/3) and UNIDO representatives and consultants (4/4).

The lists of interviewees from Kenya, Ghana and Viet Nam, as well as participants in the teleconferences, are given in Annex B.

1.2. Project background

1.2.1 Project objectives and formulation process

This project is concerned with the problems of Local Pharmaceutical Production in Developing Countries (DCs) and Least Developed Countries (LDCs). The impact goal of the project is to increase the supply of quality affordable essential medicines from producers in those countries. Initially, during the first two phases, and partly also during the third phase, 'improved access' was stated as the impact goal for the project. However, experience gained during project implementation showed that the link between local production and 'access' is not clearly scientifically established.

This learning process, together with recognition of the fact that the initial project goals were overly ambitious, were the reasons why, during the third phase, UNIDO dropped the reference to 'improved access' and modified the logframe and the impact goal to: 'Increased local production of essential medicines'. Consequently, it is against the objective of 'Increased local production' that the success of the project should be measured, whilst also taking into account that, once a national strategy has been adopted, impacts might take at least five years to become visible.

The project is a largely German-funded, donor-led activity managed by UNIDO's Business, Investment and Technology Services Branch in the Programme Development and Technical Cooperation Division. In accordance with conditions laid down by the donor, the project has a global scope although most of the interventions have so far focused on Africa, with one project implemented in Viet Nam. This global UNIDO project has been built as a successive set of projects, with each one laying the foundations for the following phase. In this way, each phase has benefited from lessons learnt during the previous one and this has helped to guide the process of building partnerships with the relevant national stakeholders and other United Nations (UN) agencies.

The three phases implemented so far have the following basic features:

- Phase 1 (January 2006 to June 2008): A fact finding and stocktaking phase. The initial focus was on the production of drugs for pandemic diseases and on Least Developed Countries (LDCs). At the time the project was designed, pandemic diseases were in the international spotlight and large international donors, such as the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to fight Aids, Tuberculosis and Malaria (GFATM), the Joint United Nations Progamme on HIV/AIDS (UNAIDS), and the international drug purchasing facility known as UNITAID, were potentially attractive sources of income for the pharmaceutical industry. On the other hand, the project's focus on LDCs reflected an assumption that a window of opportunity for building or strengthening local pharmaceutical production existed in the period up to 2016[1] when compliance with the Trade Related Aspects of Intellectual Property Rights (TRIPS) would come into effect.
- Phase 2 (July 2008 to December 2010): The scope of the project was

[1] This is also referred to as the TRIPS waiver.

broadened beyond pandemic diseases and LDCs to include essential generics and DCs in general. This move reflected the lesson learned in Phase 1 that commercial viability could hardly be expected or derived from the manufacture of a narrow range of medicines. The project adopted a holistic approach, aiming to involve all relevant stakeholders though dialogue and networking. At the same time, it delivered a broad range of training, capacity building and advisory interventions at micro, meso and macro levels. The rationale of this holistic approach was that, in order to ensure the success of the interventions and to make the development of the industry sustainable, stakeholders at the three levels – industry, institutions and policy – had to move simultaneously, reinforcing each other, towards some common agreed objectives.

- Phase 3 (January 2011 to December 2012): This project was launched as a continuation of the previous country interventions and in order to replicate these in other countries. It also foresaw the development and implementation of an enhanced UNIDO programme. However, the main activity of the Phase was in response to the African Union Commission (AUC)'s request in June 2011 for the joint elaboration of a Business Plan (BP) for the accelerated implementation of the AU's Pharmaceutical Manufacturing Plan for Africa (PMPA).

1.2.2 Project structure

The project applies a holistic approach that considers three levels of interventions: micro, meso and macro.

The micro level refers to enterprises, i.e. local pharmaceutical manufacturers, most of which are SMEs when measured by international standards; the meso level refers to the institutions that operate in the sector with regulatory or representative roles or providing specific inputs (e.g. education and training) to the sector and services to the enterprises. Finally, the macro level refers to the national and international policy making domain.

The justification and purpose of a holistic approach is the assumption that strengthening local pharmaceutical production in an effective, efficient and sustainable manner requires coordinated actions at all three levels:

1. Enterprise level support, such as plant-level technical and managerial assistance to achieve international Good Manufacturing Practice (GMP) standards or the brokering of specific business partnerships between local pharmaceutical Small and Medium-sized Enterprises (SMEs) and foreign producers of generic drugs. This has been pursued in the form of pilot projects, i.e. activities with potential for replication in similar circumstances in other countries.
2. Institutional capacity building for entities with responsibilities impacting upon pharmaceutical sector SMEs, such as National Medicines Regulatory Authorities (NMRAs), trade associations, training institutions, and entities related to the quality infrastructure.
3. Policy advice on improving the business, legal and regulatory environment for the production of generic drugs. This includes national strategy formulation and support for regional harmonization efforts.

The mix of interventions applied in each country is adjusted to the country-specific needs and opportunities. UNIDO's approach is to seek to set up partnerships with other UN and specialized international, regional, and national organisations.

1.2.3 The donor

The project is funded mainly by the Government of Germany which first became involved in promoting Local Pharmaceutical Production (LPP) in 2005 at a time when LPP was not an objective endorsed by many international organisations.

For the donor, the UNIDO project is part of a larger programme involving funding of around Euro 100 million since 2006. The share of funding allocated to UNIDO amounts to less than Euro 10 million. German funding of the budgets of Phases 2 and 3 amounts to Euro 3.2 million, and represents 85.5% of the total budget, while UNIDO contributed the remaining 15% of the budgets. Germany is disbursing most of its funding for this initiative in the form of bilateral aid and attributes high importance to the overall programme. In particular, it aims to improve competition in order to balance the influence of multinational corporations (MNCs) on the pharmaceutical sector in developing countries.

Specific interventions are tailored to countries' needs and opportunities. For instance, in Bangladesh, the key issue was the development of active pharmaceutical ingredient (API)[2] production. In Africa, one of the priorities was the establishment of bioequivalence[3] centres and one has already been set up in Ethiopia with a second one expected to start operating in Ghana by 2015. The German programme is also active in lobbying at international fora, for example, by trying to influence the European Union (EU) on the recent issue of the TRIPS waiver for LDCs.

For the programme's more technical aspects, the donor works with UNIDO on industrial sector issues and with the United Nations Conference on Trade and Development (UNCTAD) and the South Centre on intellectual property (IP) issues.

The Government of Germany acknowledges the value added of the partnership with UNIDO and UNCTAD as complementary to its bilateral cooperation in this area and hence as an integral part of its wider overall programme. It accepts that delays have often been caused by changes in government teams and the management bodies of some institutions.

[2] According to the WHO definition, an API is "(A) substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings."

[3] Bioequivalence studies are used to assess the expected in vivo biological equivalence of two preparations of a drug. If two products are said to be bioequivalent, it means that they would be expected to be, for all intents and purposes, the same. Bioequivalence with a reference product is increasingly requested by NMRAs before granting the marketing authorisation of a generic.

2. Evaluation purpose, scope and methodology

2.1 Purpose

In accordance with the Terms of Reference (ToR) (Annex A), this independent evaluation should review projects TE/GLO/08/030 and XP/GLO/09/016 (Phase 2) and TE/GLO/10/023 and XP/GLO/11/007 (Phase 3) of the Global Programme. In the case of Phase 2, this will be a final evaluation (the previous independent evaluation covered Phase 1 (TE/GLO/05/015) and Phase 2 (TE/GLO/08/030) up to the end of 2009 approximately). In the case of Phase 3, this evaluation covers activities carried out up until December 2012 although the project duration was subsequently extended to 31 May 2013 (see Figure 1)[4].

The purpose of the present evaluation is three fold:

1. To determine the extent to which the expected results, as defined in the project documents or other documents reflecting project revisions, have been achieved or to assess the likelihood of achieving these upon project completion; and to establish the degree to which recommendations from the last evaluation have been included in subsequent project design and work.
2. To identify strengths and weaknesses in project implementation, design (including the logical framework (logframe)) and management to date, including project monitoring and self-evaluation mechanisms; and to elucidate the key reasons for implementation delays.
3. To identify potential options for improvement, which could include modifications in project design, including the logframe, implementation, and management mechanism (steering committee; responsibilities of UNIDO and project staff; scheduling, etc.), especially with regard to the start of Phase 4 of the project which was imminent when this evaluation commenced. Ideally, the evaluation results would inform the preparation of a detailed work plan for that phase sometime towards the end of the first quarter 2013.

2.2 Scope

Although the project has implemented a broad range of interventions at the three defined levels (macro, meso, micro) in a number of LDCs and DCs, this evaluation is expected to focus on those areas which are of particular importance for the successful continuation and further expansion of the project, as well as for pointing out the potential for improvements in strategic areas on which the project will focus in the upcoming phase.

[4] It should be noted that there is some overlap between phases. Phase 2 was originally planned to terminate in June 2010 but was extended – with donor approval – to December 2011. Similarly, Phase 3 activities, planned to continue until December 2012, were not completed by this date and an extension was agreed with the donor, as indicated above.

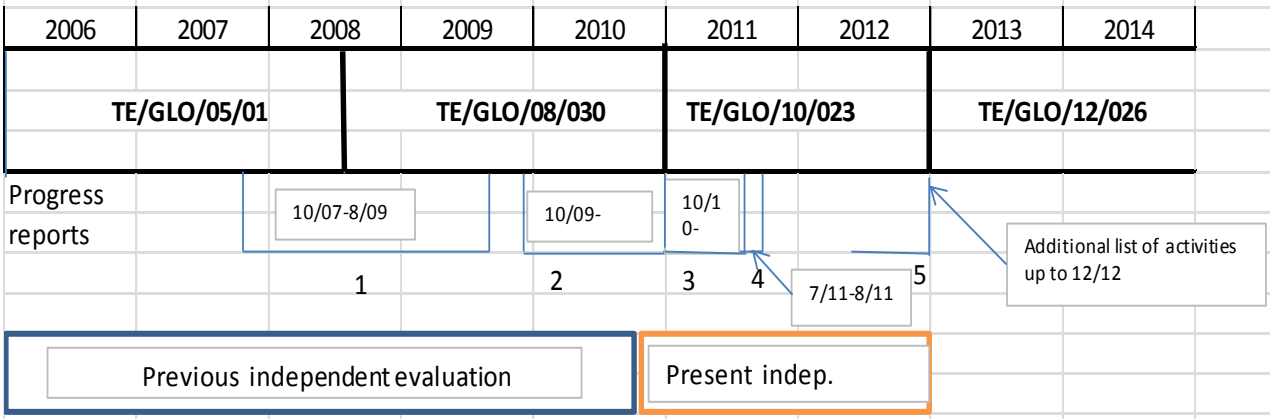
A crucial area for advancement in the field of LPP is the design of a sector specific development framework. UNIDO has already developed strategies based on a multistakeholder approach in Kenya and Ghana and is taking the first steps in this direction in Viet Nam.

A second area of interest for the evaluation is the partnership requested by the African Union Commission (AUC) in June 2011 for the joint elaboration of a Business Plan (BP) for the accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA). In this regard, the UNIDO project team sought and obtained approval from the donor for a revision of the project work plan and corresponding budget line allocations. As a result of this activity, UNIDO has been invited to continue its collaboration with the AUC with a view to managing the implementation of the PMPA BP in the years ahead.

With respect to the country selection, a focus on Kenya and Ghana was recommended as both of these countries have been fast tracked for implementation under the PMPA BP. In addition to evaluating project experiences in Africa, an evaluation of the project's experience in Viet Nam was recommended as this provides insights into a different cultural, as well as political, setting and also showcases inter-organisational cooperation with the World Health Organization (WHO).

Figure 1 shows the timing of the project phases, the progress reports and the independent evaluation time frames.

Figure 1. Initial project duration, coverage of progress reports and independent evaluations



2.3 Methodology

The methodology applied in the project evaluation included:

A review and analysis of the project documents provided by the project team, mainly progress reports which cover the period from December 2008 to December 2012, and additional documents related to the project activities and management, complemented by a review of the published academic and institutional literature, as well as interviews

withall team members during visits to UNIDO Headquarters, country stakeholders during field missions to Kenya , Ghana , and Viet Nam , and telephone conferences with some key international stakeholders.

For the interviews in Kenya and Ghana, two semi-structured questionnaires based on the evaluation questions suggested in the ToR were developed by the consultant: one for industry and the second one for public sector and international organisations.

In the case of Viet Nam, given the early stage of the project, the questionnaire was simplified. Moreover, in line with suggestions made by the UNIDO team, no interviews were carried out with individual companies, only with the manufacturers association.

The report highlights issues on which there was either broad consensus and unanimity or dissent and contradictory responses; many of the original responses are quoted directly. No attempt has been made to quantify the responses to the interviews because the questions were open and hence difficult to codify. Moreover, the number of persons interviewed was relatively small and heterogeneous and thus there was no guarantee of the representativeness of the sample.

2.4. Limitations of the evaluation

The evaluation exercise faced some difficulties due to the following factors:

2.4.1 Changes in objectives and overlapping phases

It has sometimes proved difficult to match objectives with achievements as a result of changes in the objectives and activities introduced to accommodate needs and opportunities that emerged during implementation and because of a certain degree of overlapping of phases due to the extension of their initially planned durations. This is not a criticism of the project management but rather reflects the desirable flexibility of the project, enabling it to adapt to the lessons learned and to new opportunities that emerged. All changes were agreed with the donor and duly documented. However, for the evaluator, they make the matching of objectives and achievements more complicated.

2.4.2 Multi-causality of outcomes and impact

Other difficulties encountered in carrying out the evaluation derive from the multi-causal nature of the objectives, which do not depend only on project performance but also on the attitudes and decisions of other agents. Moreover, whilst the project aims to influence the respective stakeholders, their attitudes and decisions are largely out of the direct control of the project management. Notwithstanding this, and in order to ensure ownership, the views of stakeholders must be considered and sometimes incorporated into the project design and implementation. Multi-causality often makes it difficult to determine how far the achievements or the failures are contributing to the project management or to external factors that cannot be predicted and controlled.

2.4.3 Information availability

The documentation provided to the evaluator by the project team is very comprehensive regarding the activities carried out by UNIDO before and during Phases 2 and 3. It is, however, more limited regarding the baseline situation and the evolution of key variables such as access to medicines, medicine needs, structure of the pharmaceutical industry (number, size and other characteristics of existing companies), domestic output by products, national sales, imports and exports, quality of medicines, demand and financing of medicine consumption, domestic price trends, etc. The availability of appropriate information systems and especially of comprehensive and reliable statistical information on the pharmaceutical sector is one of the main limitations in designing and implementing strategies to develop local pharmaceutical production and to improve access to medicines. Yet these should also be the primary original source for formulating many of the indicators required for monitoring and evaluating the project.

Indeed, one of the objectives of the present evaluation should be to assess whether awareness exists of the need for such information systems and whether some steps have already been taken to develop them. UNIDO has made a valuable effort in collecting and analysing existing information in a broad set of reports, such as the eight Pharmaceutical Sector Profiles already completed.

Given the information gaps mentioned above, it might be difficult to assess the impact of the project on the final objectives (improving access to quality medicines by means of price reductions and promoting domestic competitive production of pharmaceuticals). On the other hand, the project recognises that these objectives can only be attained in the mid to long term. It can therefore be argued that it is still too early to expect impacts of the project in line with the final objectives.

2.4.4 Short-term and long-term objectives

The more immediate objectives which are the short-term focus of the project – creating awareness among national governments, regional and international organisations of the need and feasibility of local production, and promoting national and regional ownership of the initiatives in order to achieve this – are of a qualitative and subjective nature and are often difficult to measure in terms of conventional indicators. Even accessibility is a highly elusive concept that is rarely measured in a regular, objective way - even in more developed countries with more mature health systems - as it requires large population surveys.

2.4.5 Potential biases

The main source of evidence for this evaluation exercise in assessing the degree to which the project's objectives have been achieved, as well as the impact of the project, has been personal interviews whose results, since they reflect perceptions, values and expectations of stakeholders, might be intentionally or unintentionally biased.

National stakeholders were selected for interview by the project team and by the UNIDO national consultants and were invited to participate on a voluntary basis. There is therefore a possibility of selection and self-selection bias in the sample as well as of

strategic responses. Companies and public organisations that are satisfied with the project might be more likely to be selected and to accept being interviewed. Moreover, responses might be rather polite and not too critical in order not to prejudice the chance of benefiting from the project in future. The national consultants working for the project were present at interviews in order to facilitate the task of the evaluator. This might also have inhibited criticism although it was clearly stated at the interviews that it was not the companies or the national consultant - but rather the project design, implementation and outcomes - which were the focus of the evaluation exercise.

It must nevertheless be acknowledged that most of the respondents seemed very open and candid and were often very critical regarding project implementation and achievements.

2.5 Results of the 2010 mid-term independent evaluation

A mid-term evaluation of the project[5] was carried out from 25 November 2009 to 31 January 2010 by an independent team consisting of two consultants. The main findings were based on qualitative and quantitative analyses of data obtained through document review, semi-structured interviews with key participants, discussions with groups of stakeholders, and observations made during field visits to Ghana and Lesotho. The main conclusions of the mid-term evaluation acknowledged the relevance of the project to DC and LDC access to medicines and economic development goals, as defined in the Millennium Development Goals (MDG), UNIDO thematic priorities and United Nations Development Assistance Framework (UNDAF) priorities.

That evaluation report stated that, although the logical framework had been defined in the project documents, it had not subsequently been updated in order to reflect changes. It further noted the postponement of the establishment of the Strategic Advisory Group.

The 18-month delay in implementation experienced by the project was attributed in the mid-term evaluation to a set of factors such as difficulties to identify experts, the understaffed management team, and the initial focus on LDCs. It was the weaknesses identified in LDCs which led to a broadening of the scope of the project to DCs. More generally, the evaluators felt that a relatively small project budget was spread over many activities in many countries. Nonetheless, they emphasized that, despite implementation delays, outputs had been produced in 14 countries and that four countries (Ghana, Kenya, Botswana and Cameroon) had been identified for upgrading of SMEs. In addition, the global market study had been used to assess individual business plans and for revising project interventions.

The main recommendations to UNIDO were:

- Project documents should clearly define the roles of counterparts.
- The logical framework and work plans should be revised at national level by a

[5] UNIDO Evaluation Group. Independent Evaluation. Strengthening the local production of essential generic drugs in least developed/developing countries. October 2010.

National Steering Committee including at least the Ministry of Health (MoH) and the Ministry of Industry (MoI).

- Objectively Verifiable Indicators (OVIs) at the impact level should be included in the logframes for countries.
- A modular approach should be considered in order to address the problem of insufficient funds.
- To establish collaboration with WHO, UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD) in developing case studies on LPP and on the contribution of LPP to accessibility and affordability.
- To support the rapid establishment of a Strategic Advisory Group (SAG) that would advocate maximum use of TRIPS flexibilities.

Most of these recommendations were taken into account in the design of Phase 3 of the project.

The project document for Phase 3 included an Annex in which the roles of the main players in the access to drugs challenge were described. WHO, the most relevant UN stakeholder in the project, was clearly committed to concentrating on the regulatory aspects, while UNCTAD would lead the Intellectual Property Rights (IPR) component. The role of national counterparts was defined in the national strategy papers and roadmaps at different stages of development in Ghana, Kenya and Viet Nam. It was also envisaged that, although the existing consultative stakeholder group arrangements in Ghana and Kenya would be maintained, the commencement anew of more specific country level activities would involve the setting up of National Project Steering Committees, chaired by National Project Directors. These would include among their members representatives of the Ministries of Health and Industry and other relevant stakeholders.

The Phase 3 logframe explicitly defined Objectively Verifiable Indicators for the activities, outputs and outcomes planned although limited progress has apparently been made in setting up an appropriate information system in order to collect and monitor the OVIs.

The recognition of the insufficiency of funds in relation to the ambitious goals of the project has led to several decisions. Phase 3 narrowed the focus of intervention to a smaller number of countries and it explicitly stated that UNIDO would not act as a provider of funds to address the investment needs of private or public institutions. Moreover, the second objective foresees the design, development and implementation of an enhanced programme with modules designed to address specific bottlenecks and a staffing plan including roles and responsibilities.

One aim of Phase 3 was to overcome the past lack of separate brief 'project documents' or output-activity schedules 'extracted' from the main project document to guide project activities in any new target country. Formal adoption of country-specific project work plans by National Project Steering Committees would be sought upfront.

3. Region/Country/Programme context

3.1. Overall situation and trends

Access to medicines is a key component of the goal of access to health services in developing countries (DCs) and of global strategies such as the Millennium Development Goals (MDGs). Although substantial progress has been achieved in the last few decades, the situation is far from satisfactory in most DCs.

The WHO report entitled World Medicines Situation 2011[6] provides some striking facts and figures on the existing problems of access to medicines and on the huge inequalities in access that affect DCs. They include:

- Per capita pharmaceutical expenditures in 2005/2006 ranged from US$ 7.61 in low-income countries to US$ 431.6 in high-income countries, with considerable variation between income groups in each country. However, compared with 1995, the rate of increase is greater in middle- and low-income countries.
- Sixteen per cent (16%) of the world's population living in high-income countries account for over 78% of global expenditure on medicines.
- Public sector availability of generic medicines is still less than 60% in the Western Pacific, South-East Asia and Africa regions.
- At least one-third of the world's population has no regular access to medicines. Inequity in access to essential medicines is part of inequity in health care. Key evidence to document such inequities is, however, rarely collected.
- The treatment of an adult respiratory infection with a seven day course of ciprofloxacin would cost the lowest-paid government worker more than a day's wage in most countries. Costs escalate when originator brands are used. The same treatment would cost the lowest-paid unskilled government worker over 10 days' wages in the majority of the countries studied; in Armenia and Kenya, over a month's salary would be needed to purchase this treatment.

The 2013 WHO World Health Statistics report[7] also highlights the progress made in relation to achieving the MDGs and in reducing the health gaps between affluent and low-income countries. Moreover, health indicators for developing countries are improving and inequalities are reducing. However, the report states that "almost half of the countries surveyed have access to less than half the essential medicines they need for basic care in the public sector. Consequently, many people living in low and middle-income countries turn to the private sector where the cost of even basic, generic medicines, can be up to 16 times higher."

[6] http://www.who.int/medicines/areas/policy/world_medicines_situation/en/
[7] http://www.who.int/gho/publications/world_health_statistics/EN_WHS2013_Full.pdf

According to a recent IMS report[8], the African pharmaceutical market is relatively small – aproximately 3% of the world market - but it is experiencing one of the highest growth rates among world regions, a 10.6% compound annual growth rate (CAGR) in line with Asia Pacific and Latin America. The same source estimates that the African market might grow to as much as US$ 30 billion and to US$ 45 billion by 2016 and 2020 respectively. The factors responsible for this evolution include demographic growth, increased wealth and healthcare investment, and rising demand for drugs to treat chronic diseases. Healthcare spending is increasing in the region at a similar rate, recording a CAGR of 9.6% since 2000.

Demand for medicines in Africa has been satisfied by a combination of imports from large innovator MNCs, large Indian and Chinese generic producers and the domestic sales of local generic producer SMEs. Imports from the second group have been the most dynamic of the three components in recent years.

Access to essential medicines is at the core of health policies as health systems are expected to grow. Moreover, there is also an overall interest in developing local pharmaceutical production in itself as an industrial and import substitution policy. The trends towards regional and sub-regional market integration are additional factors that will reinforce the demand side of the market. “The existence of trading blocs, such as the East African Community (EAC), Economic Community of West African States (ECOWAS), the Southern African Development Community (SADC) and the Common Market for Eastern & Southern Africa (COMESA), offers an increasingly attractive market opportunity characterized by the removal of trade tariffs and a move towards harmonized medicines registration processes”[9].

The commitment of large international donors to fight the pandemic diseases (AIDS, Tuberculosis and Malaria) is an added potential opportunity for pharmaceutical manufacturers but few local companies have been able to take advantage of it because their products have rarely attained WHO prequalification status, a prerequisite that most large donors impose on potential providers.

The harmonization and enforcement of highly protective IP standards since the approval of TRIPS in 1995 and through bilateral trade agreements has resulted in a substantial change in the conditions of access to technology by the pharmaceutical industry in DCs. While some considered that the extension of the TRIPS transition period for LDCs up to 2016 had opened a window of opportunity for developing a pharmaceutical industry, most experts agree that TRIPS is a growing hurdle to both affordability and local production of drugs as it grants a stronger market and negotiating power to large MNCs vis-à-vis local generic manufacturers and national health authorities (Scherer and Watal, 2002; Abbott and Reichman, 2007).

Nonetheless, the general characteristics outlined above should not hide the existence of large differences across sub-regions and countries. The PMPA BP reports that 38 countries have pharmaceutical manufacturing entities on the continent, with Nigeria topping the list with more than 200 registered pharmaceutical producers. At the other end of the spectrum, several countries, such as Cameroon, Namibia, Swaziland,

[8] IMS. Africa: A ripe opportunity. Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa. 2013.
[9] IMS, op.cit.

Lesotho and Malawi, have only one or two active manufacturers. The specific situation in the two African countries that are the focus of this evaluation, Kenya and Ghana, is at an intermediate level, with an estimated number of 42 and 22 manufacturers respectively.

3.1.1 Kenya

The main sources for describing the situation and trends in the pharmaceutical sector in Kenya are the Pharmaceutical Sector Profile: Kenya. 2010. UNIDO; and the Draft Kenya Pharmaceutical Sector Development Strategy, which includes some more up-to-date information.

There were 42 pharmaceutical companies in Kenya in 2010, including one multinational corporation, Glaxo Smith Kline (GSK). Local companies produce generic medicines and have similar portfolios. They concentrate on the formulation and packaging stages and import all Active Pharmaceutical Ingredients (APIs). Most of them operate below full capacity.

According to company sources, there are large variations in GMP standards across the industry. Although the average level is still quite good by regional standards, the lack of WHO prequalification precludes access to donor funds and some of the products manufactured now are irrelevant in terms of sales volume and public health needs.

The Pharmacy and Poisons Board (PPB) is the pharmaceutical regulatory authority in Kenya. According to the reports mentioned above, the PPB does not have the resources or capacity[10] to carry out its responsibilities effectively.

Estimates of the Kenyan pharma market range from between US$ 230 million (in 2008) and US $208.6 million (in 2007) and it is expected to grow at a CAGR of 15.1%.[11] Of the total market in 2008, “generics would have accounted for 58.7 per cent of the total, while original branded pharmaceuticals would have accounted for the balance of 41.3 per cent”. Local production is valued at about US$ 83 million.

Some 1.6 million Kenyans (9.5 million when dependants are included) are covered by the National Health Insurance Fund (NHIF). However, this fund covers only in-patient care and the costs of medicines and other health services are borne directly by the patients.

PROJECT MILESTONES IN KENYA

2009

UNIDO approached the Government of Kenya - the Ministry of Medical Services (MoMS), Ministry of Public Health and Sanitation (MPHS), Ministry of Industry (MoI) - and afterwards other key partners including the PPB, Federation of Kenya Pharmaceutical Manufacturers (FKPM), and the National Laboratory for Quality Control (NLQC). The national project consultant was appointed.

[10] The PPB has only six inspectors.

[11] It is not clear whether the quantitatively significant donor-funded purchases of medicines for the Kenyan market are included in these estimates.

The Kenya Pharmaceutical Sector Profile was the first output of the project.

2010
Two other studies followed: one on financing sources for the industry and a second one on production efficiencies.

2011
At a stakeholders' forum, it was decided to draft the Kenya Pharmaceutical Industry Strategy paper to explore the options for future development.

2012
Seven companies carried out a GMP self-assessment of the first component of the strategy, i.e. the development of a GMP roadmap with the aim of identifying priorities and timelines.
By the end of 2012, an international consultant had carried out a regulatory assessment of six companies to determine the level of GMP in relation to WHO standards.

3.1.2 Ghana

The draft Ghana strategy document, "The Future of Ghana's Pharmaceutical Industry – Building a Centre of Excellence in Africa" (2010), provides an overview of the overall situation and trends in the pharmaceutical sector in Ghana.[12]

"Ghana has 38 registered pharmaceutical manufacturers, of which 22 are currently active. The sector directly employs roughly 6,000 people. In the ECOWAS sub region it has the second largest local pharmaceutical industry."… "As with the rest of the sub region, Ghana's pharmaceutical manufacturing is focused on the final formulation and packaging stages and sources the vast majority of its raw materials from international suppliers. One company in the country has limited capacity to produce active pharmaceutical ingredients (APIs), but almost all APIs are imported from India and China. The same is true for other inputs such as packaging, excipients and engineering expertise required to maintain and service equipment, all of which are by and large imported."

Although the report recognises the lack of reliable data on the pharmaceutical market in Ghana, it estimates the size of the wholesale market to be US$ 100m of which only 30% is supplied by local manufacturers despite the fact that the country has established a list of products that cannot be imported because there is sufficient local production to satisfy local demand.

The sector is regulated by the Food and Drugs Board (FDB) established in 1992, which later became an autonomous agency under the name of Food and Drugs Authority (FDA). The FDA probably cannot be compared to the more stringent regulators found in high-income countries but its regulatory capacity appears to be well regarded by its peers in the sub region.

According to the National Health Insurance Agency (NHIA), the National Health Insurance Scheme (NHIS) dramatically increased its coverage from 6.3% to 66% of the

[12] This document was the result of an agreement between the Ministry of Health and the Ministry of Trade and Industry.

population between 2005 and 2009. However, a recent report[13] estimates the actual valid membership rate (% of population with valid ID cards) at just 17.5%.

PROJECT MILESTONES IN GHANA

2007

The Pharmaceutical Manufacturers Association of Ghana (PMAG) approached UNIDO for support during a regional UNIDO event organised in Dakar, Senegal. A UNIDO team member mission to Ghana followed. PMAG set up a committee with four members that lobbied for the industry. Contacts with the Ministry of Trade and Industry (MoTI) started and an oral agreement was reached but did not crystallise immediately.

2009

A roundtable for multiple stakeholders (ministries, regulator, private sector, academia) was organised and was chaired by the Minister of Trade and Industry. Four subcommittees were set up to deliberate on the complexities of specific issues and a first version of the strategy paper was written.

2010

A revised strategy document was submitted to stakeholders for their consideration. By exchange of letters, the Ministry of Health and the Ministry of Trade and Industry agreed to collaborate in its implementation.

2011

At the request of the Chief Director in the MoTI, a Cabinet Memo was prepared.

2012

GMP assessments of seven pharma companies were conducted and a draft GMP roadmap developed.

2013*

At the invitation of President Mahama, a consortium of partners coordinated by UNIDO visited Ghana to begin early implementation of the PMPA BP based on the national strategy developed by the UNIDO global project. A shared work plan was agreed.

**Note: Whilst falling outside the time frame for this evaluation, this major milestone is mentioned as it is the culmination of the long-term work in Ghana and the partnership between UNIDO and the AUC which developed the Business Plan for the PMPA as endorsed by Heads of State in July 2012.*

3.1.3 Viet Nam

The source of this outline of the pharmaceutical sector in Viet Nam is the Viet Nam Pharmaceuticals & Healthcare Report, Q1 2012, published by Business Monitor International (BMI) in December 2011.

According to official sources, Viet Nam has 165 drug manufacturers of which 45 have been certified as GMP compliant. The pharmaceutical market was valued at US$ 1.71 billion in 2010 (US$ 1.11 billion in 2007), representing 1.7% of Gross Domestic Product (GDP). Pharmaceutical market distribution in 2010 was:

- Patented drugs (US$ 401 million)
- Generic drugs (US$ 848 million); and
- Over-the-Counter (OTC) drugs (US$ 466 million)

[13] Essential Medicines Platform, ARHR and Oxfam International. Achieving a Shared Goal: Free Universal Health Care in Ghana. ISODEC. March 2011.

Vietnamese drug makers account for 30% to 40% of the medicines market in terms of value. The local industry produces generic medicines and imports approximately 90% of the APIs used in their production. The size of the market is expected to grow at a CAGR of 17% in US$ up to 2015.

Since 1987, Viet Nam has been moving from a centrally-managed economy to a market-based system and the pharmaceutical industry has been privatised. In 1994, all state-owned companies were transformed into stakeholder companies and the state can now only own less than 50% of the capital in an enterprise.

The regulatory entitity is the Drug Administration of Viet Nam (DAV), a department of the Ministry of Health (MoH). The BMI report points to delays in administrative procedures and unpredictable decisions, such as some of those concerned with marketing authorisations. DAV is also responsible for price regulation. Pricing is based on production costs but the industry states that the system is inadequate and far from transparent.

In 2010, a new health insurance system was set up and it is estimated that about 50 million people had some form of health insurance at that date. However, the insurance system requires substantial co-payments from some population groups. According to the MoH, 600 medicines are eligible for government reimbursement but over 90% of those insured might have to pay some sort of fees for services and pharmaceuticals.

PROJECT MILESTONES IN VIET NAM

2010

Signature of an Aide-memoire with the Government of Viet Nam outlining the implementation of activities from December 2010 to December 2011

2011

Kick-off event of the Project: Inception Workshop (June)
Pharma industry analysis and LPP policy assessment, including the WHO-UNIDO Project Industry Survey, 2011, a survey of 31 pharmaceutical companies

2012

Validation Workshop to present the results of the above analysis (February)

2013

UNIDO-WHO agreement on a technical report, "Fostering LPP in Viet Nam. WHO-UNIDO Profile of the Pharmaceutical Sector and Policy Review"

3.2 UN frameworks

The United Nations Development Assistance Framework (UNDAF) is clearly relevant to UNIDO's global project at the country level since these frameworks include health goals and objectives related to access to health services.

For example, the Ghana 2012-2016 UNDAF includes as Output 8.4: "By 2014, skills of healthcare providers in three most affected regions to increase access and uptake of ART, care and support and Human Immunodeficiency Virus (HIV)/TB services enhanced". It also lists as one of the agency results attributed to WHO, the "Increased capacity of healthcare pharmacy staff in logistics management of ARVs and a strengthened referral system between the Prevention of Mother to Child Transmission (PMTCT) program and Antiretroviral Therapy (ART) clinics".

A further example is the Kenya 2009-2013 UNDAF which states that "UN agencies will align with the direction of the Health Sector as outlined in its Policy Framework and Strategic Plan and focus on access to services".

Finally, the One Plan 2012-2016 for Viet Nam (a preparatory report for the UNDAF) mentions among the outcomes on which the UN will focus by 2016 "Increased quality and effective management of a comprehensive national health system, including health promotion and health protection, with a focus on ensuring more equitable access for the most vulnerable and disadvantaged groups."

However, no specific reference has been found in the UNDAF reports of the three countries involved in the present evaluation to UNIDO, to local pharmaceutical production, or to access to medicines in general.

3.3 Initiatives of international cooperation partners

Annex 4 of the Phase 3 project document (reproduced below as Table 1) lists the international players identified in the access to drugs challenge. WHO is obviously the central organisation involved in this issue and its mandate includes guiding health policy and specific policies related to access to medicines, as well as regulatory functions. Its prequalification programme and the capacity building support it provides on Good Manufacturing Practices (GMP) are highly relevant to the objective of strengthening local production of medicines.

Organisations such as the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), UNITAID, the *Joint United Nations Programme on HIV/AIDS (*UNAIDS), and the United Nations Children's Fund (UNICEF) and others also play relevant roles in relation to the procurement of medicines. This is a key issue for the UNIDO project as it provides potential opportunities for marketing locally produced medicines. However, only two organisations are identified in the table as specifically focusing on developing local production of medicines in specific African countries, namely Action Medeor and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ).

In recent years, there has been a change of attitude among several international organisations in relation to LPP in DCs. The most revelant case is WHO[14], which, together with UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD), has launched an initiative to support pharmaceutical industry development in DCs.

Table 1: Some of the main international organisations involved in addressing the various dimensions of the access to drugs challenge

Organisation	**Focus**
WHO	Normative function with regard to pharmaceuticals Some technical assistance general training on GMP
Procurement Focus	
The Global Fund to fight Aids, Tuberculosis and Malaria	Procurement and Distribution
UNITAID	Procurement and Distribution, Patent Pool new initiative
UNICEF	Procurement and Distribution, some cooperation with manufacturers on local procurement
The World Bank	Procurement and Distribution
DfID SARPAM	Procurement and Distribution, SADC Pharmaceutical Business Plan
Disease Specific Programmes	
WHO Global Malaria Programme and HIV department	Disease specific programmes, treatment guidelines
UNAIDS	Leading UN activities in the field of HIV/Aids
Roll Back Malaria Partnership	Global Partnership on the fight against Malaria
Stop TB Partnership	Global Partnership on the fight against Tuberculosis
Research Focus	
TDR	UN research partnership on diseases of poverty
FIND	Development of diagnostics
DNDi	Drugs for Neglected Diseases Initiative
COHRED	Building an African agenda on innovation in the pharmaceutical arena
Intellectual Property/ TRIPS Focus	
UNDP	Activities on TRIPS, training of patent officers
UNCTAD/InWEnt	Training and advice on TRIPS and use of TRIPS flexibilities
The South Centre	Programme on Innovation, Technology and Patent Policy
Drug Regulatory Harmonization	
WHO/Bill and Melinda Gates Foundation/Clinton Foundation/DfID	Drug Regulatory Harmonization within African RECs
Financing	
IFC	Provide loans and invest equity in local manufacturers
African Development Bank	Pre-feasibility studies
Local production of medicines	
UNIDO	Advisory and capacity building support at policy, institutional and

[14]Local production for access to medical products: developing a framework to improve public health. Geneva, World Health Organization. WHO. 2011.

	sector levels
Action Medeor	EU funded project “support the production of ARVs against Aids and Anti-Malarials in Tanzania”
GTZ	Pharmaceutical sector development support as part of the economic development programme in Ethiopia

TDR = Special Programme for Research and Training in Tropical Diseases; FIND = Foundation for Innovative New Diagnostics; DfID SARPAM = (UK) Department for International Development Southern African Regional Programme on Access to Medicines and Diagnostics; DNDi = Drugs for Neglected Diseases initiative; COHRED = Council on Health Research for Development; InWent = InWEnt (Germany) Capacity Building International (Internationale Weiterbildung und Entwicklung GmbH)

Ref: UNIDO, Strengthening the local production of essential medicines in developing countries through advisory and capacity-building support, Project Document (phase 3), TE/GLO/10/023, August 2010, p. 41

4. Assessment

4.1. Project design

The project's ultimate objective, according to the project documents for phases 2 and 3, was to contribute to improved access[15] to essential drugs in DCs/LDCs through the increased supply of quality affordable medicines from DC/LDC producers. However, this objective was changed in the middle of Phase 3 (early 2012) in line with a logframe adjustment.

The main assumptions of the initial objective were that:

a) Developing or increasing domestic production of high quality essential medicines in DCs is feasible and sustainable (competitive); and
b) Strengthening local production will lead to improved access to medicines in the country concerned.

The explicit reliance on the production-access link was formally dropped mid-phase 3 in line with a logframe simplification and adjustment approved by the donor on 2 March 2012. The justification for this change was the absence of evidence on the direct effect of increased local production on access to medicines and ultimately on improved health status, at least with regard to the timelines with which this project was confronted. The logframe change does not imply that 'access' was actually dismissed as an ultimate goal of the project. It rather reflects realism on the part of the project team who did not want to strive for an overambitious objective which could not subsequently be demonstrated and who was also responding to growing queries about the reasoning behind the original logframe.

In fact, there is little conclusive evidence or experience to support the two assumptions on which the rationale for UNIDO's project was based. This is especially true of the second one concerning the causal relationship between production and access. Until recently, there has been widespread scepticism among researchers and international organisations on the potential for LPP to improve local access to medicines in DCs. To a large extent, this was because it was assumed that it would be difficult for DCs and LDCs to attain the relatively high technological and manufacturing standards required to produce good quality medicines (Kaplan and Laing, 2005; WHO, 2004). Moreover, access to medicines depends on many factors, such as adequate financing and the existence of health insurance schemes, the geographic proximity of health service providers, and the availability and affordability of medicines. Local pharmaceutical production might improve access to the local population. However, the link between local production and access is not obvious.

[15] Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population. Access is a complex multidimensional concept that is usually measured using a set of WHO medicine access indicators based on medicine availability and price.

For many years, the prevailing opinion among development agencies was that trying to develop high quality drug production in an efficient and sustainable way in DCs and LDCs was either not feasible or too risky. In general, most experts doubted that it could be an efficient way to reduce prices and shortages of essential medicines in comparison with other options such as improving procurement methods, regional pooled procurement, etc. Moreover, the emergence of powerful generic industries, especially in India and China, which were apparently willing and able to supply medicines of a standard quality at affordable prices to DCs, made the case for local production – as a key tool to promote access – more questionable.

The focus of pro-access policies concentrated on ensuring appropriate financing – development of health insurance schemes and donor programmes – and on improving the capacity of DCs to implement appropriate regulatory and procurement tools which could guarantee an adequate supply of affordable high quality medicines. The so-called 'buy or make dilemma' does not seem to have an all embracing answer as it largely depends on the technological capacity and political will of individual countries to develop local industry.

The article by Kaplan et al. (2011) is the best systematic review of theoretical and empirical literature on the link between local production of pharmaceuticals and medical devices and increased local access to these products. The period covered by the review is not explicitly stated in the article but, judging by the publication dates of the most recent papers selected, it is estimated to be August 2011. The conclusions acknowledge that evidence on the link in question is sparse and inconclusive because of methodological weaknesses. Some good descriptive analyses referenced by Kaplan et al. provide evidence to the effect that local production is a feasible option to improve access to drugs but, although these local studies may correctly depict specific situations, the evidence they provide cannot be generalised.

The UNIDO project appears to be a learning process in which the ends and means are adjusted as a result of of the lessons learned by trial and error in practice.

More specifically, the logic of the project was justified by the following assumptions:

- The delay until 2016 of the obligation for LDCs to comply with TRIPS standards offered these countries an opportunity to set up pharmaceutical production in a similar way to that by which India was able to take advantage of its IP law reform in 1977 in order to build its pharmaceutical industry[16].
- The medicinal products best suited to new pharmaceutical production in LDCs were medicines against the larger pandemics in LDCs/DCs, i.e. AIDS, TB and Malaria.
- The main stakeholders to support in order to promote pharmaceutical production were assumed to be individual companies.

[16] As a result of its colonial status, from 1911 to 1970, India had a patent regime in conformity with developed countries' IP laws. In 1970, it abolished patents on pharmaceutical products. This allowed domestic firms to imitate and adapt foreign therapeutic inventions and to develop a domestic pharmaceutical industry. India subsequently became a major worldwide supplier of generics and is therefore popularly known as "the pharmacy of the poor countries".

This logical framework has been evolving since the first phase of the project in 2006[17].

It was found that, in spite of the apparent advantage offered by the postponed TRIPS compliance starting date, LDCs lacked most of the conditions that make the development of pharmaceutical production feasible such as adequate human resources, complementary industries and support services, infrastructure, etc. Therefore, the focus of the project shifted – or at least was extended – to DCs. The original focus on medicines to fight the three big pandemics was prescribed by the donor, who had requested such a focus at a time when the prevailing international funding pattern had an almost exclusive concentration on HIV/AIDS, TB, and malaria. The subsequent broadening of the product portfolio was recognition of the fact that manufacturers targeted by the project could not typically achieve commercial viability on the basis of such a narrow production portfolio. It was this that led to a shift to a wider range of products. Moreover, the products to fight pandemics were mainly financed and procured by international donors, who systematically requested WHO prequalification, something which is not easy for manufacturers in LDCs and DCs to achieve. Accordingly, the project focus shifted to the broader range of Essential Medicines List (EML) products. Finally, the project acknowledged that support to local pharmaceutical production could not exclusively or predominantly focus on individual companies. The reasons were manifold. It had become obvious that a holistic approach, involving a broad range of public and private stakeholders, was required. Moreover, the UNIDO project neither had nor expected to have in the near future sufficient resources to significantly affect the behaviour of a substantial number of companies. UNIDO's global project, with its limited resources, is not an appropriate mechanism to finance an emerging or growing industry.

The logical frameworks which are often explicit or implicit in the most recent documents, such as the proposal for Phase 3 of the global project and the PMPA BP, reflect a more cautious belief than earlier documents in the feasibility of promoting high quality domestic production of medicines with the amount of resources available to the project. They are equally cautious as to the positive effects of successfully promoting local production and improving access to drugs.

An increase in drug availability as a result of domestic production and import substitution should probably be expected *a priori*. Yet it is increasingly acknowledged that local production should not be expected to lead to any dramatic reductions in the price of medicines as a result of increased competition in view of the small size and low technical capacity of local companies as well as the substantial investment required to raise quality standards. These companies would, in fact, be likely to produce at higher prices than large foreign generic producers.

Increases in access to drugs, at least in the short term, will certainly require improvements in the financing of medicines. It should be noted that most of the generics produced in India have been exported for many years to other countries and have only marginally improved access to medicines for the local poor. A study by

[17] The revision of the Phase 3 logframe (Pdf File: P3 Logframe SAP Adjustments_clean) was approved by the donor (letter dated 2 March 2012).

Sengupta et al.[18] concludes: “It has been estimated by different sources that 50% to 80% of the Indian population are not able to access all the medicines that they need.”

The WHO's World Medicine Report 2004 found that India is the country with the largest number of people (649 million) not having access to essential medicines. Given that today India is the fourth largest producer of drugs in the world and exports medicines to over 200 countries it seems obvious to conclude that a burgeoning LPP is no guarantee of greater local access.

UNIDO nevertheless has the expectation that health benefits from LPP will indirectly come about as a result of:

a) Shortening the supply chains and thereby limiting opportunities for counterfeits to penetrate markets.
b) Allowing for enhanced regulatory oversight thereby helping to reduce the amount of substandard products in the market place.
c) Acting as a buffer where sharp increases in demand or supply restrictions limit the availability of products.

Dropping the earlier aim that LPP would improve access to drugs could have both positive and negative consequences. It can be argued that, as there is no evidence of this link, it is more prudent not to adhere to it. Indeed, the long lasting debate on that issue is still open. However, absence of evidence does not imply evidence of absence. Local production might be one among several factors that contribute to improving access but may not be enough in itself to ensure it, i.e it may be a necessary but not sufficient condition.

Large pharmaceutical producers, such as India, might not apply the additional policies necessary to improve access. Alternatively, perhaps the LPP policies applied so far are not well enough designed to both increase production and improve access simultaneously. In any case, the access goal is still endorsed by the Government of Germany's cooperation policies and by the PMPA BP as well.

The explicit abandonment of the access goal by UNIDO might have a negative consequence in that public health and access-oriented organisations might become less inclined to collaborate with UNIDO if they get the impression that it has become less committed to public health and concentrates on industrial goals.

The holistic approach adopted, with its three levels of sector intervention (macro-policy, meso-institutions and micro-companies) is one of the features of the project which obtains a broad consensus. The majority of country stakeholders interviewed – with a few anecdotal exceptions – agreed on the appropriateness of the innovative holistic approach adopted by UNIDO.

[18] Economic Constraints to Access to Essential Medicines in India (undated). Amit Sengupta, Reji K. Joseph, Shilpa Modi and Nirmalya Syam Available at www.academia.edu/468312/Economic_Constraints_to_Access_to_Essential_Medicines_in_India

4.2 Management

The project is managed by UNIDO's Business, Investment and Technology Services Branch in the Programme Development and Technical Cooperation Division.

The full-time members of the project team at UNIDO HQ are:

Project Manager: Overall responsibility and direction of the global project.

Senior Technical Adviser (STA): The expert assumes overall responsibility for steering, overseeing, coordinating and contributing substantively to the implementation of the global project, carrying out specific activities of project management, provision of technical assistance and Global Forum.

Industrial Development Expert: The expert contributes to the implementation of the global project, carrying out specific activities of project management, provision of technical assistance and Global Forum.

At the country level (Ghana and Kenya), there are full-time National Consultants.

Specific technical inputs have been provided by international consultants, who are hired on a short-term, activity-related basis. The situation is slightly different in Viet Nam as there is no national expert exclusively devoted to the project although an expert working for the UNIDO office supports several projects on the ground[19].

The UNIDO country representatives (Kenya, Ghana and Viet Nam) do not have a defined role in the project management and their level of knowledge and involvement in the project varies markedly. The UNIDO Representative in Ghana expressed interest and willingness to be more involved in the project, a factor which he considers important if UNIDO is expected to play a leading or coordinating role of UN organisations in the African region.

The main roles of the project team were:

- Acting as coordinator and broker between institutions with independent political agendas and often conflicting interests. This role has been played at micro, meso and macro levels, involving a large number of national governments and ministries, pharmaceutical companies, regional and continental organisations, manufacturers associations and other stakeholders.
- Facilitating processes aimed at reaching multistakeholder agreements on a sector strategy.
- Organising and participating in fora where issues relevant to LPP could be presented and discussed.

The project management has shown the required flexibility to adapt to the lessons learned and to the opportunities that arose in the course of the project. Revisions were introduced in order to improve the project strategy, priorities and results. These

[19] Two part-time national experts have been under recruitment since June 2013 (funded from the Viet Nam One UN budget allocation).

required a reallocation of human resources and changes in budget lines as well as obtaining donor approval. Some of the main changes introduced along the project phases include:

- A shift in focus from medicines for the pandemic diseases (HIV/AIDS, TB and malaria) to a broader range of essential generic medicines.
- A shift in the initial focus on LDCs to DCs at large in recognition of the constraints that LDCs face in providing an appropriate environment for developing LPP.
- Abandoning planned outlays for equipment (Euro 350,000) as insufficient to have a significant impact on plant quality upgrading and reallocating the funds to contracting additional international consultants.
- A decision not to support National Medicines Regulatory Authorities (NMRAs) when it became clear that the budget allocated for that purpose was not sufficient to attain the desired objectives in such a highly sensitive area.
- A shift in priorities to concentrate resources on the African Medicines Regulatory Harmonization (AMRH) process with NEPAD, WHO, the Bill & Melinda Gates Foundation, the Clinton Foundation and the UK's Department for International Development (DfID), as well as on the collaboration with the African Union Commission in the development of the PMPA BP rather than the work planned in Phase 3 at micro and national levels.

The work of the project team, national consultants, and short-term international consultants is positively valued by all national stakeholders although some expressed concerns about possibly insufficient central support from HQ to the countries.

4.3 Relevance and ownership

4.3.1 Relevance

The mid-term evaluation referred to in section 2.5 gave comprehensive arguments and justifications for the relevance of the project. It emphasized that the project goals are in line or contribute to the goals of numerous ongoing initiatives and to the agenda of several UN and other international development organisations and national governments. It is worth mentioning, among others:

- The Millennium Development Goals, especially those related to health outcomes and poverty reduction.
- The AUC's Pharmaceutical Manufacturing Plan for Africa (PMPA), which will be addressed extensively later in this report.
- The Pharmaceutical Business Plan of the Southern African Development Community (SADC).
- The World Health Organization (WHO) and United Nations Development Assistance Plan (UNDAP) activities in relation to Local Pharmaceutical Production.
- The New Partnership for Africa’s Development (NEPAD) and its aim of strengthening pharmaceutical innovation in Africa.
- The national health and industrial policies of the individual beneficiary countries prioritize access to medicines and industrial and economic growth and import substitution respectively.

- The objectives of the project are in line with the development priorities of the national governments and the AUC.

In fact, all stakeholders interviewed during field missions support the relevance of the project for their own countries and for the region.

The continuous trend towards sub-regional economic integration in Africa, especially measures that directly affect the pharmaceutical market, such as the African Medicines Regulatory Harmonization (AMRH) initiative, increase the feasibility of LPP by enlarging the potential market for local manufacturers and facilitating economies of scale.

The progressive effect of TRIPS enforcement is likely to limit the role of India and China – and other exporting countries – as worldwide suppliers of affordable quality generics to low-income countries. Moreover, many of the largest generic manufacturers, once fully focused on and committed to supplying generic medicines to DCs, aim at becoming integrated producers with a stronger Research and Development (R&D) focus, while others have been acquired by large MNCs. They are therefore likely to shift their attention to on-patent products and DCs and LDCs might not be able to rely on them as a future source of affordable quality generics.

The general acknowledgement that attaining international quality standards is a precondition for taking advantage of global donor funding and gaining access to foreign markets is likely to induce new countries to seek advice and support for the sound and sustainable development of LPP.

Moreover, the pharmaceutical markets of DCs and LDCs are expected to grow at a faster rate than those of high income countries. This opens, on the one hand, increasing opportunities for local producers based on their privileged proximity and knowledge of their national markets. On the other hand, it makes these markets more attractive to MNCs and will put additional competitive pressures on LPP.

4.3.2 Ownership

Ownership of the project seems well embedded in the Business Plan of the Pharmaceutical Manufacturing Plan for Africa, which contains the key ideas of the UNIDO project and at the same time is considered an AU initiative.

However, at national level, the findings are less unanimous. Most respondents from the private sector highlighted the openness of the design process and their involvement in defining the national strategy. Yet their remarks sometimes suggest that they are trying to use the project for their own interests rather than for becoming a partner in an inclusive and shared undertaking. In government sectors, there were also some signs of limited commitment and ownership in relation to the project and some industry stakeholders also express this sentiment. For example, the Ministry of Trade and Industry in Ghana is closely involved in the project but this is not at all the case in Viet Nam.

The limited presence in the project of certain key institutions is noticeable. For example, patent offices, statistical offices, and World Bank/IFC country offices in the

three countries are not involved although these bodies could and should play an important role in bringing experience and implementing changes in some essential topics within the project's holistic approach.

Another group of organisations not included in the available documentation is those representing the interests of patients and consumers, i.e. the so-called pro-access community. A more active involvement of those NGOs and associations would provide additional support to LPP strategies from these vocal and increasingly influential actors.

4.4 Efficiency

The project probably has insufficient resources in relation to its ambitious originally stated objectives. Euro 3.2 million is a relatively modest amount when compared with the size of the effects it is trying to induce in a large number of countries in three continents. For instance, a manufacturer's upgrading plan in order to attain the desired level of quality might imply capital investments of the order of US$ 5 million to US$ 15 million. In this respect, in view of the overall results attained, it can be said that the resources invested in the project are providing good value for money.

All stakeholders expressed high satisfaction at the quality of the inputs: role of UNIDO, activities carried out by the national and international consultants, etc. Training activities (e.g. by the Saint Luke Foundation) and expert advice provided by the project were very positively valued.

However, many stakeholders, and mainly industry representatives, also express dissatisfaction at implementation delays. Some industry representatives claim that there is too much talking and few concrete sustained activities and tangible outcomes which many interpret as meaning direct support to companies. In fact, the original idea was to identify companies whose leadership, management, track record or quality of business planning was such that – with limited catalytic project support – they might generate an 'LPP success story'. This task proved, however, to be difficult and not very fruitful. The project downgraded activities at the enterprise level because it was felt that for interventions at the micro level to make sense, significantly higher project outlays would have been required. This was one of the lessons learned and inputs at the micro level were then reduced to demonstration/piloting efforts.

Delays in scheduled activities in Phase 3 of the project are mainly attributed to the shift in focus to the PMPA. This was an unexpected opportunity that arose in the middle of Phase 3, allowing UNIDO to become involved in the PMPA but also slowing down work at the country level.

Delays in implementation are also attributable to other reasons:

- The inevitable learning-by-doing which is inherent in an innovative approach, with a mix of successes and failures.

- The project objectives were probably too ambitious and spread across too many countries in relation to the team's capacity and the budget.

- Flexibility in adapting the project to the lessons learned and to key opportunities that could not have been foreseen (e.g. the invitation to participate in the PMPA BP) and which could not be missed.

- External factors, such as elections, changes of persons in key positions, etc. are a cause of delays in any project. This problem is, however, more acute in the case of a holistic, multiparty approach since the absence of a single key stakeholder can put a brake on the entire process.

The documentation available to the evaluator shows that the UNIDO project management team has been sensitive to the ongoing initiatives of other international and national organisations and has taken the necessary steps to ensure collaboration and coordination with programmes being implemented by other relevant organisations. The team has similarly contributed to the initiatives of others. In fact, the best (success) example is the collaboration with the AUC and other parties in developing the BP. Also noteworthy is the work of the project in Viet Nam, which started by trying to agree a common country strategy with WHO in order to effectively coordinate the goals and activities of the two organisations in that country.

This collaboration – which embodies the holistic approach – is essential for avoiding duplication and sending contradictory messages to the target countries. It also allows development organisations to focus on the areas where they have their specific expertise and can therefore be more efficient.

4.5 Effectiveness

4.5.1 Achievements of the project at the end of Phase 3

Tables 2 and 3 show the actual status of the outcomes attained against the project logframes as at 31 December 2012. As the logframes have changed along the phases of the project, the planned outputs of Phases 2 and 3 have been consolidated by the project into a single set in Table 3 and are compared with the outputs and outcomes attained in the two phases, which are reported together because there is significant overlap in the implementation of the phases.

Table 2. Actual status of outcomes against the project logframes
(as at 31 December 2012)

PHASE 2 OUTCOMES

OUTCOMES	**Status as at 31 December 2012**
O.2 Export opportunities provide extended market for generic drugs	No significant increase in exports has been reported.
O.3 Institutions offer demand-oriented support services to SMEs in the	• The regulators are more open to dialogue and to answer questions from the companies.

OUTCOMES	Status as at 31 December 2012
pharmaceutical sector	• KEMRI acknowledges training at Saint Luke Foundation as enabling it to provide advice to the industry, help companies prepare dossiers for registration and is prepared to assist companies along the whole process of product development. • One company is offering support to training programmes for industrial pharmacy by allowing students to practice in its factory. • SAGMA is becoming operational. PMAG keeps being operational
O.4 Capabilities for pilot local production in place	• GMP assessment of companies in Kenya has been carried out. Some companies have taken advantage of the project to attain WHO-PQ level. One company is planning a US$ 4 million investment for raising QS. A second one decided to invest to upgrade QS and attain WHO-PQ levels, as a result becoming more competitive. • In Ghana, two companies received substantial support to apply for WHO-PQ. One seems to have abandoned the effort while a second one was planning to submit the dossier in 2013.
O.5 Project examples are accessible and can be used for replication	

PHASE 3 OUTCOMES

OUTCOMES	Status as at 31 December 2012
1. Increased capacity for competitive local production of quality essential medicines in target DCs/LDCs.	A number of companies have received technical support, situation assessments and training from the project and a few are in the process of upgrading their quality standards by investing in their facilities. There is, however, no evidence that these steps have crystallised in the form of a more competitive production profile, i.e. more affordable prices, higher quality, increased export capacity or capacity to respond to supply shortages and emergencies in general.
2. Enhanced UNIDO Programme to enable the pharmaceutical sector in DCs/ LDCs to increase the availability of essential health products funded and operational.	Pursuing this output was put on hold when the PMPA Business Plan work began on the understanding that the latter would ultimately provide for the formulation of a larger-scale technical cooperation project in support of PMPA Business Plan implementation and the assumption that UNIDO would assume the key management role in its implementation.

Output-Outcome Table Phases 2 and 3[20]			
	Phase 2 (01/2008-12/2011)	**Phase 3 (01/2010-05/2013)** **Status of project 31 Dec 2012**	
Output description	**Output 1**	**Output 1.1**	
Strategies and policies for increased local manufacturing of essential generic drugs are in place and acted upon in selected DCs	Ghana: • Roundtable Forum and sub-committees serve as platform for public-private dialogue on pharmaceutical sector development (06/2009). • Draft pharmaceutical sector development strategy ready. Kenya: • Sector profile published 11/2010. • Draft "Kenya Pharmaceutical Sector Development Strategy (KPSDS)" ready and discussed with private sector (08/2011). Viet Nam: • MoU on MoH-WHO-UNIDO Collaboration on fostering Local Pharmaceutical Production followed by kick-off workshop for pharmaceutical sector strategy building process (06/2011) .	Ghana: • Detailed draft implementation/operational plan for pharma industry strategy prepared. • Draft GMP Roadmap for Ghana prepared and discussed with stakeholders. Kenya: • Draft KSPDS ready and discussed with private sector and government stakeholders. • Draft GMP Roadmap for Kenya prepared and discussed with stakeholders. Viet Nam: • Pharma industry analysis and LPP policy assessment conducted in Viet Nam (in cooperation with WHO) and discussed with stakeholders. • Additional funding for follow-up work raised from One UN Fund Viet Nam (EUR 55,000; 2012-13). PMPA Business Plan: • Research to inform PMPB Business Plan on pharmaceutical industry in Maghreb countries. • PMPA Business Plan drafted and reviewed by AU Technical Committee. • In principle commitment expressed by international agencies to join consortium for	• Ghana: pharmaceutical sector development strategy adopted by MoTI and MoH. • Kenya: Pharmaceutical Sector Development Strategy endorsed by Ministry of Medical Services and Ministry of Industrialization. • In Kenya the Pharmacy and Poisons Board has adopted the GMP Roadmap approach and intends to start implementation in 2014. • PMPA BP approved by AU Ministers of Health at CAMH5, Geneva, 05/2012. • PMPA BP endorsed by AU Heads of State and Government at Summit, Addis Ababa, 07/2012. • Far reaching awareness of PMPA BP through extended distribution of document to all AU governments, regional economic communities,

[20] Phases 2 and 3 are reported on together because there is significant overlap in the implementation of the two phases.

		implementation of the PMPA BP.	development partners, etc. ● UNIDO invited by AUC to coordinate set-up of consortium of partners for PMPA BP implementation.
	Output 1 (cont'd)	**Output 2.1 Studies to inform programme development**[21]	
	Diagnostic/analytical inputs generated for implementation of pharma sector development strategies (Ghana and Kenya): ● Needs analysis in the field of access to finance. ● Study on Economics of Pharmaceutical Production: generic manufacturing business models and cost structure of production in India.	● Study on 'The logic of incentives for the development of domestic production of drugs in Ghana'. ● Concept note on Human Resource Development as part of PMPA BP implementation. ● Concept note on 'Partnerships and Business Linkages Programme'.	● Studies inform strategy implementation work in Ghana and Kenya and the further operationalization of the PMPA BP.
	Output 2	**N.a.**	
Intra-regional trade of essential medicines facilitated through improved drug regulatory harmonization	● Liaising with RECs and WHO, NEPAD initiative on the occasion of African Union Workshop on the PMPA in Chad, 06/2011 ● Liaising with RECs on the implementation of the 'Accelerated Industrial Development for Africa' (AIDA) initiative and the relationship to the PMPA in Addis, 09/2011	Note: When phase 2 of the project had started, the African Medicines Regulatory Harmonization (AMRH) initiative was launched by a consortium consisting of NEPAD, WHO, Bill & Melinda Gates Foundation, Clinton Foundation and the UK's DfID. UNIDO participated in the initiative's inaugural workshop in January 2009. Subsequently, close communication was maintained with the initiative on medicines regulatory harmonization. This close exchange with partner agencies replaced originally planned activities 2.2-2.5 which were dropped from the project as the AMRH was and continues to be better placed to have an impact in this area.	
	Output 3	**Output 1.2**	

Institutional support capacities for the promotion and development of the local manufacturing by SMEs of essential generic drugs upgraded	SAGMA: • Workshop with the organizing committee defining Vision and Mission of new association. • Draft Constitution for SAGMA in line with pertinent regulations for associations. • Public Launch of SAGMA, 04/2011. FAPMA: • MoU to found a Federation of African Pharmaceutical Manufacturing Associations (FAPMA) signed by the three regional associations, 04/2011. • WAPMA (03/2010) and Pharmaceutical Society of Botswana (05/2010) hold conferences on promoting local production. IPAT: • Participants from industry, regulatory authorities and universities complete Industrial Pharmacy Advanced Training (IPAT) at Kilimanjaro School of Pharmacy, Moshi, Tanzania (2009/10: 20)	SAGMA: • SAGMA forms an industry position on the SADC Regulatory Harmonization process. • SAGMA engages in relevant events as an industry representative. FAPMA: • FAPMA develops strategy and agrees on founding documents (11/2012). • Inaugural meeting and Public Launch is set for 1/2013. IPAT: • 25 participants graduate from IPAT 03/2012 and 08/2012. • 26 participants enrolled and completed first module in 08/2012. • Industrial Pharmacy Advanced short training course: Modern Tablet Coating – Practical Aspects and Trouble Shooting, taught by BASF, at ITPU 06/2012.	• The Southern African Generic Medicines Association (SAGMA) was inaugurated 12/ 2009. • SAGMA positions itself as the voice of the private sector in the field of generic medicines in the SADC region. • FAPMA constitutes the first umbrella BMO representing pharmaceutical manufacturers in Africa (with the exception of Northern Africa which FAPMA plans to attend to). • IPAT Alumna Prof Peace Babalola from Ibadan University, Nigeria, received USD 1m grant from MacArthur Foundation, USA, to set up a Centre for Drug Discovery and Development in Nigeria which, inter alia, is foreseen to emulate the IPAT course from 2014 onwards.
	Output 4: Upgrading of pilot local production of essential medicines facilitated	**Output 1.3: Viability of international standard production demonstrated at plant level**	
Plant Level	• Botswana: Conceptual design study for a new manufacturing plant completed. Follow-up advice with a focus on partnership building for	• Kenya – Three companies received advice on efficient pharmaceutical manufacturing 03/2012.	• Botswana: Results are used by the project to deduct a general case study on the viability of green-field investments and partnerships in developing

	Gemi Pharmacure. • Ghana: Danadams improved materials (business plan and information leaflet) for investor search and support for due diligence (11/ 2009, 09/2010). • Ghana: Lagray – quality assurance of documentation for submission to WHO PQ (06/ 2010). CAPA (corrective action and preventive action) report in 09/2010. Key production personnel trained on essentials for WHO PQ. • Cameroon: Cinpharm – Training of key personnel on International GMP (11 participants in study tour to India 08/2009 and Audit training at the site 09/2010). CAPA report on gaps to WHO PQ (09/2009).	• Identified Operational Excellence in Pharmaceutical Production (OPEX) model as tool to benchmark and ultimately improve plant level efficiency of pharma production in African companies 09/2012.	countries. • Ghana: Investor search conducted in a more professional manner. • Kenya: at least one company willing to follow-up on expert recommendations and take measures to increase efficiency.
	Output 5:	**Global Forum contributions**[22]	•
Positive project results effectively communicated	• 05/2009: IPC meeting with focus on LPP co-hosted. • 11/2010: UNIDO Industrial Development Board (IDB) side event on fostering pharmaceutical industry in developing countries leading to favourable IDB decision (IDB 3. Dec 7). • 03/2011: Round Table on Pharmaceutical Industries "Improving access to medicines – what role for African industry" at the Conference of African Ministers of Industry (CAMI) Meeting. • 04/2011: International Conference on Local Pharmaceutical Production in Africa, Cape Town, South Africa.	Contributions to conferences & other international meetings, e.g.: • 02 & 05 & 11/2012: WHO Stakeholder and coordination meetings on EU financed WHO/UNCTAD/ICSTD project. • 03/2012: EC inaugural meeting of DGEI Project Group on Local Capacity Building on access to medicines in DCs. • 03/2012: Launch of African Medicines Regulatory Harmonization (AMRH) Project for the EAC region. • 04/2012: EU Conference "Innovation in Healthcare without Borders". • 05/2012 & 12/2012: Interagency Pharmaceutical	• IPC agencies active in the field of public health are aware of debate around benefits of local production in Africa. • Favourable IDB decision encouraging the organization to expand the programme on pharmaceuticals. • Inclusion of the Pharmaceutical Sector as a priority in Accelerated Industrial Development for Africa (AIDA) initiative. • Initiative to form FAPMA and cooperation with AUC on the PMPA BP emerged from 'Cape Town Conference'. • ALMA Manufacturers Conference focussed on promoting local production.

[22] *This output was not included in the initial project document but was incorporated during the implementation period.*

	• 06/2011: AUC Workshop on the development of a Business Plan for the implementation of the PMPA, Chad. • Exchanges with other agencies at meetings and conferences, e.g.: - 05/ 2010 RBM Board Meeting - 06/2010 and 09/2010 SADC Advisory Group - 05/2011 Friends of ALMA Manufacturers Forum, Nairobi - 04/2011 First coordination meeting for the Pharma industry in the GCC and Yemen, Doha	Coordination (IPC) Group. • 06/2012: AUC-UNIDO Conference on Economic Diversification and Manufacturing, Addis Ababa With special session on Pharma. • 01/2013: UNIDO DG referred to PMPA BP in formal address to AU Heads of State at summit (closed session), Addis Ababa.	• Issues surrounding the promotion of LPP as one means to address access to medicines in developing countries enjoy increasing attention at the level of African governments, industry players and development partners alike. UNIDO's work has led to a growing stream of enquiries about its experience and the substantive know-how generated, as evidenced in numerous invitations to contribute to conferences, workshops and other events linked to the pharmaceutical industry in DCs.
	N.a.	**2.2 UNIDO programme document prepared**	
		In line with the preparation of the PMPA BP the intended elaboration of a UNIDO programme document for an expanded UNIDO programme supporting the local production of pharmaceuticals and other health commodities was put on hold. Instead, the work that was started towards the early implementation of the PMPA BP (consortium building, resource mobilization, refinement of solutions/tools) was expected in 2013/14 to generate a programme/project document tailored to the requirements of one or several specific funding sources for an initial PMPA BP implementation support intervention.	
Other		• Conduct of 'Gender Review' on project to date Q4/2012. • Communications: inputs/footage collected for PMPA BP promotional video 12/2012.	• Gender Review identified entry points for the possible inclusion of gender-specific aspects/ activities in Phase 5 of the project.

The overall achievements can be summarised as follows:

UNIDO has acquired a better understanding of the specifics of pharmaceutical sector development in DCs/LDCs since the first global project to strengthen the local production of essential generics started in January 2006.

At the time the project was launched, most of the international community was rather sceptical with regard to the strategy of improving access via local production. Now, however, there is a general recognition of UNIDO's key pioneering role in raising awareness of the importance of strengthening local pharmaceutical production (LPP) and of its potential leading role in coordinating UN organisations in this initiative. This achievement has been acknowledged in an increasing number of requests, enquiries or mandates for assistance and/or collaboration, including:

- The Clinton Foundation highlighted UNIDO plant level support in various Sub-Saharan Africa (SSA) countries on the occasion of the launch of the Affordable Medicines Facility - malaria (AMFm).
- The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property unveiled by the World Health Assembly in May 2008 mentions UNIDO as a partner for promoting technology transfer and the manufacture of health products in developing countries.
- UN General Assembly Resolution A/C.2/63/L.46 mandated UNIDO to respond to the significantly increasing weight that local manufacture of pharmaceuticals has assumed on the African continent's political agenda, referring specifically to the Pharmaceutical Manufacturing Plan for Africa launched in 2007 at an African Union summit meeting in Ghana.
- UNAIDS is willing to explore joint action with UNIDO in support of the implementation of the PMPA BP.
- Invitation to join (i) the Interagency Pharmaceutical Coordination (IPC) group[23] chaired by WHO in 2006. In response to a request from UNIDO, the 2009 IPC sub-group meeting focused on LPP; (ii) the Roll Back Malaria Partnership (RBM)'s Procurement and Supply Chain Management Working Group (PSMWG) in 2009; as well as (iii) the SADC Pharmaceutical Task Team (July 2010) designed to steer the further implementation of the SADC Pharmaceutical Business Plan.
- WHO approached UNIDO in early 2010 proposing a joint intervention in support of local pharmaceutical production in Viet Nam.
- The Government of Italy, alongside the Department of Trade and Industry of South Africa, endorsed the conclusion of a tripartite cooperation agreement in support of a broad programme on HIV/AIDS (ongoing Euro 0.9 million).
- The UNIDO Industrial Development Board (IDB) decision of November 2010 (IDB.38/Dec.7) encouraging an enlarged mandate for UNIDO's work on pharmaceuticals and other health commodities.

[23] The IPC is an informal group of UN organisations that meets twice a year in order to coordinate and give coherence to their respective pharmaceutical agendas.

- The invitation to UNIDO by the AUC in June 2011 and subsequent formalisation of an agreement to provide technical support for the development of the BP.

Moreover, UNIDO has shown its capacity for leading the holistic, multistakeholder approach required to ensure the development of LPP by:

- Making companies aware of their quality status and of the need to upgrade it.
- The pharmaceutical industry was listed as a priority sector by the Ghanaian government.
- The pharmaceutical sector was defined as a priority in the Action Plan for the Accelerated Industrial Development of Africa (AIDA)[24].
- Several recommendations by UNIDO were incorporated into the draft of a new pharmaceuticals law in Viet Nam.

4.5.2 Areas where the planned targets have not been met

These include:

At the micro level, some general dissatisfaction has been expressed by companies with the slow implementation of the project in relation to the expectations raised.

At enterprise level, no significant observable changes have taken place as a result of UNIDO's interventions. Several company-level interventions are delayed or have been abandoned. In Cameroon, assistance to help one company reach WHO Prequalification was stopped when it abandoned the pursuit of WHO PQ as a medium-term target in order to focus on products that do not require this status. In Ghana, the Lagray Chemical Company's progress towards WHO PQ has also been delayed. The Lesotho initiative has been abandoned.

Collaboration with the U.S. Pharmacopeial Convention (USP) on the GMP roadmap did not reach fruition as USP decided to continue working on the roadmap independently.

In Viet Nam, implementation of the project has also experienced a substantial delay, partly associated with the difficulties in aligning views and agreeing detailed action with WHO under the ongoing cooperation. Other project objectives which seem to be either delayed or on standby include:

- Making case studies and publications on the project experiences accessible and available as a benchmark for replication.
- Establishing baseline indicators and self-monitoring mechanisms in order to assess the progress of project outcomes and of the final impact. Unless key objective indicators are defined and regularly collected from the start of the interventions – and, ideally, earlier – it will not be possible to assess the actual impact and effectiveness of the project.

[24] See CONFERENCE OF AFRICAN MINISTERS OF INDUSTRY (CAMI, 18TH ORDINARY SESSION. 24-28 OCTOBER 2008, DURBAN, and REPUBLIC OF SOUTH AFRICA. AU/MIN/CAMI/3(XVIII) Available at https://www.unido.org/fileadmin/user_media/Services/Investment_and_Technology_Promotion/Implementation_Strategy.pdf

- The UNIDO Pharmaceutical Production Partnership Platform (U4P).
- An enhanced UNIDO Programme to enable the pharmaceutical sector in DCs/LDCs to increase the availability of essential health products funded and operational. This was, however, explicitly replaced by the work undertaken on the PMPA BP.

The third and fourth points (U4P and the enhanced programme) have apparently been substituted by the generic solutions package proposed in the PMPA BP. Nonetheless, little progress seems to have been made so far in that direction.

4.6 Sustainability

The holistic approach of the project, with its emphasis on raising awareness and actively involving and cooperating with national stakeholders and international organisations, is the most appropriate one for ensuring sustainability since it is based on the involvement and empowerment of the parties concerned. The latter are supported yet, at the same time, are encouraged and expected to show initiative and leadership.

Whilst it is still too early to make a full assessment of the sustainability of the project, there are some discernible factors that can contribute to the desired sustainability:

- Providing support and help in building institutions that ensure the sustainability of the process, such as the Saint Luke Foundation in the area of training, and the launching and strengthening of pharmaceutical manufacturers associations that can become valid and effective counterparts, such as the Southern African Generics Medicines Association (SAGMA); the Pharmaceutical Manufacturers Association of Ghana (PMAG); and the Federation of African Pharmaceutical Manufacturers Associations (FAPMA).

- The contribution of the project to the establishment of manufacturers associations and the approval of the PMPA BP are key achievements of this holistic approach.

- The project has contributed to the perception by companies, regulators and other parties that improving quality standards is a prerequisite for simultaneously achieving both public health and economic objectives. All parties are becoming aware that exporting, for instance, will be progressively more difficult for companies that do not attain international quality standards. There is also an increasing acceptance that price competition within a country is only fair for both consumers and suppliers as long as all companies are required to comply with the same minimum quality standards. Likewise, it is recognised as being unfair that a buyer pays the same price for products of different quality. All these values are likely to transform the entrepreneurial and regulatory culture in a permanent way, helping the implementation of changes in business and regulatory models and consolidating these changes.

- Stakeholders accept the holistic, inclusive approach of the project, which is therefore more likely to become sustainable without future external support than more resource-intensive and externally-driven interventions, such as loans for activities at individual company level. Although the latter might have more tangible short-term effects, they are more likely to be discontinued when the incentives and external support that made them possible come to an end.

4.7 Impact

The project defines 'impact' as the effects on pharmaceutical production - and initially also as the induced effects of this improved production on access to medicines - but it does not set or estimate defined timelines for achieving these effects. As in the case of sustainability, it is too early for these medium or long-term goals to have materialised at the time of this evaluation. This is equally so in the case of some outcomes and outputs. Moreover, these effects depend on multiple external factors, which are neither under the control of the project team nor can be predicted with a high degree of certainty. This is why the impact on access was removed from the logframe as a consequence of experience gained in implementing the project.

The Phase 2 project document stated that the activities would “ultimately benefit the producers of high quality medicines against HIV/AIDS, Malaria, Tuberculosis and other neglected tropical diseases” as a result of “the successful implementation of national and/or (sub) regional strategies and policies to promote the local manufacturing of essential generic drugs” that would facilitate “a more conducive environment for local pharmaceutical production to increase the access to medicines”.

DC producers were also expected to benefit from “Moves towards the harmonization of drug licensing/registration processes and procedures, related intellectual property rights and trade at (sub) regional levels aim(ed) at increasing the size of relevant sales markets for DC producers, thereby enabling them to benefit from scale economies and to cut costs of drug registration when making use of new export opportunities”. Finally, producers were expected to “gain from direct plant-level support geared towards the production of one or a range of target medicines in a commercially viable manner, while complying with high quality standards”. These expected benefits have not materialised so far or at least not to a significantly large and observable extent.

Many respondents at the country level acknowledge that the impact of the project in terms of improved access (or health), larger national market share for local producers, increased imports, etc. might still take several years to come to fruition.

4.8 Crosscutting issues

4.8.1 Gender

Recognising that gender topics had not played a specific role in project design and implementation in the past, a specific report, Gender Review of the Global UNIDO Project, was commissioned from an expert on that subject at the end of 2012.

This assignment resulted in preliminary ideas and recommendations on how gender can be adequately reflected in the project in future interventions at the policy and institutional levels. The findings were expected to be built into the work plan for phase 4 of the project covering the period 2013 to 2015.

The review highlights the fact that the project design assumes a level playing field between African men and women and that it contains no gender disaggregation at all in planning and implementation. It suggests areas where gender issues should be addressed and proposes many topics to consider in each area, as well as how to address them. The areas highlighted are:

1. Human resource development
2. Provision of incentives to manufacturers
3. Technical assistance to regulators
4. Partnership and business linkages
5. Employment and the brain drain issue (education to career)
6. Entrepreneurship

However, one issue that the gender review does not address is the disadvantaged position of women in access to medicines and healthcare in general. Women and children's health needs are often given limited attention and low priority in the health policies of developing countries, leading, for instance, to less availability of treatments and medicines to address their specific health problems.[25]

4.8.2 Environmental sustainability

The project shows no evidence of major environmental risks, either to date or in the near future.

Low levels of pharmaceuticals are detected in surface, ground, and drinking water worldwide as a result of the natural excretion of medicinal products by humans and livestock (Heberer T., 2002). It has, however, been suggested that waste water from drug production can potentially be a source of much higher concentrations in certain locations. It has also been argued that large pharmaceutical MNCs are increasingly relying on the procurement of APIs in DCs in order to avoid the costs of the stricter environmental regulation in developed countries.

Fick et al. (2009) investigated the environmental fate of active pharmaceutical ingredients in a major production area for the global bulk drug market near Hyderabad, India. Very high concentrations of some APIs were found in the effluent of the treatment plant, raising serious concerns regarding the development of antibiotic resistance and signifying a major challenge for producers and regulatory agencies.

These risks should certainly be considered as part of the regulatory issues in any strategy to develop LPP. However, as long as the pharmaceutical manufacturing is limited to the final stages of the manufacturing process – formulation and packaging –

[25] On women and child discrimination in access to health services, see:
http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities
http://siteresources.worldbank.org/INTPRH/Resources/Stigma_Discrimination-rev.pdf

and does not imply API production, it does not seem to pose a major threat to local populations or require special attention.

4.8.3 South-South cooperation

South-South cooperation can take many forms: increasing trade between countries, joint education and R&D initiatives, technology transfer, lobbying together at international fora, harmonizing regulation, and so on.

In the pharmaceutical sector, there are some examples of South-South cooperation, such as trilateral (Brazil, India, South Africa) cooperation or the collaboration between Brazil and Cuba in the area of biotechnology.

South-South cooperation was taken into account in UNIDO's project design and implementation. In the broad sense of the term, the South-South initiatives in the project include the training activities of the Saint Luke Foundation, the cost sharing of a study tour by 11 production professionals from Cameroon to Cipla's facility in India and the Harmonization of Registration in the SADC Region initiative by the SAGMA Medicines Regulatory Working Group. The PMPA also provides a platform for collaboration in many areas, including the possibility for the region to act in a coordinated way at international fora, such as WHO and the World Trade Organization (WTO).

However, South-South cooperation has not played a significant role in areas such as technology transfer, with the exception of training activities by the Saint Luke Foundation, which could be described as a form of technology transfer and collaboration in production or R&D initiatives.

5. The WHO-UNIDO partnership in Viet Nam

One of the topics explicitly mentioned in the TOR of the present evaluation as an important issue to be addressed is the WHO-UNIDO partnership in Viet Nam and the potential for such a partnership in future interventions.

Originally, the WHO programme in Viet Nam was aimed at strengthening the health system in general and, in 2009, the Organization started work on improving access to medicines. WHO is traditionally concerned with improving the various dimensions of accessibility, especially availability and affordability. However, it became clear in consultations with the Government that the latter was mainly interested in the industrial development component. Aware of its limitations in this respect, WHO turned to UNIDO for support and collaboration in its project.

In November 2010, the Government, through the Ministry of Health (MoH), signed an Aide-memoire with the United Nations Industrial Development Organization (UNIDO) and the World Health Organization (WHO) on tripartite collaboration in promoting local pharmaceutical production. The first step planned was an assessment of the operating environment for local pharmaceutical production (in the form of a Pharmaceutical Sector Scan or Profile) and also of the overarching government policies affecting this environment.

The overall objectives of the collaboration were to:

- Conduct a review of the capacity and viability of the local pharmaceutical industry
- Identify the challenges of local pharmaceutical production in Viet Nam
- Review the policy and regulatory framework surrounding local pharmaceutical production
- Develop policy recommendations to the Government and industry
- Provide inputs into the development of the national strategy for the local production of pharmaceuticals in Viet Nam

The WHO-UNIDO project in Viet Nam has been a pioneering experience for these two organisations in working simultaneously with the same objectives in the same country. Activities have involved a rather broad-based collection of data and information from multiple stakeholders for the purpose of preparing a reliable pharmaceutical industry profile (informed by a sample industry survey of 31 (out of 185 existing) companies, plus a compilation and assessment of policies and policy measures impacting (by design or implicitly) on the country's pharmaceutical industry. The final report, "Pharmaceutical Sector Profile and Policy Review", was intended to be the main deliverable under the ongoing UNIDO/WHO collaboration.

A validation workshop to present preliminary results was held on 14 February 2012 and the two organisations have since been working on its finalisation. At the end of the evaluation period, the draft still contained some contentious points, mainly on the role

of public procurement as a means to promote local production. Eventually, since WHO and UNIDO could not agree on the role of public procurement to promote local production, no recommendation of this issue was made in the report. Nevertheless, the output is a solid piece of work that has attained the initially agreed objectives and provides the background information and analysis required to design future interventions.

For an external observer of the process, it is not easy to objectively identify the causes of the implementation delays although a number of diverging views and approaches on some questions seem to have played a major role.

In order to improve future collaboration, it is important for both WHO and UNIDO to understand the position of the other party on the potentially contentious issues that affect pharmaceutical policies. These differences do not seem to emanate from the diagnosis of the situation but rather from the objectives and priorities of the interventions required and from some of the tools to implement them, on which no conclusive evidence of effectiveness is available.

The following paragraphs discuss some of the apparent differences between the respective positions of WHO and UNIDO on LPP and related topics: quality, product focus, procurement and prices. Agreeing or at least reaching a compromise on these issues is likely to facilitate WHO-UNIDO collaboration and would avoid delays in the development and implementation of joint projects.

5.1 Local Pharmaceutical production

UNIDO's mandate is to work in the field of industrial development although it would clearly not advocate industrial development that runs counter to public health and would always take into account the aspect of long-term sustainability.

The project under review has sought to help local companies to upgrade the standard of drugs currently produced. Whilst recognising that rigorous evidence that LPP of quality generics will automatically improve the affordability of medicines in the same country is not available, such production is still very likely to have a positive impact on access and health in both the producing country and in the countries to which these medicines are exported. Therefore, what counts are the projected net benefits to be expected from an approach that includes time-bound, performance-driven incentives that policymakers might wish to use in order to stimulate industrial output.

The principal mandate of WHO is to improve public health and the Organisation has not hitherto been concerned with industrial development. Nonetheless, its position on regulation, quality standards and other topics has an impact on LPP. In recent years, WHO's stand on LPP has evolved from a very cautious attitude (WHO, 2004) to a more favourable one (WHO-UNCTAD, 2011; Zarocostas, 2011). The Policy Framework Initiative (Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, WHO-UNCTAD, 2011) appears to broadly reflect WHO's current position on the topic26. Although not highly enthusiastic about promoting LPP

as a tool to improve access, the present view seems to be that, whilst there is no clear evidence of a direct causal link between local production and access to drugs, the development of the local drug industry is now a fact and, consequently, efforts should be made to harness this production so that it also improves access to drugs and contributes to other public health goals.

5.2 Quality

Improving quality standards is also one of the main goals of the UNIDO project as emphasised in project documents and in the present evaluation. However, in a potential public health versus industrial development dilemma, positions might diverge. UNIDO's view is that achieving WHO GMP standards represents a major challenge for most companies in the developing world. It is not politically feasible to rush to enforce such standards when many companies are simply not able to comply. Consequently, given the prevailing technical, financial and manpower constraints, a step-by-step roadmap is necessary if GMP standards are to be improved whilst, at the same time, avoiding unnecessary harm to the local industry.

As part of its efforts to establish national policies on medicines, as well as to promote the use of generics as the best strategy to ensure affordability and accessibility of medicines in DCs, WHO has demonstrated an ongoing commitment to support the capacity building and upgrading of National Medicines Regulatory Authorities (NMRAs) in order to ensure the quality of medicines. One of the principles upheld by the WHO Policy Framework Initiative is that LPP must operate to GMP standards.

Moreover, the WHO Prequalification of Medicines Programme (PQP), which started in 2001, is aimed at helping procurement agencies to attain acceptable standards of quality, safety and efficacy. At the end of 2012, the WHO List of Prequalified Medicinal Products contained 316 medicines for priority diseases, mainly HIV/AIDS, tuberculosis and malaria. The PQP was welcomed and regularly used by most large international donors as a tool to ensure quality and to protect the risks to their reputation.

A recent article by Hoen E.F., Hogerzeil H.V., Quick J.D., and Sillo H.B. entitled 'A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme' published in the Journal of Public Health Policy in January 2014 provides a comprehensive picture of the PQP and concludes that it has improved access to quality life-saving medicines in developing countries although it does not provide conclusive evidence of this impact. The PQP has nevertheless received some criticisms in that it might be contradictory to the objective of making NMRAs responsible for ensuring quality standards as it allows them to rely on WHO PQP. If the PQP becomes a substitute, national regulation enforcement could be neglected. The PQP might also favour the large, well-established generic MNCs and discriminate against and discourage the development of LPP.

5.3 Product focus

The WHO-UNCTAD Policy Framework also recommends that LPP should focus on specific products and the national Essential Medicines List is assumed to provide an adequate framework for product selection. In other words, in line with the WHO position, public support should provide incentives for specific classes of products rather than indiscriminately promoting pharmaceutical manufacturing. Priority should be given to specific essential medicines, i.e. medicines that address essential needs for which local production might bring clear health benefits or where the local industry has some specific advantages, as might be the case of anti-malarials in Viet Nam[27].

UNIDO's approach is somewhat broader and aims to promote an improved business environment, helping local companies to upgrade the standard of drugs currently being consumed and, at base level, leaving decisions on actual production portfolios to businesses and to the market. UNIDO's thinking in the present project has been to refrain from a micro level perspective which is why the project seeks to improve the operating environment of pharmaceutical manufacturers.

5.4 Procurement and prices

In principle, WHO opposes granting higher prices or market protection to domestic manufacturers. Permitting higher prices for local producers is perceived as a threat to affordability and is not an option contemplated in the Framework. It would, however, support the idea proposed by UNIDO of creating an industrialisation fund from which subsidies/premium prices could be paid to the local industry as an incentive for supplying certain products rather than making the health sector pay for them in the form of higher prices.

5.5 Conclusions

There are strong reasons for UNIDO and WHO to work in collaboration, taking advantage of their respective expertise and potential synergies in spite of their different perspectives. Indeed, most stakeholders view this partnership very positively. Nevertheless, the respective mandates, values and capacities of the two organisations differ just as similar differences will usually exist at national level and even within the same government.

The overarching issue on which progress, albeit slow, has been made internationally is to bridge mind-sets that lean excessively towards public health or industrial development. Consequently, when collaborating in the design of pharmaceutical policy strategies, divergent views may arise on the desirable objectives and on the best options to select to address specific objectives. In order to facilitate collaboration and minimise delays in future interventions, two points could be considered. First, a generic approach to guide country interventions could be discussed and agreed between the

[27] According to WHO, local production in Viet Nam concentrates on a narrow set of off-patent products where there is a lot of competition (e.g. paracetamol) while the market share of local production is much smaller in key strategic essential medicines. For instance, 80% of ARVs are provided by PEPFAR and local manufacturers are excluded from this market because they are not prequalified.

two organisations. Second, at country level, the collaboration could initially focus on developing country profiles and a diagnostic of problems, leaving normative and policy approaches to a second phase when the national authorities would be involved and could define their own objectives and priorities.

6. The Pharmaceutical Manufacturing Plan for Africa (PMPA)

The PMPA was initially launched at the summit meeting of African Union (AU) Heads of State and Government in Accra in 2007. Subsequently, the Conference of African Ministers of Health in 2011 pushed for the development of a Business Plan, the Terms of Reference (ToR) of which were agreed at a later meeting in Chad. The African Union PMPA Technical Committee has provided leadership and has played the key political role in obtaining the support of the Assembly of Heads of State and Government[28] in setting objectives, conducting studies, building the required partnerships and ensuring member countries' involvement in developing an operational Business Plan. In June 2011, the AU Commission (AUC) invited UNIDO to become a partner in the joint elaboration of the Business Plan for the accelerated implementation of the PMPA.

The overall objectives of the Business Plan are to develop a sustainable supply of affordable, quality, essential medicines; to improve public health outcomes; and to contribute to industrial and economic growth. More specifically, the Plan states that:

"The key objectives should take into account that:

- This programme is intended to benefit all member states.
- The quality of pharmaceutical production should be raised to international GMP standards and ultimately it should be a non-negotiable requirement that manufacturers must meet if they are to supply our people.
- There is a need to expand the range of drugs that our manufacturers produce (subject to the manufacturer meeting international GMP standards).
- The industry must be sustainable in the long term and competitive whilst operating to international standards.
- NMRAs will be advised to limit the range of products that companies can produce unless they meet GMP requirements.
- There is a need to develop and implement coordinated strategies at the national level.
- A fundamental long-term requirement is that regulatory capacity is strengthened and that, in resource-constrained environments, efforts are targeted at those aspects of regulatory activities that are critical to protecting public health.
- Some of our more advanced member states have well developed manufacturing systems but wish to reduce their reliance on imports and possibly develop/expand their export markets to include those overseen by stringent regulatory authorities.
- We have some companies that are prequalified for manufacture of products by WHO and/or other stringent regulatory authorities and there are others who are striving to achieve this milestone. We need to increase the number of internationally certified products from African manufacturers (increased number of manufacturers and broader product range)" (PMPA BP, p.99).

[28] All African countries – with the exception of Morocco –, 54 in total, are members of the AU.

According to the BP, the main weaknesses and limitations to developing LPP in African countries which justify the initiative include large variations in quality standards, weak regulatory capacity, very limited manufacturing of APIs, and the challenges posed by state-supported competition from Chinese and Indian manufacturers.

The Plan proposes an approach based on a generic package of solutions for implementation at local level. “This can then be tailored to the specific needs of each of our countries. The solutions package includes guidance on incentives in support of the sector; a Good Manufacturing Practice (GMP) roadmap and associated risk assessment of WHO’s Essential Medicines List (EML); a syllabus for developing the human resources required for the long-term sustainability of the industry; various mechanisms for accessing know-how in the short term, including a Partnership and Business Linkages Platform (that would also assist companies to, for example, establish relationships with local, regional and international players in order to increase product ranges, mobilise investment, etc.); and includes technical assistance to enable regulators to devise and implement organisational development plans. It also proposes a process by which the different stakeholders in a country can come together to develop a shared strategy for the sector and a means by which this strategy can be implemented.”

As a follow up to its technical collaboration in drawing up the PMPA BP, UNIDO has been invited to be a core partner in accelerating the implementation of the Plan. Its main role will be to set up a consortium of key partners and to play a planning and coordinating role at central and field level. Work on these aspects is ongoing, with funds available under phase 4 of the global project.

In order to implement the plan, a budget in the order of US$ 54 million is envisaged to cover the estimated cost of technical assistance (TA) over a five year period. The needs of industry, regulators and other players are not included in this figure and the required capital investment will have to be addressed by other sources, such as the World Bank.

It is envisaged that the PMPA Business Plan will be implemented in four phases: 1. Set up phase; 2. Pilot phase; 3. Scale up phase; and 4. Full scale implementation. A complete budget proposal for implementation will depend on the details of the action plan to be developed by the consortium partners (PMPA BP, p.103). UNIDO, together with the AUC, is expected to mobilise the necessary resources for technical assistance. It is proposed that the Organization should hold a trust fund for central PMPA TA resources which will be disbursed to consortium partners and other stakeholders in accordance with the action plan developed.

A notable feature of the PMPA BP is that, whilst it expects companies and countries to express their aspirations in relation to pharmaceutical manufacturing, it also foresees that countries not willing or able to develop or strengthen pharmaceutical production will be able to benefit through the enhancement of their regulatory systems and improved access to high quality suppliers in the region. “The quality standards to which our manufacturers adhere vary significantly between countries and within countries …We have examples of companies across our continent that have reached or are striving for international standards. We have others that have the ambition to do so but who have, as yet, not been able to access the detailed technical know-how or the investment needed to progress towards this mark. There are other entities that are

happy to continue with the current *status quo* given that they operate with a relatively low cost base and there is limited political power or capacity for NMRAs to take action against them." It further states that "The PMPA BP respects the sovereignty of individual nations to take decisions and to work bilaterally with institutions as desired. Similarly, the autonomy of our Regional Economic Communities is also respected by this Business Plan and interventions at both levels under the PMPA would be subject to invitation from the respective political bodies."

The contribution to the PMPA[29] is by far the most important achievement of the project at macro/continent level and it is likely to become the main reference point both for the development of LPP and for UNIDO's future activities in Africa within the framework of this global project.

[29] A summary of the PMPA BP is available at:
http://www.unido.org/fileadmin/user_media/News/2011/Flyer%20Three%20pager_AUC-UNIDO_fin.pdf

7. Conclusions and recommendations

7.1 Conclusions

7.1.1. General conclusions

The relevance and appropriateness of UNIDO's global project and its holistic design is positively valued by the majority of stakeholders, as is the logic of the intervention. The need to upgrade quality infrastructure to international standards is also recognised by most stakeholders.

UN organisations involved in the pharmaceutical sector are willing to accept the leadership of UNIDO in the design and implementation of collaborative LPP strategies and this position is shared by most industry associations, national governments and companies.

However, the perception of a large number of stakeholders interviewed is that translating the project into operational strategies and work plans seems to lag behind. Whilst some companies are dissatisfied because of delays in implementation and limited resources, others acknowledge that some companies did not actually try to take advantage of the opportunities offered by the project. Delays in implementation are attributed to lack of sufficient support (from government and UNIDO), lack of clarity on the amount of resources to be put into the project and to local elections.

Other causes of delays are the need for learning-by-doing, with a mix of successes and failures, which is inherent in an innovative approach. The initial project objectives were probably too ambitious and were spread across too many countries in relation to the team's capacity and the budget. Moreover, the emergence of key opportunities such as the invitation to participate in the Business Plan of the Pharmaceutical Manufacturing Plan for Africa, together with external factors such as elections, changes of persons in key positions, etc. could not have been foreseen.

Other companies expected the project to result in more access to financing – although the project documents clearly state that UNIDO would not be the source of funding for investment in productive capacity – and more sustained concrete activities as well as more clarity in specific strategies and roadmaps.

Several adjustments have been introduced in the logframe as a result of the lessons learned and the new opportunities that appeared during implementation. One of the most notable changes is the abandonment of access to medicines as an explicit final goal of the project and changes in the objectives and strategies are justified by the novelty of the holistic approach applied and the lack of solid evidence on the links between LPP and access.

7.1.2 Kenya

Several positive changes in the sector are attributed to the UNIDO project, which is considered relevant and appropriate by most stakeholders.

For example, country profiles were considered important in order to establish where the pharmaceutical industry stands. Moreover, UNIDO is seen as having promoted dialogue and collaboration, turning former 'enemies' into 'allies'.

Complaints over slow implementation were frequently raised during interviews and the local industry is looking for more leadership from the Ministry of Medical Supplies (MoMS) and the Ministry of Industry (MoI) which are expected to collaborate in the implementation of the project.

The training of industrial pharmacists and the availability of consultants for longer periods are seen as crucial inputs by industry and they are prepared to pay for this if necessary.

A general impression arising from the interviews is that industry in Kenya is aware that it is up to the national stakeholders (both government and industry) to take the ownership and leadership of the project and not to rely only on UNIDO and other external sources of assistance.

7.1.3 Ghana

The main counterpart of the project in Ghana is the Ministry of Trade and Industry (MoTI), which hosts the national UNIDO consultant and has frequent regular meetings with him. The Ministry acknowledges some progress in the project but complains of the lack of a detailed project document. It also mentioned that “so far no single company has been upgraded”. On the other hand, public health organisations seem less involved.

Some recent institutional developments are likely to improve the prospects of support for the project. The Food and Drug Board has become an independent agency under the name of the Food and Drug Authority (FDA) and the local industry association, the Pharmaceutical Manufacturers Association of Ghana, has become a valid and active counterpart for the industry.

The offices of several key international organisations in Ghana recognise the expertise of UNIDO and expect it to lead the initiative to strengthen pharmaceutical production of essential generics whilst they support the project from their own fields of expertise and mandates.

Industry appreciates the design of the project and the quality of the interventions and activities carried out so far by UNIDO. The main objective is assumed to be to set common standards of quality, safety and efficacy of locally produced medicines and to strengthen the capacity of the regulator. However, industry representatives express strong dissatisfaction with the slow progress of implementation, which so far does not match their expectations.

There seems to be a widespread lack of clarity among potential stakeholders regarding their expected roles and responsibilities and on what UNIDO wants to achieve and is prepared to provide. According to many of them, this is due to the lack of an agreed project work plan which, at the time the evaluation took place, was still in the making. Both the MoTI and the Ministry of Health are looking to this work plan as a means of formalising the Government's commitment to the project.

Some companies would like UNIDO to play an advocacy role and to facilitate access to long term financing, such as helping to convince institutions to put money and resources into the industry, as well as providing other inputs such as transfer of technology and know-how, training and advice, market situation analyses, etc.

7.1.4 Viet Nam

The report entitled 'Pharmaceutical Sector Profile and Policy Review' is the main deliverable under the ongoing UNIDO/WHO collaboration and it has been presented and validated at two workshops. An important outcome of the project is that the Ministry of Health is preparing an amendment to the existing Drug Law of 2005 and this will incorporate many of the recommendations made by the international consultant contracted under the project. The Ministry was planning to submit the draft law to the Government in mid-2013, with a view to placing it before Parliament by the end of the year.

DAV does not appear to have staff with the requisite technical expertise to lead the project. Its staff are mainly trained pharmacists working on technical issues. They have limited managerial and economic experience, a key factor in demonstrating a comprehensive overview of the project. In view of DAV's essentially technical role within the Ministry of Health, it is unlikely to be able to provide the insight expected of a high level institution which should lead the project and be able to involve other ministries and institutions.

Moreover, the position of Vice-Minister for Pharmaceuticals was vacant at the time of the evaluator’s field visit. This further weakens MoH's potential leading role in ensuring that the project makes progress. Although there was a past initiative to strengthen DAV and to make it (more) independent from the MoH, this seems to be no longer on the political agenda. The officials interviewed acknowledged DAV's limitations when it comes to adopting a global view. They think, in fact, that this judgement can be extended to the pharmaceutical sector in its entirety since it has traditionally focused on the internal market.

The Ministry of Industry and Trade (MoIT) is not included among government stakeholders in the project on the grounds that it is responsible for the chemical but not the pharmaceutical industry which falls under the MoH. Nonetheless, it is hard to understand that MoIT has no role in a project aimed at local industry development. Ministries of Health are usually expected to carry out the role of collective consumer of medicines by selecting and procuring the appropriate products. They also participate in the regulatory functions related to quality, safety, and efficacy. In some cases, they are also involved in price regulation. However, they are not expected - and hence do not have - the expertise and capacity to promote industrial development. This apparent

contradiction should be tackled at cabinet level where the roles of ministries can be reassigned.

Financing is not viewed as a major constraint to quality upgrading or increasing production. In fact, the Viet Nam Pharmaceutical Companies Association (VNPCA) representatives claim that the industry has excess capacity and that the real problem is its limited ability to access foreign markets.

Price regulation seems to be a source of uncertainty for the industry, which is not happy with the present system although it does not seem to have put forward a solid alternative other than lobbying for the removal of the prevailing system. It would also like to see the introduction of export subsidies. The main vision of the VNPCA in the short term is to establish itself as a provider of capacity building.

7.1.5 The Pharmaceutical Manufacturing Plan for Africa (PMPA)

The PMPA BP reflects most of the features of the global project, as might be expected given the involvement of UNIDO in providing technical support to its elaboration. For instance, it highlights international quality standards as one of the key requirements as well as the need to involve regulators in implementing GMP and overseeing the market place. It also points to the opportunities for LPP to contribute to health outcomes.

Moreover, the launching of the PMPA Business Plan opens up new opportunities for a supranational strategy where countries might specialise in certain types of production and others might find it feasible and preferable not to address access from the LPP option but to rely on imports of quality and affordable pharmaceuticals from neighbouring countries[31, 32].

7.1.6 The WHO-UNIDO partnership in Viet Nam

The WHO-UNIDO project intervention in Viet Nam has been a pioneering experience for these two organisations in working simultaneously with the same objectives in the same country. The aim was to prepare a comprehensive pharmaceutical industry profile and to analyse the pharmaceutical policies in place. In spite of some difficulties in aligning the objectives and priorities of the two organisations, the opportunity for them to work together as equal partners from the outset offered many potential advantages since possible future problems were spotted more quickly and could be duly addressed and rectified. All stakeholders judge this partnership positively and note that the project activites have made a concrete contribution towards the revised pharmaceutical legislation.

7.2 Recommendations

To UNIDO

In order to facilitate the establishment of holistic global and country-specific strategies, inter-agency collaboration in a more structured manner is necessary. The PMPA BP is a successful regional initiative that could be replicated at regional or global level. The Interagency Pharmaceutical Coordination Group (IPC) is a valid step in this direction but it is not sufficient as it lacks resources and an institutional structure.

Most stakeholders judge the WHO-UNIDO partnership very positively. However, it is important to avoid the perception that national stakeholders are, in some sense, left out of the initial design phase, particularly since this could undermine the sense of ownership of the project.

The explicit tunning down of the access goal by UNIDO could have negative consequences. Public health and access-oriented organisations might become less inclined to collaborate with UNIDO if they get the impression that it has become less committed to public health and concentrates on industrial goals.

One of the main obstacles to designing and implementing successful strategies for improving LPP and access to pharmaceuticals is the lack of evidence on the effectiveness, or otherwise, of interventions. The global project provides UNIDO with a privileged opportunity to contribute to this knowledge by assessing its own interventions.

M&E should be put in place in order to assess the future impact of UNIDO interventions. The PMPA BP also states the need for setting up M&E mechanisms at continent and country level. This might require the involvement of national statistical offices as stakeholders in the national strategies.

In order to properly evaluate the effects of project interventions on the expected outcomes, it would be advisable to set up quasi-experimental evaluations by comparing the movements in a selected set of indicators on access, quality and competitiveness between countries benefiting from the project and a control group of countries that do not. However, this approach would only be feasible if the volume of interventions at country level was substantial enough to be properly measured. Moreover, this type of work is costly and would probably only be justifiable once a broad-based upgrading programme takes off in an individual country.

Analysing the impact of developing LPP on medicine prices could be feasible since the methodology and some of the data required are already available and could serve as the baseline. The HAI-WHO methodology for estimating local prices of medicines could be used to assess the effects of the project on prices. In Ghana, Kenya and Viet Nam, HAI-WHO price surveys were carried out in the period 2004-2005, shortly before the global project started. Replicating these surveys might demonstrate the impact of the project on one of the key intended outcomes of the project. Similarly, WHO's Global Price Reporting Mechanism (GPRM) provides a source of data that can be used to compare the price trends by country for a set of medicines, mainly, ARV, TB and Malaria.

The importance of producing case studies and publications on the project and making these accessible and available as a benchmark for replication was also cited in the mid-term evaluation. UNIDO is committed to taking the lead in a development approach on which little previous evidence exists. Many of the assumptions in the logframe are reasonable but uncertain. It is therefore important that the global project should see itself as a learning experience and devote a substantial portion of resources to properly documenting, evaluating and disseminating the successes and failures. In this way, it will help to identify good and bad practices for future interventions. The articles by Wilson et al. (2012) and Chaudhuri et al. (2010) are good examples of how

to report on LPP development programmes so that they provide lessons for similar future initiatives.

In the light of the frequent complaints and frustration voiced by national stakeholders in relation to perceived delays in implementation, it would be advisable to be more realistic in future phases of the project with regard to the expected outcomes and also to try to define achievable timelines for the outcomes and impact.

A management option to consider for future phases would be to shift resources from UNIDO headquarters to the countries where interventions are taking place. This would probably result in decisions being taken more quickly, bottlenecks being overcome, and some delays being avoided. There is probably also a good case for a team member to be located in an African country. In the case of Viet Nam, the presence of a team representative would also be necessary[30], at least for an initial period until the project takes off and can continue on its own.

Setting up National Steering Committees should also be a priority in order to ensure ownership and sustainability.

Attention should be given to pricing policies within the national strategies. This is especially justified in the case of medicines supplied under monopolistic conditions[31]. However, studies on the price of medicines done by Health Action International (HAI) and WHO in developing countries provide evidence of large price divergences and unaffordable prices among multisource products. Many DCs still rely on pricing according to the cost of production criterion. This usually discriminates against LPP because import prices – with their implicit profit margins – are accepted as costs, while locally produced products are controlled by their cost components. Pricing policies are a potential tool for providing incentives to (or, at least, not distorting) the goals of LPP strategies. They are also a topic that could encourage the involvement of ministries with economic portfolios in the project since price issues usually form part of their mandate.

Although UNIDO's LPP development strategies are mainly broadly based on improving the business environment and leave decisions on actual production portfolios to businesses, it might be worthwhile exploring the feasibility and appropriateness of product-oriented approaches. Incentives for the production of specific medicines are usually implemented by means of demand-side policies[32], mainly by including medicines considered essential to satisfy the health needs of the population in a positive list. These medicines are provided free, or highly subsidised, in order to ensure access and public financing indirectly provides a firm incentive for companies to produce these medicines, especially in countries with a strong public health system in which public sector purchases account for a substantial share of the pharmaceutical market.

[30] Two part-time national experts have been under recruitment in Viet Nam since June 2013 to allow for smooth progress of activites in between field missions (currently at intervals of four to six weeks) by the leading international expert.

[31] Hellerstein (2012) estimated that DCs pay 50% higher prices when monopolies are present.

[32] Demand-side policies include public financing and subsidies on medicines, providing appropriate information, education and incentives to prescribers and consumers and other measures aimed at the demand units.

However, in principle, there is no reason not to focus on supply-side policies[33] in relation to specific categories of medicines and no reason not to try to give priority to the production of essential medicines that cover important local health needs or pose special problems in terms of availability and affordability. The PMPA Business Plan also points to the need to prioritize the local production of certain medicines as well as the need for a dedicated field presence to ensure effective country level implementation. The selection of medicines that would qualify or have priority in supply-side policies should be decided by appropriate technical committees – certainly not by UNIDO or WHO representatives alone - that could collectively identify the most needed and appropriate medicines for LPP.

South-South cooperation should be strengthened in areas such as the transfer of technology and also in attaining unified African positions in defending the common interests of the region and of DCs in international fora. One key area is intellectual property because developed countries have shifted their strategy away from global (TRIPS, WHO, WIPO) to bilateral negotiations in order to weaken the position of DCs.

The project should also consider and eventually address some unintended negative consequences that might ensue. For instance, building strong manufacturers associations allows UNIDO and other stakeholders to have a well-defined counterpart that represents an important stakeholder with whom to negotiate. These entities are therefore an important factor in promoting LPP. However, they might become very powerful and end up imposing their private interests over those of governments and consumers. They might then lobby to obtain and maintain permanent subsidies or privileges in local procurement. Such demands can prove difficult for governments to oppose because of the political repercussions of letting companies go out of business, thus implicitly recognising the failure of the policy. The project has recognised this risk and has sought to address it from the outset. Such an assessment has informed (among other things) the formulation of the GMP Roadmap approach.

To the donor

It is recommended that the donor should ensure the coordination of all organisations funded by it within the framework of its project to promote LPP and access to medicines, and especially the aspects related to IPR which are implemented by UNCTAD. The appropriate management of IPR should be a key factor in improving LPP and access to medicines in DCs.

As long as it is satisfied with the performance of the UNIDO project and is in accord with its future plans, the donor should consider funding the appropriate budget increase to allow the UNIDO project to expand its scope to some key activities, such as building the knowledge base to make LPP promoting activities more evidence based and hence more effective and efficient.

[33] Supply-side policies are those that directly affect the production and distribution of medicines, such as tax exemptions and subsidies to manufacturers, quality and price regulation, IP management, etc.

To national governments

National governments in countries that benefit from international cooperation activities intended to improve LPP and access to medicines should recognise that their commitment is essential to the success of UNIDO's holistic approach. They must ensure that the relevant ministries and agencies, mainly those responsible for health and industrial policies such as the NMRAs and the health insurance agencies, have the legal capacity, commitment and support to take full advantage of such projects. They should ensure collaboration and agreements at supra-ministerial level on the global objectives and establish priorities and trade-offs between potentially conflicting public health and industrial objectives of the interventions and align external technical assistance with their overall national policies.

To the Evaluation Group

In order to make independent evaluation of a multiphase project more meaningful, the time frame of the evaluation should preferably end at the time the project or project phase to be evaluated has finished and the self-evaluation reports by the project team have been delivered. A substantial change of logframe or project objectives might also make sense as the date for defining the time frame of an external evaluation.

Based on the experience of this evaluator, evaluation reports would benefit from greater involvement of the UNIDO Evaluation Group in providing methodological guidance to the independent evaluator on UNIDO's evaluation policy and the guidelines on technical cooperation projects[34].

[34] The project document of Phase 3 of the global project provided for an independent terminal evaluation to be carried out by a team consisting of an expert nominated by the donor and one staff member of UNIDO's Evaluation Group.

ANNEXES

ANNEX A. TERMS OF REFERENCE

18 October 2012

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

TERMS OF REFERENCE

Independent Evaluation of UNIDO global project

TE/GLO/08/030 & XP/GLO/09/016 ['phase 2']

STRENGTHENING THE LOCAL PRODUCTION OF ESSENTIAL GENERIC DRUGS IN DEVELOPING COUNTRIES (DCS)

and

TE/GLO/10/023 & XP/GLO/11/007 ['phase 3']

STRENGTHENING THE LOCAL PRODUCTION OF ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES THROUGH ADVISORY AND CAPACITY-BUILDING SUPPORT

1. Background and context

Unsatisfactory access to essential quality drugs is a key limitation that impacts on the health of the populations in developing and least developed countries (DCs/LDCs): The UN gap task force report 2012 pointed at a survey in selected DCs, revealing an average availability of selected essential medicines of 51.8 per cent in public sector health facilities and 68.5 per cent in the private sector over the period 2007-2011 with only slight improvements over time.

Despite the recent progress in the supply of essential medicines to combat pandemic diseases (such as HIV/AIDS, malaria and tuberculosis), the gap between the type and volumes of required drugs and those that are affordable by the poor segment of the population in developing countries remains substantial.

The issues linked to the access-to-drugs challenge are multitude and complex, and include weak healthcare systems, drastic shortages of healthcare professionals, inefficient distribution channels, limited funding for products, intellectual property restrictions and many more. A further problem is ensuring the quality of medicines that are available in the market.

This project is looking at the access problem from a production point of view in order to contribute to improved access to essential drugs through increased supply of quality affordable medicines from DC/LDC producers (impact).

The industry is currently facing a bundle of constraints, typically be found at the levels of policy, industry regulation and support measures, of sector-specific support institutions as well as of the manufacturing plants themselves. By overcoming these limitations, locally produced medicine (currently at approx. 30% of the market volume in sub-Saharian Africa (SSA)) offers a potential for increase medicine supply and could mutually contribute to health and economic goals.

Starting in 2006, UNIDO has been running three phases of a largely German funded global project on strengthening the local manufacturing of essential generic medicines (TE/GLO/05/015 & XP/GLO/07/026 ['phase 1'], TE/GLO/08/030 & XP/GLO/09/016 ['phase 2'], and TE/GLO/10/023 & XP/GLO/11/007 ['phase 3']) the latter of which is scheduled to end in December 2012. The initial focus (phase 1) was the local production of drugs against the three pandemic diseases (HIV/AIDS, Malaria, TB) in LDCs against the background of a number of safeguard provisions, notably an exemption granted to LDCs until 2016 for compliance with the TRIPS Agreement .

The second phase of the project saw a broadening towards developing countries at large and also recognized that healthy local pharmaceutical manufacturing capacity requires consideration of the whole range of products and indications outside of the three pandemic diseases. The objectives were pursued through a combination of advisory, promotional and capacity-building activities geared at three levels: Macro level (policy advice), meso level (institutional support) and micro level (enterprise support in the form of pilot/demonstration efforts), drawing on UNIDO's technical expertise, networks, tools and methodologies in the area of private sector development (PSD) and SME promotion.

Phase 3 provided for advancement in two respects: (i) the continuation and deepening of interventions in existing as well as their replication in additional project countries, and (ii) the development of a platform from which to expand UNIDO's activities in the field of pharmaceutical sector development into an enhanced UNIDO program at the interface of public health and private sector development. (i) was to be achieved through a continuation and roll out of activities that had been conducted in target DCs and LDCs during previous phases and (ii) by designing, developing and beginning the implementation of an enhanced UNIDO program on developing industries for health products.

A mid-term evaluation of the project (phase 1 and – partly – phase 2) was carried out from November 2009 to January 2010 by an independent team consisting of two consultants.

Project Budget

The total budget of the Phase 2 and Phase 3 of the project (including support costs) was calculated at Euro 3.2 million with GOG contributing the majority of funds. To-date, 86.2 % of the allotments (Ph2 + Ph 3) are committed and/or spent.

Table 1. Project budget

		Phase 2	Phase 3	Total
Total allotment		**1,453,638**	**1,261,947**	**2,715,585**
from GOG(excl. sc.)	TE GLO 08 030 TE GLO 10 023	**1,218,191**	**1,061,947**	**2,280,138**
from UNIDO	XP GLO 09 016 XP GLO 11 007	**235,447**	**200,000**	**435,447**
Total expenditure as at 31 10 2012		**TE 1,206,357** **XP 233,840**	**TE 804,075** **XP 97,707**	**2,341,979**
Rate of expenditure (%)		99.1%	71.5%	86.2%
13% Support Costs (GOG)		158,365	138,053	
Total budget (including support cost)		**1,612,003**	**1,400,000**	**3,012,003**

Source: UNIDO INFOBASE as of 31 October 2012 and project documents

Project duration

Phase 2 started in November 2008 with a planned duration of 18 months, originally until June 2010, extended with donor approval to December 2011. Phase 3 activities were scheduled for 24 months and commenced in January 2011, but will not be completed by end-2012 (and, hence, an extension is firmly agreed with the donor).

Rationale and purpose of the evaluation

In accordance with the UNIDO Evaluation Policy, the Guidelines for the Technical Cooperation Programmes & Projects and the project document, the UNIDO pharma team in cooperation with the Evaluation Group (OSL/EVA) will commission an independent evaluation of project phases 2 and 3 to an external evaluation consultant, tentatively scheduled for the December 2012 to March 2013 period. For phase 2 this will be a final evaluation and for phase 3 it will consider the activities conducted by then, which should include the predominant part of the project. The purpose of this mid-term evaluation is three fold:

- Determine the extent to which the expected results as defined in the project documents or other documents reflecting project revisions have been met or to assess the likelihood of achieving these upon project completion; the degree to which recommendations of the last evaluation have been included in project design and work;
- Identify strengths and weaknesses of the project implementation, design (including log frame) and management so far, including project monitoring and self-evaluation (M&E) mechanisms, and elucidate key reasons for implementation delays, and
- Identify potential options for improvement, which could include modifications of the project design, including the logical framework, implementation and management mechanism (steering committee; responsibilities of UNIDO and project staff, scheduling, etc.), especially with regard to the imminent start of phase 4 of the project: Ideally, the evaluation results will inform the preparation of a refined/detailed work plan for this phase sometime in late Q1/2013.

2. Scope and focus

In the phases examined by this evaluation, the project has implemented activities/ interventions at three levels in a number of LDCs and DCs as follows:

Levels	Interventions

Macro – policy advice	• 8 sector profiles published
	• Preparation of the Pharmaceutical Manufacturing Plan for Africa – Business Plan (PMPA BP):
	  ○ Inception Workshop in cooperation with the AUC in Vienna (August 2011)
	  ○ Hosting of PMPA Technical Committee meeting in Addis Ababa (May 2012)
	  ○ Several consulting missions/tasks on various topics/areas (e.g. LPP in Maghreb region, economics of pharma manufacturing, financing in LPP)
	  ▪ GMP Roadmap assessments of 5-6 companies in each Ghana and Kenya conducted

Levels	Interventions
	▪ Concept note on HR solution package ▪ Concept mote on Business Linkages solution package o Printing and publishing of PMPA o Meeting of Core Partners in Vienna (November 2012) • National dialogue: o Pharma strategies developed in Ghana and Kenya ▪ Work on implementation plan in Ghana under way o Pharma industry scan and LPP policy assessment conducted in Vietnam (in coop. with WHO) • Global Forum contributions and international agenda setting: o Regional workshop on LPP in Lusaka (Nov. 2008) o Side event at meeting of UNIDO Industrial Development Board (IDB, November 2010), resulting in Board Decision IDB.38/Dec.7 including a enlarged mandate of UNIDO for LPP o Conference on LPP in cooperation with BMZ and GIZ in Cape Town (April 2011) o Roundtable on Pharmaceutical Industries as input to Conference of African Ministers of Industry (CAMI-19), Algiers, 27-31 March 2011 o Co-organization (together with ALMA, RBM, GFATM and MMV) of Friends of ALMA Manufacturers' Forum, Nairobi, 30-31 May 2011 o Attend WHO Stakeholder and coordination meeting on EU financed WHO/UNCTAD project on local production and access to medicinal products in Geneva (February/ November 2012) o Consultations with UNAIDS on a UNAIDS paper on Local Production of Pharmaceuticals, May 2012 o Panel contribution at EC Conference on "Innovation in Healthcare without borders", Brussels, 16-17 April 2012 o Attend BMZ/GIZ on the German Contribution to UNIDO for the implementation of the AU African Pharmaceutical Manufacturing Plan for Africa event in Addis Ababa, (November 2012)

Meso – Institutional capacity building	• Support for the formation, launch and early operations of the Southern African Generics Medicines Association (SAGMA):
	  ○ Study, working group and workshop on Regulatory Harmonization in SADC region (2012)
	  ○ Training Needs Analysis launched in (November 2012)
	  ○ Support progress towards the formation of the Federation of African Pharmaceutical Manufacturing Associations (FAPMA)
	• St. Luke Foundation, Moshi/UR Tanzania: Sponsoring of modular training course on advanced industrial pharmacy; advising on sustainable business model

Micro – Enterprise support	• Direct support to enterprises in Botswana, Cameroon, Ghana Kenya regarding: Efficiency of production or GMP standards • Exploratory talks with the University of St Gallen about the opportunity to use the OPEX model to benchmark and ultimately improve efficiency of pharma production in African companies

The scope and focus of the evaluation are guided by the strategic importance of the selected areas for the successful continuation and further expansion of the project as well as for pointing out the potential for improvements in strategic areas which the project will focus on in the upcoming phase:

A major unforeseen development during phase 3 was the receipt by UNIDO of an official communication from the Commissioner for Social Affairs, AU Commission (AUC) in June 2011, inviting UNIDO to partner up with the AUC for the joint elaboration of a Business Plan (BP) for the accelerated implementation of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA), a document originally endorsed by AU Heads of State in 2007. In view of the opportunity associated with such a partnership to significantly increase the awareness of the LPP agenda at continental level as well as to catalyze hoped for favourable stakeholder (including funding) responses, the UNIDO project team sought and obtained approval from the donor for a revision of the project work plan and corresponding budget line allocations which allowed for the generation of the aimed-at deliverable – the PMPA BP – in line with AUC requirements. The BP that was eventually approved by AU Ministers of Health (in May 2012) and subsequently endorsed by AU Heads of State (in July 2012) constitutes a milestone achievement on the way to a more consistent, coordinated approach of fostering pharmaceuticals manufacturing in Africa at large.

While UNIDO has been invited to continue its collaboration with the AUC towards managing the implementation of the PMPA BP in the years ahead, the resources that had to be devoted to PMPA BP preparations between September 2011 and the present time implied a reduction in the means available for deepening and expanding the project's country level work for the larger part of phase 3.

Work on the PMPA BP and the increasing use being made of the UNIDO project team as a resource for advice on the potential benefit of a commercially viable, quality prone pharma manufacturing sector in DCs/LDCs contributed to the further build-up of a profile for the 'local pharmaceutical production (LPP) agenda' which until recently had

been a widely neglected dimension in efforts geared at resolving the access to medicine challenge. The evaluation may provide further insights for additional UNIDO action to effectively fulfill its Global Forum function in the subject area.

Another crucial area for advancements in the field of LPP is the design of a sector specific development framework. UNIDO already developed strategies based on multistakeholder approach in Kenya, Ghana and is taking first steps in this direction in Viet Nam. As the upcoming project phase 4 and the PMPA BP envisage the development of the pharma sector in additional African countries, strategy development will play a crucial role for the success. In addition, a detailed analysis and evaluation of the respective steps towards strategy development will pave the way for a successful subsequent implementation phase.

With respect to the country selection it is recommended to focus on Kenya and Ghana, as both of them have been fast tracked for implementation under the PMPA BP. In addition to the African countries, it is recommended to evaluate the project's experiences in Viet Nam as it provides insights into a different cultural as well as political setting and also show-cases inter-organizational cooperation (WHO).

3. Evaluation issues and key evaluation questions

Project identification and formulation

The evaluation will specifically investigate and assess the extent to which:

(i) A participatory project identification process including all main stakeholder groups was instrumental in selecting problem areas and counterparts requiring technical cooperation support.

(ii) The project had a clear thematically focused development objective and immediate objective and/or outcomes based on a logical framework, the attainment of which can be determined by a set of verifiable indicators.

(iv) A logically valid means-end relationship has been established between the project objective(s) and outcomes and the higher-level programme-wide or country/continent level objectives.

(v) Lessons from earlier UNIDO projects/phases were taken on board in the formulation process including lessons and recommendations given on existing evaluation reports at the time.

Ownership and relevance

The evaluation will specifically investigate and assess the extent to which:

(i) The counterpart(s) and/or target beneficiaries has (have) been appropriately involved and were participating in the identification of their critical problem areas (needs assessment) and in the development of technical cooperation strategies;

(ii) The counterpart(s) is/are actively supporting the implementation of the project approach including through in-kind and cash contributions;

(iii) The project is relevant to the:

- Needs of pharmaceutical enterprises and support institutions
- Development priorities and strategies of the Governments of participating countries
- UNDAF objectives in selected countries
- UNIDO's thematic priorities
- The Government of Germany's policies and priorities

(iv) The project's design is adequate to address the problem(s) at hand;
(v) The outputs as formulated in the project document are relevant and sufficient to achieve the expected outcomes and objectives;
(vi) The project remains relevant taking into account the changing environment and if there is a need to reformulate project design and log frame given changes in the country and operational contexts.

Efficiency of implementation

The evaluation will specifically investigate and assess the extent to which:

(i) Donor, UNIDO and Government/counterpart inputs have been provided as planned and were adequate to meet requirements;
(ii) The quality of UNIDO inputs and services (expertise, training, methodologies, etc.) was as planned and led to the production of outputs;
(iii) The interventions were cost-effective;
(iv) The project's activities are in line with the schedule of activities as defined by the project team and annual work plans;
(v) The disbursements and project expenditures are in line with budgets;
(vi) There was coordination with other UNIDO and other donors' projects and possible synergy effects;
(vii) The project has reached the expected number of beneficiaries (institutions, targeted companies, etc.) within the expected time frame.

Effectiveness

(i) To what extent have the expected outputs been achieved or are likely to be achieved on the relevant levels (micro, meso macro)?
   a. How do the stakeholders perceive their quality?
   b. Were the targeted beneficiary groups actually reached?
   c. Do they use the output?
(ii) What intended and unintended outcomes has the project achieved so far (both qualitative and quantitative results)?
   a. Have the outcomes be used through the utilization of outputs?
   b. To what extend has the project generated any results that could lead to changes of the assisted institutions' operations?
   c. Have there been any unplanned effects?

Impact and sustainability

(i) Which long term developmental changes (economic, environmental, social) have occurred or are likely to occur as a result of the intervention and are these sustainable?
(ii) To what extend are the benefits from the project likely to continue after the project completion in terms of political, financial, institutional, technical and environmental sustainability and local ownership?
(iii) Was the project replicated/had a multiplying effect?

(iv) Was any sustainability strategy formulated?
(v) Does the project have an exit strategy? Is it accurate and realistic?

Project coordination and management

The evaluation will specifically investigate and assess the extent to which:

(i) The UNIDO HQ based management, coordination, quality control and technical inputs have been efficient and effective;
(ii) The national management and overall field coordination mechanisms of the project have been efficient and effective;
(iii) Changes in planning documents during implementation have been approved and documented;
(iv) Synergy benefits can be found in relation to other UNIDO activities in the country or elsewhere;
(v) Each partner did have specific roles and responsibilities from the beginning. (Did each partner fulfil its role and responsibilities (e.g. providing strategic support, monitoring and reviewing performance, allocating funds, providing technical support, following up agreed/corrective actions, other?);
(vi) Monitoring and self-evaluation were carried out effectively, based on indicators for outputs, outcomes and impacts. (Is there any annual work plans? Was any steering or advisory mechanism put in place? Did reporting and performance review take place regularly?).

Private sector development

(i) Has there been a rational choice of the PSD approach (e.g. industrial upgrading; cluster development; value chain development; entrepreneurship; etc)?
(ii) Has there been a rational choice of the structure that is to provide BDS to target companies (private BDS providers; public "centre"; direct UNIDO support; etc.)?
(iii) Is the intervention relevant within the existing framework conditions at micro (enterprise), meso (institutional) and macro (policy) levels?
(iv) Have private sector institutions/associations been involved in the project design and implementation?
(v) Have market potentials and access been analysed?
(vi) Has the issue of possible market distortions been considered:
    a. Have beneficiary companies been selected based on transparent and relevant criteria?
    b. Is UNIDO filling in market gaps or competing with existing companies & services?
    c. To what extent are private companies being subsidized by the UNIDO intervention and/or are companies paying for services?
(vii) If the project has worked with a limited number of selected companies, can the results be expected to be replicated to achieve wider impact?
(viii) Has the issue of financial services been given due consideration?
(ix) Can enterprise effects be expected to lead to socio-economic impact such as employment generation, gender, and poverty reduction?
(x) Has an M&E system been established, including baseline information, to allow for measurement of results and impact?
    a. Does this include follow-up surveys to measure impact after the project is ended?
(xi) Have synergies with other UNIDO branches/services been exploited, in particular TCB, Environment, Agribusiness and Energy?

4. Evaluation approach and methodology

The evaluator will develop an appropriate methodology for the evaluation and propose it in the inception report.

While maintaining independence, the evaluation will be carried out based on a participatory approach, which seeks the views and assessments of all relevant parties. It will address the following issues:

The evaluation will be carried out in keeping with UN evaluation standards and the UNIDO Evaluation Policy.[35] The evaluation shall determine as systematically and objectively as possible the evaluation issues set out above (see 4). To this end, the evaluation will assess the achievements of the project with special attention towards its focus and scope (see 3). It will also identify external factors that have facilitated or impeded the achievement of the objectives.

5. Time schedule and deliverables/outputs

Task	Description / *Deliverables*	Date
Contract signed with evaluators		18 Dec 2012
Desk review	The evaluation team will review and analyze available documents related to the project (e.g. design and progress reports; technical reports from consultants/subcontractors; methodological documents, former evaluation report, tools and training guidelines, etc.). Relevant documents from the Government of Germany, selected countries and other development organizations will also be consulted.	19 Dec 2012 - 28 Jan 2012
Delivery of draft inception report (using the EVA format)	*Inception report* is containing work plan, key findings of desk review, methodology, sampling technique, evaluation tools such as questionnaires and interview guidelines.	29 Jan 2012
Briefing of evaluators at HQ	Briefing with the UNIDO Evaluation Group, project managers and representatives of the donor. Stakeholders meeting on inception report in HQ, if appropriate.	30 Jan 2012
Deskwork and interviews at HQ, Vienna	Interview the UNIDO project manager/s, Senior Technical Advisor, Industrial Development Officer, Unit Chief and Director of the Business, Investment and Technology Services Branch. Interview a sample of consultants and/or institutions that were hired by UNIDO to support the project in the countries. For each type of interview (field & HQ), the evaluator will develop and use guidelines/guidance suitable to capture the information required.	31 Jan 2012
Revised inception report	*Revised inception report* including inputs/ insights provided through the briefing in HQ.	08 Feb 2013

[35] Available from: http://www.unido.org/index.php?id=o5122

Evaluation mission (briefing of evaluators in the field, possible testing of evaluation tools, field visits, field research, interviews, observation, questionnaires, etc.)	Visit to Viet Nam, Ghana and Kenya to carry out in-depth interviews with representatives of all stakeholder groups (government counterparts, donor, supported institutions, enterprises, investors, private sector representatives; etc) and visit project sites. Field interviews can take place either in the form of focus-group discussions or one-to-one consultations. The evaluation team will present its preliminary findings to the local stakeholders at the end of each field visit and take into account their feed-back in preparing the evaluation report.	11 Jan 2013 - 23 Feb 2013 24 March 2013 29 March 2013
Present overall findings and recommendations to the stakeholders at UNIDO HQ (incl. travel)	A *presentation* of preliminary findings will take place at HQ after the field visits, including recommendations for upcoming phase IV	29/30 April 2013
Delivery of draft report	The length of the *draft evaluation report* should be around 30-35 pages with a 3-page executive summary in English. The draft report will be shared with UNIDO and project staff, the Governments of countries visited (Viet Nam, Ghana and Kenya) and of Germany (as donor) for factual validation and comments.	till 15 May 2013
Revision of draft report	On the basis of this feedback, the evaluation team will prepare the final report.	till 22 May 2013
Approval of final report	The *final evaluation report* will be approved by UNIDO	31 May 2013
Dissemination (Management Response Sheet, evaluation brief, newsletter, articles)	These activities will be carried out by the UNIDO project team.	June 2013 - July 2013

6. Evaluation team composition

The evaluation team will consist of one individual possessing the skills defined in the Job Description (JD) in Annex 2.

7. Quality assurance

All UNIDO evaluations are subject to quality assessments by the UNIDO Evaluation Group. The quality of the evaluation report will be assessed and rated against the criteria set forth in the Checklist on evaluation report quality, attached as Annex 1.

Annex A.1. Checklist on quality of evaluation report

Report quality criteria	UNIDO Evaluation Group Assessment notes	Rating
(a) Did the report present an assessment of relevant outcomes and achievement of project objectives?		
(b) Were the report consistent and the evidence complete and convincing?		
(c) Did the report present a sound assessment of sustainability of outcomes or did it explain why this is not (yet) possible?		
(d) Did the evidence presented support the lessons and recommendations?		
(e) Did the report include the actual project costs (total and per component or project)?		
(f) Quality of the lessons: Were lessons readily applicable in other contexts? Did they suggest prescriptive action?		
(g) Quality of the recommendations: Did recommendations specify the actions necessary to correct existing conditions or improve operations ('who?' 'what?' 'where?' 'when?)'. Can they be implemented?		
(h) Was the report well written? (Clear language and correct grammar)		
(i) Were all evaluation aspects specified in the TOR adequately addressed?		
(j) Was the report delivered in a timely manner?		

Rating system for quality of evaluation reports

A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1, and unable to assess = 0.

ANNEX B. ORGANISATIONS VISITED AND PERSONS INTERVIEWED IN KENYA, GHANA AND VIET NAM

Table B.1 Total number of interviews and (interviewed persons) in the field and through telephone conferences

	Government and Public Sector	Companies and Industry Associations	International Organisations	NGOs	Academics and Independent Experts	UNIDO Representatives	TOTAL
Kenya	7 (12)*	8 (11)	-	-	2 (2)	1 (1)	18 (36)
Ghana	3 (5)	8 (8)	3 (3)	-	-	2 (2)**	16 (18)
Viet Nam	3 (5)	1 (2)	1 (1)	1 (1)	1 (1)	1 (1)	6 (9)
Telephone conferences			1 (1)				
TOTAL	11 (20)	17 (22)	5 (5)	1 (1)	3 (3)	4 (4)	41 (64)

** One interview was done by mail due to the absence of the person concerned at the time of the mission period. (**) One interview was done by telephone conference due to the absence of the person during the mission period.*

Table B.2 Kenya: Persons interviewed, organisations and observations

Date	Name and position	Organisation	Email	Observations
11-2-2013	H Chepkwony, former Chief GMP Division, Pharmacy and Poisons Board, MoH	Kenya Medical Training College	Kcheph@yahoo.com	Former Director of the National Quality Control Laboratory, the technical arm of the regulator (Pharmacy and Poisons Board) for the establishment of quality standards. He was a member of the UNIDO working group.
11-2-2013 *Information withdrawn 15-3-2013*	Viktar Proshchanka, General Manager Dr. David Rutere, Director of Regulatory Affairs	Norbrook Kenya Limited	viktar.proshchanka@norbrook.co.ke and david.rutere@norbrook.co.ke	Company size: Medium - GMP status: developing Norbrook requested the removal of all information because: "verbatim captured in the interview does not represent whatever was said regarding the industry... The contribution was on general basis and did not at any time refer to any institution..."
12-2-2013 *Revised on* *15-3-2013*	Dr. Arale Ali Abdullahi, Director, and three co-workers	National Quality Control Laboratory (NQCL)	arale@nqcl.go.ke	Dr. Arale Ali became Director of NQCL in 2011.
12-2-2013	Dr. F.M. Siyoi, Deputy Chief Pharmacist and Deputy Registrar Dr. S.W.A. Sifuma, GMP Division.	Pharmacy and Poisons Board, Ministry of Medical Services	fmsiyoi@gmail.com sifuma@pharmacyboardkenya.org	
13-2-2013	Julius Kirima George Makateto	Ministry of Industrialization (& Enterprise Development	kirima2001@yahoo.com	
13-2-2013	Dr. Rohin Vora	Regal Pharmaceuticals Ltd.	rohin@regalpharmaceuticals.com	Company size: Large - GMP status: First class

Date	Name and position	Organisation	Email	Observations
14-2-2013	Dr. James Kimotho, Production Department	Kenya Medical Research Institute (KEMRI)	JHkimotho@kemri.org	Technical Director took up his position in Sept 2012. The purpose of KEMRI is to turn research into findings. It works with the pharmaceutical industry (e.g. on GMP auditing)
14-2-2013	Dr. Nasser Nyamwaya, Lecturer in Pharmaceutics	School of Pharmacy, University of Nairobi		
14-2-2013	Dr. Margaret Oluka	School of Pharmacy, University of Nairobi		She participated in the 2004 survey study on medicine prices sponsored by WHO-HAI and later (2006) she worked on a study on distributors and import of pharmaceuticals in Kenya.
14-2-2013	Dr. Weru M. Douglas, Company Pharmacist/QAM Abdiwahab Ahmed Nur, CEO	Skylight Chemicals Ltd.	Dr.werud@skylightchemicals.co.ke abdi.ahmed@skylightchemicals.co.ke	Company size: Small - GMP status: Developing Dr. Douglas joined the company in 2010.
14-2-2013	Mr. Santosh	LAE	santosh@laballied.com	Company size: Large - GMP status: Developed
14-2-2013	E. Misati, Senior Patent Examiner	Kenya Industrial Property Institute, Ministry of Industry	memisati@kipi.go.ke	
15-2-2013	Dhirendra Shah	Biodeal	dvshah@biodealkenya.com	Company size: medium - GMP status: developing
15-2-2013	Dr. Prakash K Patel, Chairman and Managing Director Vimal Patel	Cosmos Limited	admin@cosmos-pharm.com	Company size: Large - GMP status: developed (reconstructing plant) Cosmos is the first company to be granted a voluntary licence.
15-2-2013	Palu Dhanani, Managing	Universal Corporation Ltd.	palu@ucl.co.ke	Company size: Large - GMP status: developed (WHO

Date	Name and position	Organisation	Email	Observations
	Director			prequalified). The company is not the largest in volume of sales, but probably the most advanced in terms of technological level.
25-2-2013	Dr. John Munyu, CEO	KEMSA	john.munyu@kemsa.co.ke	This questionnaire was completed and sent by email by the respondent.

Table B.3 Ghana: Persons interviewed, organisations and observations

Date	Name and position	Organisation	Email	Observations
18-2-2013	Yaw Opare-Asamoah, Managing Director	Dannex	john.opare@googlemail.com	Company size:Medium - QS Category: C/D
18-2-2013	Samuel Boateng, Director of Procurement and Supplies	Ministry of Health	samuel.boateng@moh.gov.gh	The organisation procures for public health facilities in the country.
18-2-2013	Nii Ansah-Adjaye Chief Director Mr. Tandoh Deputy Director for Industry	MOIT (Ministry of Trade & Industry)	nansah-adjaye@moti.gov.gh robtandor@yahoo.com	He joined the MOIT two years ago.
18-2-2013	K. Amponsah-Efah, Current President of PMAG and Managing Director of Amponsah-Efah Pharmaceuticals Ltd.	(Pharmaceutical Manufacturers Association of Ghana (PMAG) Amponsah-Efah Pharmaceuticals Ltd	a-efah@a-efah.com	Company size: Large - QS Category: C
19-2-2013	Dr. Paul A. Lartey, President and CEO	Lagray	paul.lartey@lagray.org	Company size: Small- QS Category: A
19-2-2013	Mark Owiredu, Factory Manager	Ernest Chemists	yawmso@gmail.com	Company size: Large - QS Category: B
19-2-2013	Mr. Kwabena Asante-Offei, Executive Secretary	PMAG	pmagsecretariat@yahoo.com	
20-2-2013	Yaw Adu Gyamfi, Founder &	DANADAMS	ceo@danadamsgh.com	Company size: Large - QS Category: B

Date	Name and position	Organisation	Email	Observations
	CEO			One of the first two companies to engage in collaboration with UNIDO
20-2-2013	Clara Tigenoah	Oxford Committee for Famine Relief (OXFAM)	cvalentinetigenoah@oxfam.org.uk	
20-2-2013	Dr. Michael Addo, CEO and Governor	Kama Health Industries	mikeaaddo@hotmail.com	Past president of PMAG Company size: Small - QS Category: D
21-2-2013	Mr. B.K. Asante	Geo Medicore Ltd.	kboison60@hotmail.com	Company size: Small - QS Category: D
21-2-2013	Mr Agyeman Duah Mr. Thomas Amedzro, Post Marketing Surveillance	FDA (Food and Drug Authority)	agyeduah2004@yahoo.com tom62kk@yahoo.com.au	
22-2-2013	Ms. E. Awittor, Senior Operations Officer	World Bank (Ghana Office)	eawittor@worldbank.org	
22-2-2013	Louis Nortey, National Consultant	UNIDO	louisnortey@hotmail.com	
22-2-2013	Dr Idrissa Sow, WHO Representative	WHO	sowi@gh.afro.who.int	Dr. Sow joined the WHO Ghana Office in April 2012
22-2-2013	Mr. Girmay Haile, Country Coordinator	UNAIDS	haileg@unaids.org	Mr. Haile took up his present position in September 2012. At his previous station in Kenya, he worked closely with UNIDO (UNDAF exercise)

Table B.4 Viet Nam: Persons interviewed, organisations and observations

Date	Name and position	Organisation	Email	Observations
25-3-2013	Dr. Socorro Escalante	WHO	escalantes@wpro.who.int	
26-3-2013	Mr. Phan Cong Chien, Deputy Head of Division, Pharmaceutical Business Control Division Ms. Dang Thi Minh Hang, Deputy Director, Division of Drug and Cosmetics Quality Control	Drug Administration of Viet Nam (DAV) , Ministry of Health	chienpc@dav.gov.vn hangqld@dav.gov.vn	
27-3-2013 *Revised on 24-4-2013*	Mr. Nguyen Quy Son, Chairman of VINAPHARM and Vice-Chairman of VNPCA Mr. Tran Duc Chinh, Vice-Chairman cum Secretary-General of VNPCA	Viet Nam Pharmaceutical Companies Association (VNPCA)	nguyenquyson58@yahoo.com chinhhientd@yahoo.vn	Mr. Son was a former consultant for UNIDO-WHO
28-2-2013 *Revised on 25-4-2013*	Prof. Le Van Truyen, Freelance Senior Consultant		levantruyen@gmail.com	Former Vice Minister of Health and consultant to the WHO-UNIDO project

International stakeholders interviewed by teleconference

Zafar Mirza, Department of Public Health, Innovation and Intellectual Property, Innovation, Information, Evidence and Research, WHO.

Frank S. Schmiedchen, Governmental Director in the German Federal Ministry for Economic Cooperation and Development.

ANNEX C. LITERATURE SEARCH AND BIBLIOGRAPHY

1. Literature search

A literature search was planned within the evaluation exercise as a tool to identify evidence on the link between LPP and local access to medicines. The keywords used for the search were: 'pharmaceutical production'; Drug OR pharmaceutical OR MEDICINES; domestic OR local; production; 'developing countries'. The search was done in the databases EconLit and PUBMED and also in WHO, UNIDO and World Bank.

The initial results were 865 hits.

Search results in EconLit and search description: 'Production' AND 'Developing Countries' AND ('Pharmaceutical' OR Drug OR MEDICINES): 97 references

Search results in PUBMED: (Drug OR pharmaceutical OR MEDICINES) AND (domestic OR local) AND production AND "developing countries": 217 references

Other sources: databases WHO (3), UNIDO (547) and World Bank (1)

Documents which required paying a fee or a complex procedure for access (mainly books and book chapters) were discarded. A further selection was made by screening first the titles of the references found and, afterwards, by reading the abstracts of the summaries of the documents to assess their relevance for the purpose of the search.

One of the references found at an early phase of the search was the literature review on the same topic by Kaplan et al. (2011), which had retrieved publications on the identical topic up to mid 2011. The search provided 14 additional references. Two more were added through a quick search on environmental sustainability. (See list below)

References

Abbott F.M., Reichman J.H. The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions. Journal of International Economic Law 2007. December 2007;10(4):921-987.

Ca T.N. Turning Science into Business in Developing Countries: The Case of Vaccine Production in Vietnam. Journal of Technology Transfer 2007. August 2007;32(4):425-434.

Chaudhuri S., Mackintosh M., Mujinja P. G M. Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. European Journal of Development Research 2010, 22(4) pp. 451–468.

Fick J., et al. Contamination of surface, ground, and drinking water from pharmaceutical production. Environmental Toxicology and Chemistry 2009. 28:2522–2527.

Ford N., Wilson D., Costa Chaves G., Lotrowska M., Kijtiwatchakul K. Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. AIDS 2007. July 21. Suppl 4:S21-9.

Heberer T. Tracking persistent pharmaceutical residues from municipal sewage to drinking water. Journal of Hydrology, September 2002. 266 (3–4):175-189

Hellerstein R. What Do Drug Monopolies Cost Consumers in Developing Countries? Economics Letters 2012. July 2012. 116(1):108-111.

Jadhav S., Datla M., Kreeftenberg H., Hendriks J. The Developing Countries Vaccine Manufacturers' Network (DCVMN) is a critical constituency to ensure access to vaccines in developing countries. Vaccine 2008. Mar 20. 26(13):1611-1615.

Kaplan W., Laing, R. Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines – An overview of key concepts, issues and opportunities for future research. 2005. World Bank. HNP discussion paper, Human Development Network.

Kaplan W., Ritz L., Vitello M. Local production of medical technologies and its effect on access in low and middle income countries: a systematic review of the literature. South Med Review 2011. 2011 December. 4(2):51-61.

Longo C.J. Encouraging Pharmaceutical Innovation to Meet the Needs of Both Developed and Developing Countries. International Journal of Development Issues 2011. 10(1):92-101.

Malhotra P., Lofgren H. India's pharmaceutical industry: hype or high tech take-off? Australian Health Review 2004 Nov 8;28(2):182-193.

Scherer F.M., Watal J. Post-TRIPS Options for Access to Patented Medicines in Developing Nations. Journal of International Economic Law 2002. December 2002. 5(4):913-939.

't Hoen EF1, Hogerzeil HV2, Quick JD3, Sillo HB A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme. J Public Health Policy. 2014

WHO. Local production for access to medical products: developing a framework to improve public health. Geneva, World Health Organization. 2011. http://apps.who.int/medicinedocs/documents/s19060en/s19060en.pdf

WHO. Executive Board. Manufacture of antiretrovirals in developing countries and challenges for the future. Report by the Secretariat. 114th Session, 29 April 2004. http://apps.who.int/iris/bitstream/10665/20177/1/B114_15-en.pdf

Wilson K.R., Kohler J.C., Ovtcharenko N. The make or buy debate: considering the limitations of domestic production in Tanzania. Global Health 2012. June 29;8:20.

Zarocostas J. World's poorest countries can improve access to medicines through local production, says United Nations. British Medical Journal 2011. May 18;342:d3101.

ANNEX D. LOGFRAMES

Phase 2 Logframe

NARRATIVE SUMMARY	OBJECTIVELY VERIFYABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS
DEVELOPMENT GOAL Enhancing access to essential medicines needed to combat pandemic diseases, thus improve the public health situation in DCs enabling the population to fully mobilize their productive capabilities, thus contributing to enhanced economic growth.	• Change in consumer prices of essential generic drugs in target DCs. • Change in number of parties with access to essential generic drugs.	• Drug price listings/reviews. • Number of people receiving treatment (National health statistics).	
PROJECT OBJECTIVE: Enhance the supply of the population in selected DCs with a range of generics at affordable prices, through promoting the local production by SMEs of high quality essential drugs.	• Change in volume of essential generic drugs produced/available domestically. • Quality of products is improved.	• Production statistics, company records • Certification that allows for export obtained by producer (International GMP, WHO-Pre-Qualification)	• Locally manufactured drugs can be sold at lower prices than imported alternatives. • Availability of funds to purchase essential drugs for an increased number of patients. • National health systems able to administer drugs to an increased number of patients.
OUTCOMES O.1 Strategies and policies for increased local manufacturing of essential generic drugs in project DCs implemented O.2 Export opportunities provide extended market for generic drugs O.3 Institutions offer demand-oriented support services to SMEs in the pharmaceutical sector	O.1 First joint measures implemented. O.2 Exports of essential medicines increase. O.3 Demand for services offered; quality and outreach of service provision. O.4 x% of plants assisted are operational.	O.1 Progress report from partners. O.2 Company records. O.3 Number of agreements for service provision, evaluation of customer satisfaction.	• Production of essential generic drugs is economically viable given the circumstances.

O.4 Capabilities for pilot local production in place O.5 Project examples are accessible and can be used for replication.	O.5 Project examples available as publications and on-line; Events have taken place.	O.4 Registration of drugs with Medicines Regulatory Authority. O.5 Participation in events, distribution of publications.	
<u>OUTPUTS</u>: O.1 Strategies and policies for increased local manufacturing of essential generic drugs are in place and acted upon in selected developing countries. O.2 Intra-regional trade of essential medicines facilitated through improved drug regulatory harmonization. O.3 Institutional support capacities for the promotion and development of the local manufacturing by SMEs of essential generic drugs upgraded. O.4 Upgrading of pilot local production of essential medicines facilitated. O.5 Positive project results effectively communicated.	O.1 Strategy agreed through public-private dialogue and/or joint policies adopted in selected DCs. O.2 Regional Harmonization Meetings have taken place. O.3 Improved performance of selected institutions. O.4 Feedback from companies. O.5 Project examples available as publications and on-line; Events have taken place.	O.1 Strategy/policy document and/or Minutes of Meetings available. O.2 Minutes of Meetings available. O.3 Evaluation at company level. O.4 Evaluation at company level. O.5 Participation in events, distribution of publications.	• Commitment of target beneficiaries (management and staff of target pharmaceutical SMEs and support institutions) to upgrade and apply knowledge and skills gained through assistance. • Government ready to remove barriers to increased local generics production encountered during implementation. • Government ready to remove barriers to trade and harmonise regulatory functions. • Firms willing and able to invest in the production of medicines

Phase 3 Logframe

INTERVENTION LOGIC	OBJECTIVELY VERIFYABLE INDICATORS	SOURCES OF VERIFICATION	IMPORTANT ASSUMPTIONS
IMPACT/ **DEVELOPMENT OBJECTIVE:** Improved access to drugs through increased supply of quality affordable medicines from DC/LDC producers	• Changes in supply/availability of select essential drugs from producers in target countries and/ or sub-region(s). • Interim targets for quality improvements as established by MRAs are enforced.	• Government drug procurement data/statistics. • US Pharmacopeia market surveys on sub standard products available in some countries • Where not available records of sanctions taken against companies not meeting requisite standards and documentation testifying to those that have.	
OUTCOME(S)/ **IMMEDIATE OBJECTIVE:**			
1 Increased capacity for competitive local production of quality essential medicines in target DCs/LDCs 2 Enhanced UNIDO Programme to enable the pharmaceutical sector in DCs/ LDCs to increase the availability of essential health products funded and operational. *(Program will deliver full range of expertise, initiatives and guidance to support and drive local production, utilising internal products and through working with partners.)*	• Rising sales (volumes, values) and market share of locally produced essential medicines. • Funding mobilized for enhanced UNIDO support program.	• Pharmaceuticals markets: business intelligence reports, national statistics (health authorities/drug procurement bodies). • Funding agreements (Trust Funds, other) concluded for expanded UNIDO program from 2012.	• Local manufacturers make active use of improved framework conditions and expand their business. • Locally manufactured drugs are competitive in relevant market terms (incl. local preferences). • Availability of funds to purchase essential drugs for an increased number of patients. • National health systems able to administer drugs to an increased number of patients. • Political agenda overall favourable of local production topics.
OUTPUTS:			
O.1 Pharmaceutical sector development strategies in Ghana and Kenya agreed and implementation initiated. Sector development strategies agreed for two additional countries	• Strategy documents agreed by stakeholder community and implementation plans initiated. • Existence of a country coordinating mechanism and dedicated personnel (whether in ministry or separate secretariat).	• Strategy document/ implementation report. • Minutes from meetings of country coordinating mechanism.	• Agreed/required changes in legislation and regulatory stipulations pass requisite procedures. • Willingness of governments/ Regional Economic Communities to implement and finance programs that enable the pharmaceutical industry to develop and use regional market opportunities.

INTERVENTION LOGIC	OBJECTIVELY VERIFYABLE INDICATORS	SOURCES OF VERIFICATION	IMPORTANT ASSUMPTIONS
			• The high level interest in countries is maintained and translates into commitment from stakeholders at the operational level.
O.2 Strengthened institutions supporting the development of the sector including national and regional BMOs, training centres and other support entities	• In Kenya FKPM becomes the preeminent voice for the industry, and engagement by companies increases. • Extent, quality and success rate of BMO involvement (national and regional) in preparation and implementation of pharmaceutical sector-related government policies and programs (advocacy). • Demand for SLF course increases.	• Minutes from FKPM meetings, and attendance at meetings. • Records of interactions with the respective institutions. • Protocols of, and other feedback received on public-private sector consultations concerning the health/pharmaceutical sector. • Number of applications to SLF.	• SAGMA is develop itself in a way that attracts sufficient members to sign up. • Actions to develop detailed policies and strategies instigated and conducted by regional bodies in SADC such that SAGMA has a field of operations. • Sufficient common ground can be established with a critical mass of companies for FKPM and other BMOs given the diverse range of business models and resultant perspectives. • SLF model can be developed into a sustainable approach and the willingness to pay for training improved.
O.3 Viability of international standard production demonstrated at plant level	• At least three companies receiving UNIDO support pass WHO mock inspections. • At least one early stage company has sourced investment, sourced technology, agreed plant plans and broken ground for the plant.	• Mock inspection reports. • Construction of new plant underway.	• Industry conditions remain stable and conducive for investment. • Macro-economic factors (e.g. exchange rates, interest rates etc.) do not compromise economic viability. • Leading companies demonstrate that operating GMP facilities is sustainable. • Regulatory oversight provided by MRA limits "competition" by sub-standard products. • Human resources to run GMP plants can be found.
O.4 Studies closing key knowledge gaps during project implementation conducted. *(Issues will include economics of production and other subjects such as policy options in support of local production.)*	• At least two technical reports published • Insights incorporated into expanded program and acted upon as part of wider activities • Results shared with partners	• Reports posted on the website • Program document/ background notes on program activities • Presentations to partners and records of reports being shared with them	• Other stakeholders are receptive to findings, and vested interests do not block impartial assessment of findings.

INTERVENTION LOGIC	OBJECTIVELY VERIFYABLE INDICATORS	SOURCES OF VERIFICATION	IMPORTANT ASSUMPTIONS
O.5 UNIDO Program document for an enhanced program on pharmaceutical industry development prepared *(Includes detailed design of modules to cover key issues such as access to capital, HR development, technology requirements and working with partners.)*	• Program document including philosophy, description of initiatives, staffing plan, roles and responsibilities, budget, partnerships etc. is written. • Memorandums of understanding or partnerships agreed, otherwise informal agreement on specific initiatives established.	• Detailed document available. • Documented evidence of agreements. • Mission reports describing discussions with potential partners.	• There is sufficient interest from member states such that requisite resources can be mobilised to deliver on an enhanced program. • Donors and Partners recognize value of a comprehensive long-term approach and do not insist on short-term wins. • Individuals within partner organisations do not derail potential agreements and working relationships on the basis of dogmatic perspectives.
ACTIVITIES:			
A1.1 Further develop and manage country coordinating mechanisms in Ghana and Kenya.	• National coordinator in place • Role and responsibilities agreed and adjusted according to reality • Levels of support from HQ and local office agreed and functioning • Reporting mechanisms established and operating	• Contracts in place • Informal internal communication establishing the specific support that will be rendered by HQ and local offices. • Reporting mechanisms for national coordinator in ToR • International consultants recruited to work in conjunction with local coordinator	
A1.2 In two new countries agree with high level national representatives on objective of the work, and design a suitable national level management structure, which is then implemented	• Initial survey conducted • National coordinator in place • Conduct of meetings between project HQ staff and senior local representatives and agreement in place. • Stakeholder meetings convened • Management structure agreed and implemented	• Availability of initial survey, and comments from stakeholders on the report • Minutes of meetings • Operating management structure in place, as determined by assessment of progress by local beneficiaries.	
A1.3 Conduct research on local issues to inform strategy development and its implementation. *(For example may include establishing details of market sizes in the country and*	• Consultant contracts in place • Output from Research	• Availability of contracts and ToRs • Research output available as are comments from target recipients	

INTERVENTION LOGIC	OBJECTIVELY VERIFYABLE INDICATORS	SOURCES OF VERIFICATION	IMPORTANT ASSUMPTIONS
region.)			
A1.4 Provide technical advice and guidance for policy and institutional development, and specific components of a strategic plan. (*Using knowledge and relationships with other organizations in a systematic*	• Project partners working with regulators as part of the UNIDO sponsored strategy development and implementation process • Insights into policy approaches have been fed in to strategy development and implementation process	• Mission reports from project partners • Feedback from regulators • Detailed plans on matters such as human resource development available.	
A2.1 Assist individual BMOs in Kenya, Ghana and the SADC region to develop improved business models (Management, service provision, advocacy)	• Contracts for BMO experts have been implemented • Workshops have taken place • For FKPM, constitution of organisation revised. • Description of services and business plan to deliver them available	• Consultant reports • Workshop report • Updated constitution available • Business plans available for organisations	
A2.2 Coach SLF in providing sustainable industrial pharmacy training in East- and West- African and support ongoing activities	• Develop a plan to improve sustainability prospects for Moshi training centre • Detailed plans for SLFs western Africa operations embraced by key players and implementation commenced • Graduates from SLF work for key public and private players in the pharmaceutical sector	• Reports from consultants available • Plans for Moshi and Western Africa available Implementation of recommendations by SLF • List of graduates	
A3.1 Follow up support for LaGray, Dan Adams (Ghana), Gemi Pharmacure (Botswana) and Cinpharm (Cameroon).	• Additional technical and managerial support services provided to LaGray, Dan Adams, Gemi Pharmacure and Cinpharm • Strong rationale for specific support	• Contracts with experts • Requests from companies, and write up of internal assessment of case for support	
A3.2 Provide assistance to additional companies that have strategic importance in making the case for local production (as with A3.1 could include co-financing of bioequivalence studies)	• Interest from additional companies to receive catalytic support • Support to one or two additional companies agreed – with strong case for strategic value based on feasibility analysis	• Submissions of CPPs • Contracts with experts • Write up of internal case for support	

INTERVENTION LOGIC	OBJECTIVELY VERIFYABLE INDICATORS	SOURCES OF VERIFICATION	IMPORTANT ASSUMPTIONS
A4.1 Identify and define baseline indicators and self-monitoring mechanisms	• Baseline indicators are specific and measurable and can be tracked in regular intervals • Self-monitoring mechanism is appropriate and manageable	• Evaluation Group	
A4.2 Conduct study on the economics of pharmaceutical production	• Detailed description of objectives of work as determined prior to issuing of the tender • Availability of output on economics of production	• ToRs for work • Final report and other outputs such as interactive model if included.	
A4.3 Identify and conduct additional research to inform key aspects of strategy development and implementation for local production.	• Detailed description of objectives of work as determined prior to issuing of the tender • Availability of output on specific topics	• ToRs for work • Final report and other outputs such as interactive model if included.	
A5.1 Conduct expert group and other consultative meetings to inform the design of an extended program.	• Meetings have taken place, and stakeholders agree to the concept for an expanded program that is proposed • Colleagues have agreed to collaborate as part of an expanded program	• Approval of senior management • Internal memorandums establishing colleagues' agreement	
A5.2 Conduct partnership building efforts to establish the basis for a broader alliance.	• Meetings have taken place with substantive discussions towards genuine working partnerships occurring • Joint activities with partners have been implemented • Website regularly updated	• Records from meetings and mission reports • Reports from joint operations describe joint activities • Impromptu review of website reveals documents up to date	
A5.3 Design program and prepare document describing in detail the philosophy, objectives, structures, modalities, staffing plans, roles and responsibilities, and budget.	• Program document presenting a holistic approach to the sector's development is agreed to by senior management in UNIDO • Additional resources to fund an extended program are mobilised	• Implementation of extended program • Increased resources available for activities in pharmaceutical sector	

Source: UNIDO Global Project, TE/GLO/08/XXX, Strengthening the local production of essential generic drugs in Developing Countries (DCs). Annex A.1.

Phase 3 Logframe SAP Adjustments (approved by donor on 2 March 2012)

INTERVENTION LOGIC	KEY PERFORMANCE INDICATOR (KPI)	TARGET/BASELINE	IMPORTANT ASSUMPTIONS
IMPACT/DEVELOPMENT OBJECTIVE: Increased local production of quality essential medicines			
OUTCOME(S)/IMMEDIATE OBJECTIVE:			
OUTCOME 1: 1 Improved operating environment Description: Operating environment for pharmaceutical manufacturers is improved OUTCOME 2: 2 Enhanced UNIDO programme Description: Enhanced UNIDO Program in support of pharmaceutical sector development in DCs/LDCs funded and operational.	• # of enterprises effected by policy • $ of additional investment Detailed Explanation: • Funding mobilized for enhanced UNIDO support programme on LPP	• Baseline: 0 • Target: 200 (National strategies only GHA: 40, KEN: 50, VTN 110) • Baseline: 0 • Target: 5,000,000 EUR	• Local manufacturers make active use of improved framework conditions and expand their business. • Locally manufactured drugs are competitive in relevant market terms (incl. local preferences). • Availability of funds to purchase essential drugs for an increased number of patients. • Political agenda overall favourable of local production topic.
OUTPUTS:			
1.1 LPP strategies adopted Description: Pharmaceutical sector development strategies agreed (PMPA, GHA, KEN, VTN) and select implementation initiated	• # of new policies, strategies, laws, regulations, prepared Detailed Explanation: • PMPA Business Plan • 3 National Pharmaceutical Sector Development Strategies (GHA, KEN, VTN)	• Baseline: 0 • Target: 4	• Agreed/required changes in legislation and regulatory stipulations pass requisite procedures. • Willingness of governments/ Regional Economic Communities to implement and finance programs that enable the pharmaceutical industry to develop and use regional market opportunities. • The high level interest in countries is maintained and translates into commitment from stakeholders at the operational level. • Governments make resources available for implementation of strategy or funds can be mobilised from other sources • Governments are willing and able to act on the holistic approach i.e. involve all relevant actors and agencies.
1.2 Support institutions strengthened Description: Support institutions like BMOs and training centres strengthened	• # of services offered by institution / service provider Detailed Explanation: BMO (SAGMA) and Training provider (SLF)	• Baseline: 1 (IPAT) • Target: 4	• SAGMA develops in a way that attracts sufficient members to sign up and hence can credibly represent the sector. • Actions to develop detailed policies and strategies instigated and conducted by regional bodies in SADC such that SAGMA has a field of operations. • SLF model can be developed into a sustainable approach and the willingness to pay for trainings is improved.

INTERVENTION LOGIC	KEY PERFORMANCE INDICATOR (KPI)	TARGET/BASELINE	IMPORTANT ASSUMPTIONS
1.3 LPP viability demonstrated Description: Viability of international standard production demonstrated at plant level	• # of companies adopting best practices/new technologies Detailed Explanation: • Progressing towards International GMP while maintaining competitiveness	• Baseline: 0 • Target: 3	• Industry conditions remain stable and conducive for investment. • Macro-economic factors (e.g. exchange rates, interest rates etc.) do not compromise economic viability. • Companies' management and owners remain committed to obtaining International GMP/WHO PQ and necessary investments are made • Regulatory oversight provided by MRA limits "competition" by sub-standard products. • Human resources to run GMP plants can be found.
2.1 Studies to inform prog devt Description: Knowledge base enhanced to inform on-going activities and to prepare enhanced program.	• # of reports / technical publications prepared/distributed Detailed Explanation: Economics of Production/Efficiency of Production, Incentives	• Baseline: 0 • Target: 3	• Other stakeholders are receptive to findings, and vested interests do not block impartial assessment of findings.
2.2 UNIDO prog doc prepared Description: Document for enhanced UNIDO Program at public health/ industrial development interface in support of LPP *(Includes detailed design of modules to cover key issues such as access to capital, human resource development, technology requirements and working with partners.)*	• # of reports / technical publications prepared/distributed Detailed Explanation: UNIDO Programme Document	• Baseline: 0 • Target: 1	• There is sufficient interest from member states such that requisite resources can be mobilised to deliver on an enhanced program. • Donors and partners recognize value of a comprehensive long-term approach and do not insist on short-term wins. • Individuals within partner organisations do not derail potential agreements and working relationships due to disease specific focus.