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Independent Evaluation

Strengthening the local production of essential generic drugs in least developed/developing countries

UNIDO project: TE/GLO/05/015 and TE/GLO/08/030
Funded by the Government of Germany

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Abbreviations and acronyms

AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
ARV	Antiretroviral medicines
BAU	Business Advisory Unit
BEP	Business Environment and Policy Support Unit
BMZ	Bundesministerium fuer wirtschaftliche Zusammenarbeit und Entwicklung
COHRED	Council on Health Research for Development
COMESA	Common Market for Eastern & Southern Africa
CPP	Company Project Profile
DC	Developing country
DEG	Deutsche Investitions- und Entwicklungsgesellschaft mbH
EAC	East African Community
EC	European Commission
ECOWAS	Economic Community of West African States
EML	Essential Medicine List
EUR	Euro
FDA	Food and Drug Administration
GFATM	Global Fund to Fight Aids, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HIV	Human Immunodeficiency Virus
IPC	Interagency Pharmaceutical Coordination Group
IPR	Intellectual Property Rights
KfW	Kreditanstalt für Wiederaufbau
LDC	Least Developed Country
LNDC	Lesotho National Development Corporation
MDG	Millennium Development Goal
MOF	Ministry of Finance
MOTI	Ministry of Trade and Industry
MRA	Medicine Regulatory Authority
M&E	Monitoring and Evaluation
NEPAD	New Partnership for Africa's Development
NGO	Non Governmental Organisation
NMP	National Medicine Policy

NSC	National Steering Committee
OVI	Objectively Verifiable Indicator
PDR	People's Democratic Republic
PMAG	Pharmaceutical Manufacturer Association of Ghana
PMPA	Pharmaceutical Manufacturing Plan for Africa
PNSU	Pharmaceutical Networking Support Unit
PTC	Programme Development and Technical Cooperation
PSC	Project Steering Committee
PSD	Private Sector Development
QC	Quality Control
R&D	Research and Development
SADC	Southern African Development Community
SAG	Strategic Advisory Group
SAGMA	Southern African Generics Medicines Association
SECO	Swiss State Secretariat for Economic Affairs
SMEs	Small and Medium-Sized Enterprises
SSA	Sub-Saharan Africa
STA	Senior Technical Advisor
SWOT	Strengths, Weaknesses, Opportunities, Threats
TB	Tuberculosis
TCB	Trade Capacity-Building Branch
TFDA	Tanzania Food and Drug Authority
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
UNIDO	United Nations Industrial Development Organization
UNITAID	International Drug Purchase Facility
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Glossary of evaluation-related terms

Term	Definition
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.
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 resources/inputs (funds, expertise, time, etc.) are converted to results.
Impacts	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.
Institutional development impact	The extent to which an intervention improves or weakens the ability of a country or region to make more efficient, equitable, and sustainable use of its human, financial, and natural resources, for example through: (a) better definition, stability, transparency, enforceability and predictability of institutional arrangements and/or (b) better alignment of the mission and capacity of an organization with its mandate, which derives from these institutional arrangements. Such impacts can include intended and unintended effects of an action.
Lessons learned	Generalizations based on evaluation experiences with projects, programs, 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.
Logframe	Management tool used to improve the design of interventions, most often at the project level. It involves identifying strategic elements (inputs, outputs, outcomes, impact) and their causal relationships, indicators, and the assumptions or risks that may influence success and failure. It thus facilitates planning, execution and evaluation of a development intervention. Related term: results based

	management.
Outcome	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 which result from a development intervention; may also include changes resulting from the intervention which are 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 should be linked to conclusions.
Relevance	The extent to which the objectives of a development intervention are consistent with beneficiaries' requirements, country needs, global priorities and partners' 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 (intended or unintended, positive and/or negative) 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

The World Health Organization (WHO) considers Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), tuberculosis (TB) and malaria as the three big killers. Enhancing availability and affordability of the essential pharmaceuticals against the pandemics would improve the public health situation in developing countries and would enable the population to fully mobilize their productive capabilities for enhanced economic growth.

The project “Strengthening the local production of essential generic drugs in Least Developed and Developing Countries” is co-funded by the German Government and UNIDO. The project covers activities in 14 countries, with a total budget of 3.3 million Euros over five years. The project is being implemented at three levels: i) macro-level policy advice, ii) meso-level institutional capacity building, and iii) micro-level direct support to enterprises.

The Mid-term Evaluation of the project was carried out from November 25th, 2009 to January 31st, 2010 by an independent team consisting of two consultants—Veronique Pomatto, public health expert and team leader, and Charles Lam, pharmaceutical consultant. The evaluation based its main findings on qualitative and quantitative analyses of data obtained through documents review, key informants semi-structured interviews, stakeholders’ group discussions, and observations at field visits to Ghana and Lesotho.

Project design: The project is being implemented in two interlinked phases. The first phase of the project consisted of research/fact finding at the level of LDCs for a broad capacity building assistance. A logical framework has been defined for each of the phases in the project documents but has never been updated even when the needed flexibility has led to changes in a few targets.

Relevance to least developed and developing countries: Strengthening local production of essential medicines in LDCs and DCs is needed in order to meet two responsibilities of governments—to physically make available high quality essential drugs at affordable price to all end users and to foster economic development. The two goals are different and require different priorities and regimes. In Ghana, the project is addressing the dichotomy by facilitating a dialogue between public and private sectors to see that heath and industrial policies are mutually reinforcing. An impact on health status (availability of affordable medicines) today is to some degree creating the preconditions for tomorrow’s economic development.

Relevance to global development priorities: Local manufacturing of essential medicines is directly relevant in the context of Millennium Development Goals (MDGs) 6, and 8. It is also relevant indirectly in the context of MDGs 1, 4 and 5.

Relevance to the beneficiary governments: Many Least Developed and Developing Countries are reforming their National Medicine Policy to take advantage of the flexibilities in the Agreement on Trade Related aspects of Intellectual Property Rights so as to produce drugs locally rather than buy them. Hence, the countries favour domestic production over imports. At the regional level, the trend is towards harmonisation of regional drug regulation, based on the obvious benefits that would accrue from pooling individual country resources and comparative advantages. Hence, regional cooperation in production increases the African populations' access to essential drugs through a real reduction of prices with the resulting division of labour and economy of scale. The project has rightly focused on these African regions from its inception and is cooperating with most of these initiatives.

Relevance to UNIDO thematic priorities: Local production of pharmaceuticals is particularly relevant to the first (poverty reduction through productive activities) and the second of UNIDO thematic priorities (trade capacity-building).

Relevance of the project to address the problem at hand: The project design, through its holistic approach, fosters the pharmaceutical manufacturing value chain in Least Developed and Developing Countries. The approach focuses on the role of governments in creating an enabling environment through industrial policy for the pharmaceutical sector, and in addition developing an institutional infrastructure and providing technical assistance at the enterprise level.

Relevance to UNDAF priorities: With the exception of Cameroon, the project is in line with the United Nations Development Assistance Framework objectives in the countries where it is implemented.

Project coordination and management: The project is managed by UNIDO Business Environment and Policy Support Unit within the Programme Development and Technical Cooperation Division/Industrial Policy and Private Sector Development Branch (PTC/PSD).

At the national level, although foreseen in the project document, national management units were not created but, instead, in countries with above minimal activities, national experts have been contracted. The roles and responsibilities of the counterparts (Ministries of Trade and Industry and Ministry of Health) have not been formalized in mutually agreed work plans or Terms of Reference (ToR).

At the global level, the overall coordination of the project is presently carried out by a Project Steering Committee (PSC). The foreseen creation of the Strategic Advisory Group has been postponed.

Project implementation: There has been an 18-month delay in the implementation of the project which is mainly due to:

- Difficulties to identify an international expert with a multi-disciplinary expertise in industrial development, health and medicine policies in developing countries as well as familiarity with pharmaceutical production;
- The management team being understaffed;
- The initial focus on LDCs. The results obtained show that none of the eight scanned LDCs actually met the minimum eligibility criteria.

Efficiency: The interventions implemented so far have been efficient. The global market study of the essential generic medicines has been used as an intelligence tool for the assessment of individual plant-level business plans. The data has also been instrumental for revising work plans and/or for fine-tuning (further) project interventions. Inputs for training of trainers have been cost-effective and the advisory services delivered to selected Small and Medium-size Enterprises have been efficient with the aim to contribute to upgrading their production plants in order to be World Health Organisation prequalification compliant.

Effectiveness: Outputs have been produced in 14 countries and four countries have been identified to support the establishment and/or the expansion and upgrading of Small and Medium-sized Enterprises (Ghana, Kenya, Botswana, and Cameroon).

Sustainability: The project is putting in place essential building blocks required for the production of high quality pharmaceuticals. For this purpose, the project has in place supportive policy advice, basic human skill set training and technical assistance at the enterprise-level for upgrading the production plants to become compliant to Good Manufacturing Practices (GMP) accreditation and WHO prequalification. In parallel, the project offers policy advice for the harmonization of the medicine regulations in the regions. It also offers training in GMP and the preparation of documentation required for the GMP and WHO prequalification. These activities are critical for a shift to sustainability and country ownership of a local production of pharmaceuticals.

Main conclusions: The project's follows a holistic approach of embedded plant - level interventions and support at institutional and policy levels. Despite of the 18 -month implementation delay, most of the objectives for phase one were achieved in an efficient manner and have led to the selection of four countries where support to enterprises has been defined and technical assistance to the institutional infrastructure and policy development is being implemented.

Efforts to support interregional pharmaceutical manufacturers' associations will enable the manufacturers to actively engage in the regional harmonization of trade and pharmaceutical regulations. The association has the potential to provide an appropriate setting for promoting information exchange and the harmonization of procedures and tools among countries. For these reasons, a third phase is necessary. The hiring of a senior technical adviser and the shift to

full time of an associate expert should allow a smooth implementation of the project in future.

The project has spread the relatively small budget over many activities in many countries. The initial focus on Least Developed Countries (LDCs) revealed that capacities in the pharmaceutical sector were simply too weak. The lack of partners in these countries led to the broadening of the project to Developing Countries (DCs) at large.

Recommendations:

To UNIDO:

1. The existence of project documents defining clearly the expected roles of the counterparts would facilitate communication between the national teams and their governments. At the international level, a revision of the logical framework should facilitate the tasks of all the stakeholders including the PSC in the future management and monitoring of the project.
2. A “light” National Steering Committee (NSC) including at least the Ministry of Health and Trade/Industry (or any national mandated by law corporation) and national experts should define with UNIDO the specific national log frames and work plans, to continuously monitor the project without compromising the presence of sub- regional Pharmaceutical Networking Support Units (PNSUs), if needed.
3. The inclusion of impact Objectively Verifiable Indicator (OVIs) in a specific country’s log frame that would be in accordance with the national strategy indicators (from national drug policy, health policy or other national texts) will improve the harmonization and managing for results commitment of the Paris declaration on aid effectiveness.
4. There are insufficient funds to cover the costs of stand-alone activities such as equipment, support to quality infrastructures, the setup of bio-equivalence centres and Research and Development (R&D) activities. For this reason, it might be worth to consider a modular approach where additional donors could fund related modules.
5. Currently, there is a dearth of case studies on DCs and LDCs that have entered technology transfer arrangements to manufacture essential medicines locally. This gap may be filled by the ongoing WHO/UNCTAD/ICTSD Initiative that is working on case studies on technology transfer in (L)DCs. The project management should look for ways to collaborate with this initiative and to harness the benefits from the results to be generated from the initiative.

   Similarly, there is no information on whether or not and under what conditions domestic production of pharmaceuticals actually make a meaningful

contribution to access and affordability of essential medicines to patients who need them most.

6. Support an early setup of the SAG as soon as possible, including representatives of such organizations as pharmaceutical companies, WHO, Global Fund to Fight Aids, Tuberculosis and Malaria (GFATM) and key NGOs involved in advocating for the maximum use of TRIPS flexibility as Médecins Sans Frontières.

To the donor:

7. The third phase, expected to start in 2011 for two to three years, with a budget of around two million Euros, should follow the same holistic strategy but focus on:
    - Phase II achievements and, specifically, the regional pharmaceutical and trade harmonization in COMESA, ECOWAS, EAC and SADC through the support of regional pharmaceutical manufacturers' associations and networking activities. UNIDO role should be to facilitate meetings and provide international consultants for advice on the definition of regional regulations and on action plans.
    - Achieving convincing results in Ghana, Kenya, Cameroon and Botswana and suspending any activities in Asia until models and increased funds are available.
    - Considering undertaking a feasibility study to facilitate the setting up of a regional bio-equivalence centre and upgrading reference laboratories for prequalification monitoring (in collaboration with WHO) required in every economic region. GTZ is already building up a bio-equivalence centre for Ethiopia and Kenya. No such centre is available in the ECOWAS region. At least one WHO prequalified laboratory per region would be enough to support needs in the four selected countries in Africa.

Lessons

The challenges that local manufacturers of essential medicines in LDCs and DCs face are formidable. A comprehensive approach that addresses the constraints at the policy, institutional and enterprise levels at the same time offers the best chance for success. This holistic approach is feasible, enhances sustainability and ownership as in the Ghana model.

It is necessary to put in place a national management mechanism at the start of the implementation of a project. In Ghana, the project made a significant progress from the time the national expert was hired.

I

Context

A. Background

The World Health Organization (WHO) considers Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), tuberculosis (TB) and malaria as the three big killers. Two million people die of TB every year. Another 2.7 million succumb to malaria. The parasite has become resistant to mainstay forms of treatment, particularly in Sub-Saharan Africa (SSA) where 90 percent of malaria deaths occur. Some 40 million people are living with HIV/AIDS (UNAIDS, 2009). While several countries have made substantial progress towards increasing access to essential medicines and treatments to fight HIV/AIDS, malaria and tuberculosis, access to essential medicines in Least Developed and Developing Countries ((L)DCs) is still largely dependent on donor support. Enhancing availability and affordability of essential pharmaceuticals against the pandemics would improve the public health situation and would enable the population to fully mobilize their productive capabilities for enhanced economic growth.

According to non-governmental organizations (NGOs), one of the greatest obstacles to access affordable medicines is their high price, due to the monopoly power of intellectual property rights. Intellectual property rights at the global level are governed by the World Trade Organization (WTO), through the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The agreement was introduced in 1995 to give researchers the right to patent any inventions, whether products or processes, in all fields of technology without discrimination for twenty years. Hence, no other company can make use, sell, offer to sell, or import the patented medicines (Wagenberg, 2009). The TRIPS Agreement as it stands, does offer a number of flexibilities, which are often not fully exploited by countries in the process of framing national legislation. Provided certain conditions are fulfilled, it allows governments to make exceptions to the rights of patent holders, such as in cases of national emergencies and with regard to anti-competitive practices, or if the holder of the right does not supply the product. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. Under this

declaration, the TRIPS Agreement does not and should not prevent WTO member states from taking measures to protect public health. The member states underscored the ability of countries to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. Developing countries with a high manufacturing capacity, such as India, were given until 2005 to bring their Intellectual Propriety (IP) legislation in line with TRIPS, while LDCs were allowed to disregard patents until 2016 (Perkins S, 2007).

B. Project description

The project "Strengthening the local production of essential generic drugs in Least Developed and Developing Countries" is co-funded by the Government of Germany and UNIDO. The project has covered so far activities in fourteen countries, and has a total budget of 3.3 Million Euros over the five-year period 2006-2010.

The overall development objective of the project is based on national poverty reduction strategies and on the Millennium Development Goals (MDGs):

"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".

The project's immediate objective is to "Enhance the supply of the population in DCs with a range of generics at affordable prices, through promoting the local production by Small and Medium Size Enterprises (SMEs) of high quality essential drugs*".*

To achieve this objective, the project intends to promote the establishment and/or expansion and upgrading of SMEs in three or four selected LDCs or DCs for the local production of internationally recognized, high-quality, essential generic medicines. This enterprise-oriented approach is complemented by interventions at the macro- and meso levels to remove constraints in the policy and business environments. Hence, the project is being implemented at three levels:

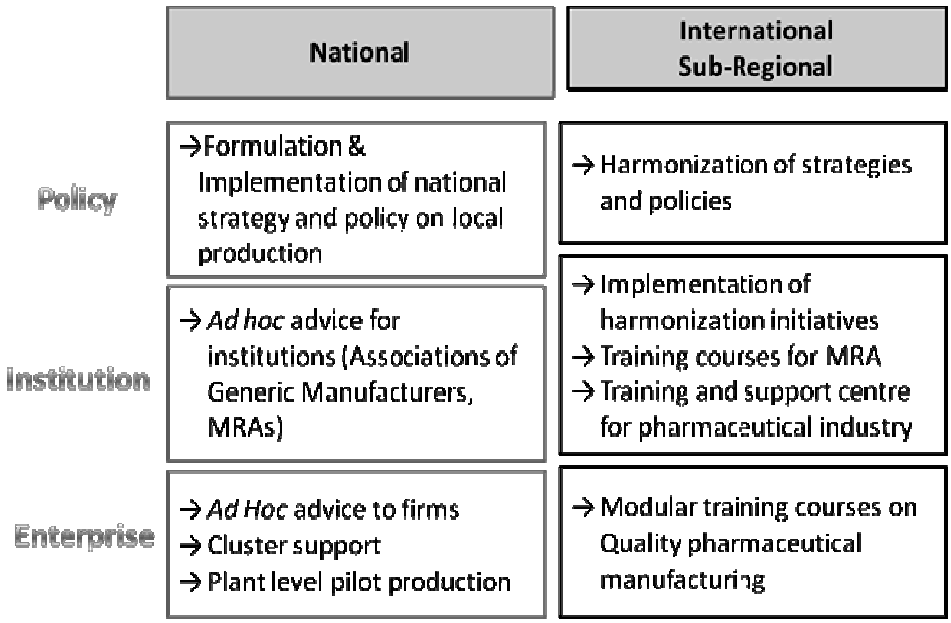
- Macro level: Policy advice towards improving the business, legal and regulatory environment for the local production of generic drugs. This includes national strategy formulation and support to regional harmonisation efforts.
- Meso level: Institutional capacity building of support entities of pharmaceutical-sector SMEs, such as Medicines Regulatory

Authorities (MRAs), pharmaceutical manufacturers associations, or quality infrastructure bodies.

- Micro level: Direct support to enterprises, such as technical and managerial assistance to achieve international standards or preparing feasibility analyses.

In addition, at the international and sub-regional level (see Figure 1), UNIDO is promoting a greater market integration that may penetrate global value chains beyond the reach of individual countries.

Figure 1. The intervention strategy



C. The Mid-term evaluation

The evaluation was conducted in three phases between the 25th of November 2009 and the 31st of January 2010 by a team consisting of two consultants: Véronique Pomatto, a public health expert (Team Leader), and Charles Lam, a pharmaceutical consultant. The evaluators had not been involved in the design or in the implementation of the project.

The first phase consisted of i) a briefing in Vienna with the project manager, his team, and members of the UNIDO Evaluation Group, ii) reviewing the project files and other available documentation, iii) formulating the evaluation plan, the tentative chronology of the mission (see the actual chronology in Annex D), developing the methodology for the mission and preparing the inception report.

The second phase was a five-day field mission, each in Ghana and in Lesotho. The evaluation team used an interactive, participatory approach based on meetings and interviews with key stakeholders and direct project beneficiaries. At the end of each field mission, a debriefing was held to present the preliminary findings and analyses to all informants. The debriefing presentation slides were also shared with staff at UNIDO headquarters in order to get initial feedback before the presentation in Vienna on 11 January, 2010.

The third phase of the evaluation focused on desk analyses of the data collected from the field mission, teleconferences with additional stakeholders whom the team did not meet face-to-face, and with international experts who had been involved in the project.

The main findings were based on analyses of qualitative and quantitative information obtained through document review (see Annex C), key informants' semi-structured interviews, stakeholders' group discussions and observation at sites. Stakeholders' perceptions are based either on a requested score or on ideas and comments that were expressed by more than half of all the interviewed stakeholders.

The lists of informants from Vienna, Ghana, and Lesotho as well as the participants at the teleconferences are presented in Annex B; the Terms of Reference (ToR) in Annex A.

Limitations of the evaluation*:*

The team did not visit Botswana because the main stakeholder was out of the country during the period of the field mission. A phone conference was organized with the Chief Executive Officer of Gemi Pharmacure Ltd, an enterprise identified for support through this project. A comparative review of the two similar cases (Lesotho and Botswana) according to the Terms of Reference was not performed in this evaluation.

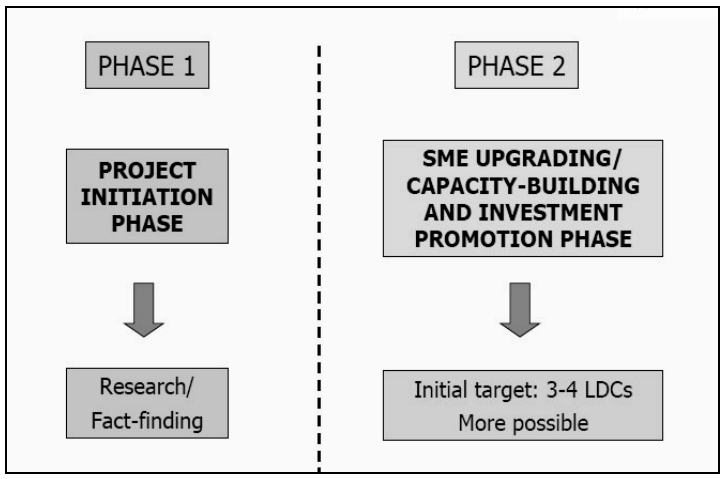
II

The project

A. Design

The project is being implemented in two interlinked phases. The first phase of the project consisted of research/fact finding at the level of LDCs with a view to providing broad capacity building assistance.

Figure 2. The project's two phases



Source : Intro_TE-GLO-05-15 Strengthening local production_Pres.pdf

The objective of Phase I was to identify three to four countries where SMEs would be selected for technical assistance during the second and main phase.

The project was designed to be flexible enough to incorporate any specific project requirements that would arise during the course of implementation. The flexibility was also to improve the coordination between parallel ongoing donor-funded interventions at both bilateral and multilateral levels.

These flexibilities have led to:

- Extension of the targeted countries from LDCs only to both LDCs and DCs.
- Extension of the list of targeted medicines to be manufactured at the national level from medicines against HIV/AIDS, TB and malaria to generic medicines included in the national Essential Medicines List (EML) and to those combating neglected tropical diseases.
- Focus on plant-level and provision of institutional-level assistance in countries where project support had started.

A logical framework was developed for each of the phases of the project document but was never updated even though there have been changes in relation to some objectives.

Phase I

In the Phase I log frame, the outputs are presented without any outcomes. This is probably due to a misunderstanding of these words. The Objectively Verifiable Indicators (OVIs) are not always specific or time-bound. Moreover, “Change in consumer prices of essential generic drugs in target LDCs” could be a result of a lot of different factors that are not directly related to the project. Furthermore, the expected change is neither quantitatively defined nor is the time indicated within which the indicator is expected to be measured.

Phase II

In the Phase II log frame, outcomes and outputs are presented but are sometimes confused. Assumptions are realistic except the first one: “Locally manufactured drugs can be sold at lower prices than imported alternatives”. It does not take into account the frequently found exception clause in national procurement tenders, allowing to buy a locally produced medicine at a 10 to 20% higher price than an imported product as long as the quality is comparable. This procurement mark-up on foreign companies tendering gives the opportunity to stay competitive with pharmaceutical products from China and India. This assumption would be more relevant if formulated as “Locally manufactured medicines are competitive given the respective circumstances”.

Outcome 2 is “Export opportunities provide extended market for generic drugs”. Its OVI “Export of essential medicines increases” could have been formulated as follows: “Export figures increase at least x% of at least two or three supported manufactures by the end of the project”. The “x” is to be defined in accordance with the market potential of the targeted medicines. A more precise formulation

would have helped to collect relevant baseline data at the early stage of the project in order to measure the increase that the project has contributed to, in the export figures of the supported manufactures (see subchapter on Coordination and Management).

Outcome 3 is “Institutions offer demand-oriented support services to SMEs in the pharmaceutical sector”; its indicator is “Demand for services offered; quality and outreach of service provision”. The mean of verification of outcome 3 indicator is currently an evaluation of customer satisfaction. The measurement of this indicator could be expensive and requires significant baseline data. Its measurement may lead to the detriment of the project intervention because of the weak resources. Furthermore, changes in customer satisfaction may take a long time to appear after the outputs have been produced.

The OVIs are not time bound and the targets to be reached are not precisely defined. For instance, “Quality of products is improved” could represent a very important indicator because the capacity building that UNIDO provides is to improve the quality of the locally produced medicines. This project aims to enhance export of medicines combating HIV/AIDS and/or TB & malaria and/or EML medicines. In the case of medicines for the three pathologies targeted by the MDG, to be sold and exported, these medicines must be prequalified by WHO. Thus, the indicator could be formulated as “Quality of locally produced products is improved to the level of international standards in the supported plants at the end of project”. The means of verification are the Good Manufacturing Practice (GMP) certificates and the WHO prequalification certificates.

The evaluation team suggests the following recommendations in order to provide the project with a useful management tool for the current and possible future phases:

- Break down the outcomes under the defined strategies (policy level, institutional level and plant level) in order to avoid as far as possible repeating the same activity under different outcomes of the log frame and to improve the clarity of the intervention logic.
- Define realistic and “SMART [1] ” indicators that will enable efficient monitoring and evaluation.
- “Harmonization” and “Managing for Results” commitments to improve aid effectiveness should be taken into account by developing specific log

[1] **S**pecific to the objective it is supposed to measure, **M**easurable (either quantitatively or qualitatively), **A**vailable at an acceptable cost, **R**elevant to the information needs of managers, **T**im e-bound, so we know when we can expect the objective/target to be achieved.

frames at the national level and choosing impact indicator(s) in line with existing national strategies or expressed in national policies and Poverty Reduction Policy Papers (see B. Relevance).

B. Relevance

Project's design relevance to address the problem at hand

Pharmaceutical production is complex, requires capital, technology transfer, an appropriate institutional framework and is knowledge intensive. Technical expertise is absolutely critical, both in terms of sufficient numbers and appropriate skills. At the policy level, the legislative framework needs to be favourable to regionalized local production. This goes beyond a framework that ensures GMP and other aspects of product regulation, but also extends to legislation regulating related duties on imported raw materials and intermediates and related taxes. In fact, nascent manufacturing of pharmaceuticals in (L)DCs has little chance of competing head-to-head with established firms in developed countries. If the new firms are given protection—perhaps by tariff, they would be able to cover their higher production costs and remain in business.

The project's holistic approach offers the best chance to form an economically viable backbone of a pharmaceutical manufacturing value chain. The approach focuses on the role of Government through industrial policy advice to create a business environment conducive to the pharmaceutical sector specifically. Support infrastructure is strengthened through training of trainers and the required capacity building while the private sector gets direct support through technical assistance to SMEs for their upgrade to GMP accreditation and WHO prequalification status. The flexibility in the implementation allows the project the freedom to respond according to the ever changing environment.

Relevance to least developed and developing countries

Strengthening local manufacturing of generic drugs in LDCs and DCs is justifiable to meet both public health goals and pharmaceutical sector development objectives. As shown in Table 1, the two policy objectives are very different and require different priorities and interventions. While public health care policy is primarily concerned with safeguarding sustainable supply, quality and safety, improving health and containing the costs, the industrial policy seeks to protect national labour markets and industries and their international competitiveness and efficiency. Overlying the dichotomy is a two-level game that countries play in an international community as they seek to reconcile domestic priorities and needs with international objectives.

Table 1. Competing policy interests between maximizing access to affordable medicines and promoting pharmaceutical industry development

Public health policy—to produce medicines locally for maximum access to end users	Industrial policy objective—to create a pharmaceutical sector for economic growth
– Guaranteeing physical availability of safe, high-quality and efficient medicines – Cost reduction and improving quality, efficiency and equity in health services and care – Improving prescribing and promoting the use of generic drugs – Ensuring maximum access of medicines to end users – Innovative cures for diseases prevalent in the country	– Fostering and promoting local Research and Development (R&D) capacity – Implementing the legal and regulatory reforms needed to attract various actors to engage in local manufacturing of pharmaceuticals (e.g., strong patent protection) – Improve long-term sustainability and international competitiveness of the pharmaceutical sector – Generating and protecting employment – Contributing to a positive trade balance

Source: Consultants' analysis.

The competing policy interests between a government's role as a provider of affordable essential medicines versus a role as a maximizer of economic growth requires a balancing act to unify health and industrial policy objectives. From a public health perspective, the government wants to ensure that safe, high-quality and efficacious medicines are available at affordable price to all those who need them. The government also wants to ensure that domestically produced medicines are both clinically- and cost-effective in comparison to relevant alternatives available from the international market. On the other hand, industrial policy is by definition a national policy, seeking to promote specific industrial objectives and economic growth and employment. The issues related to a pharmaceutical industrial policy are quite complex and entail the entire spectrum of regulatory aspects—safety, efficacy, quality—and issues such as R&D support, employment issues, SME policies, supporting university science and research bases, and intellectual property protection, among others. The focus is often on the spill-over benefits that accrue to the local economy from having a sustainable domestic manufacturing of pharmaceuticals. An economically viable manufacturing of pharmaceuticals may also save foreign exchange through import substitution and increase exports if the locally produced medicines are of international standards and able to compete with products from other countries.

The dichotomy between health and industrial policy arises from the disparate objectives of different government portfolios. In many countries, particular tensions arise between the goals of the Department of Health—which promotes a

public health agenda (access to affordable medicines)—the Department of Trade and Industry—which promotes an economic development agenda (promoting and attracting local R&D activity) and the Department of Finance—which promotes cost containment and improved efficiency in the use of scarce resources (funding delivery). To ease the tension, usually a National Medicine Policy (NMP) regime is established. The regime incorporates a framework of partnerships between the various ministries with elements of social and economic policy to guide and unify pharmaceutical policy. The overall aim of such a regime is to meet the Country's health needs while maximizing health outcomes within a given budgetary limit. In Ghana, a public-private dialogue is being used successfully to ease and balance the tension whereas in Lesotho it was not possible to resolve the tension.

Relevance to global developmental priorities

Local manufacturing of essential medicines is directly relevant in the context of MDG 6, ("Combat HIV/AIDS, malaria and other diseases") and MDG 8, Target 17 ("In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries"). It is also relevant indirectly in the context of MDG 1 ("Eradicate extreme poverty and hunger") because of its potential to generate and protect employment and overall resulting economic growth. With the extension to the production of the national EMLs, the project is also relevant for MDG 4 ("Reduce child mortality") and MDG 5 ("Improve maternal health"),

Relevance of local manufacturing of pharmaceuticals to the regional and sub-regional level

Public health is a shared concern in all regions of the world—whether least developed or developing countries. The support for implementing AU Manufacturing Plan for Africa, the SADC Pharmaceutical Business Plan and WAHO activities on local production are relevant to address this issue.

Furthermore, this project is also in line with the New Partnership for Africa's Development (NEPAD) initiative that aims at strengthening pharmaceutical innovation in Africa, to support decision makers in their respective countries to understand how they can benefit from pharmaceutical innovation strategies and build relevant capacity in their countries.

Relevance to the beneficiary governments

At the national level in Ghana, the central goal of the new Growth and Poverty Reduction Strategy is to accelerate the growth of the economy so that Ghana can achieve the status of a middle-income country within a measurable planning period (2020). Export of oil is planned for the year 2010. Emphasis is placed on changing the structure of the economy by developing the private sector and

diversifying exports. Furthermore, the National Health Policy is to strengthen the manufacturing of medicines in the country.

In Lesotho, the National Medicines Policy (2005) prescribes Government's willingness "To manufacture good quality essential medicines at an affordable cost, the Ministry of Health and Social Welfare will ensure that local manufacturers have appropriate infrastructure meeting GMP requirements, appropriate qualified personnel and a technical partnership".

On the TRIPS implementation, with the exception of Lesotho, both Ghana and Botswana are in the process of reforming their patent laws. Ghana's 2003 Patent Act has already favoured a non-voluntary licence for domestic production over imports (JC Cohen, 2005). Also, as mentioned earlier, there are bilateral approaches that are being implemented by GTZ and the Swiss Government and the Government of Ghana is intending to revise Ghana's Patent Act to fully exploit the flexibilities enshrined in the TRIPS Agreement. Botswana is similarly exploiting Article 7 of the TRIPS Agreement that "calls for Intellectual Property Rights (IPR) protection to be instituted in a manner conducive to social and economic welfare". By encouraging technology investment both domestically and internationally, the TRIPS agreement widens the scope of prospective pharmaceutical development (Guzik, 2008). With the new patent reforms both Botswana and Ghana hope that they can increase the proportion of domestically produced drugs and reduce their dependence on pharmaceutical imports. Therefore, strengthening local production of pharmaceuticals is certainly a priority strategy and relevant in a number of DCs including Botswana, Ghana and LDCs like Lesotho. Indeed, one of the seven selection criteria that is spelt out clearly to be included in the project, the government of a potential candidate and the private sector must show a genuine interest and commitment (see chapter on Effectiveness).

As pharmaceutical production is capital, technology and knowledge-driven, there are many perceived benefits—such as job creation, technology transfer and attracting investment which would certainly be relevant for governments in their attempt to find strategies for alleviating poverty, controlling diseases and promoting economic and social development.

Relevance to UNIDO thematic priorities

UNIDO supports developing countries and economies in transition in their efforts to achieve sustainable industrial development. It focuses on three thematic priorities, which directly respond to global development priorities: Poverty reduction through productive activities, Trade capacity-building, and Environment and energy.

The global project focusing on a local production of pharmaceuticals is particularly relevant to the first and the second of UNIDO thematic priorities that

address MDG 1, MDG 3 and MDG 8. Since UNIDO Chemicals Unit was closed during the restructuring of the Organization in 1997, this project is an exception. It is, however, one of the few UNIDO projects that addresses MDG 6 – Combat HIV/AIDS, malaria and other diseases. Therefore it embodies an opportunity for UNIDO to prove its effectiveness in addressing health issues from an industrial development angle.

Through the first thematic priority, UNIDO seeks to enable the poor to earn a living through productive activities, thus to find a path out of poverty. The Organization provides a comprehensive range of services customized for developing countries and transition economies, ranging from industrial policy advice to entrepreneurship and SME development and from technology diffusion to sustainable production. In focusing on the pharmaceutical manufactures in developing countries, this project is perfectly aligned with UNIDO first thematic priority by interacting on both health and economic growth.

Through the second thematic priority, the Organization strengthens the capacity of developing countries to participate in global trade, considered to be critical for their future economic growth, especially after their accession to the WTO. This project offers customer-focused advice and integrated technical assistance in the areas of pharmaceutical trade policies, industrial modernization and upgrading (GMP), compliance with pharmaceutical trade standards (WHO prequalification of essential medicines) and is thus relevant to UNIDO trade-capacity building priority.

Relevance to the Government of Germany's policies and priorities

Strengthening the local manufacture of generic medicines in (L)DCs is relevant to the German Government's approach to IPRs and Health (Schmiedchen, May 2009). The Government, through its bilateral cooperation, is fostering pharmaceutical R&D and production in DCs using the TRIPS flexibilities.

The project is in line with two of the three objectives of the Government of Germany in the field of pharmaceutical sector promotion, i.e., i) Improving access to low-cost and high-quality medicines, ii) Fostering innovation, and iii) Development of local/regional pharmaceutical industry in DCs.

Relevance to United Nations Development Assistance Framework (UNDAF) objectives

The UNDAF objectives address four broad outcomes. One of these outcomes is relevant to the present project. It addresses the issue of access to anti-retroviral medicines (ARV) i.e., "Individuals, civil society organizations, national/local public and private institutions have the capacity to achieve/deliver and sustain universal

access to HIV prevention, treatment, care and support and to mitigate its impact" (UNDAF, Action Plan 2008 - 2012 Lesotho, 2009).

In Ghana, the UNDAF action plan includes six outcomes. The project is relevant to outcomes two and three, which are "National response to HIV/AIDS strengthened" and "Increased productive capacity for sustainable livelihoods especially on the most deprived areas" respectively. Concerning the latter, the project has the potential to contribute to two of five key areas "Promotion of appropriate technologies for increased productive capacity" and "Enhancement of an enabling environment for private sector development and investment" (UNDAF, Action Plan for Ghana 2006 - 2010, 2005).

In Cameroon, the framework plan includes four outcomes: social development, governance, risks prevention and management, and environment. The project is relevant to none of these outcomes. (UNDAF, Plan cadre Cameroun 2008-2012, 2007).

In Botswana, the UNDAF's five objectives are i) Governance and Human Rights Promotion, ii) Economic Diversification and Poverty Reduction, iii) Health and HIV/AIDS, iv) Environment and Climate Change, and v) Children, Youth and Women's Empowerment (UNDAF, Botswana 2010 - 2016, March 2009).

Since the project in Botswana is foreseen to intervene at the plant level only, it is relevant to the third objective on health and HIV/AIDS and its outcome « Institutions capacitated at all levels to effectively respond to HIV and AIDS and deliver preventative and curative health services ».

The available UNDAF document for Kenya only covers the period 2004 to 2008 and is thus obsolete; the new version is not yet published.

Relevance to the Paris Declaration

With regard to the Paris Declaration on Aid Effectiveness, the project is aligned to partner countries' national development strategies, institutions and procedures as detailed above. In Ghana, where it is implemented at all three levels, ownership is given since the Government has led the development of the pharmaceutical industrial strategy through broad consultative processes and will implement this strategy in collaboration with UNIDO.

The fact that the global nature of the project hinders its inclusion in the UNDAF action plans is unfortunate and raises concern that at the country level its planning, funding, disbursement, monitoring, evaluating and reporting to the Government on donor activities and aid flows may be jeopardized (Paris Declaration Indicator 9).

C. Coordination & Management

The project is managed by UNIDO Business Environment and Policy Support Unit (BEP) that belongs to the Industrial Policy and Private Sector Development Branch of the Programme Development and Technical Cooperation Division (PTC/PSD). This unit seeks, through a combination of advisory and capacity building services, to strengthen national capacities for the creation and continuous fostering of a business environment that would allow the private sector to make a greater contribution to growth, employment and income generation.

Specific technical inputs have been provided by international consultants while a project manager and an associate expert, funded by the German associate expert programme (December 2006-December 2009), formed the team that was in charge of this project until August 2009. A Senior Technical Advisor (STA) was hired in August 2009 and from December 2009, the associate expert is employed as a full-time project staff and thus fully dedicated to the project. The improved staffing situation is expected to improve monitoring, implementation, planning and communication with all the stakeholders at the international, regional and national levels.

At the national level, it was foreseen to establish national business advisory, partnership, promotion and match making units (BAUs) on the premises of the host institutions, at the beginning of Phase II. These BAUs would assume the function of project offices and constitute the institutional channel for the delivery of UNIDO support. The concentration of project activities at the plant level to a few locations, in order to achieve quick results, was decided during the second Steering Committee meeting in 2007 (PSC, 27 Feb 2007). For this reason and with the view to improve efficiency of the project, it was decided to modify the BAU concept and to create Pharmaceutical Networking Support Units (PNSUs), on a (sub) regional basis and/or in countries with major activities. However, at the time of this evaluation, neither regional PNSUs nor national BAUs were established.

The roles and the responsibilities of the counterparts (Ministries of Trade and Industry and Health) are not formalized. Nonetheless, national experts are present in the countries where the level of activity is substantial i.e. in Ghana and Kenya, and one was on board in Lesotho. They have clear and precise ToRs.

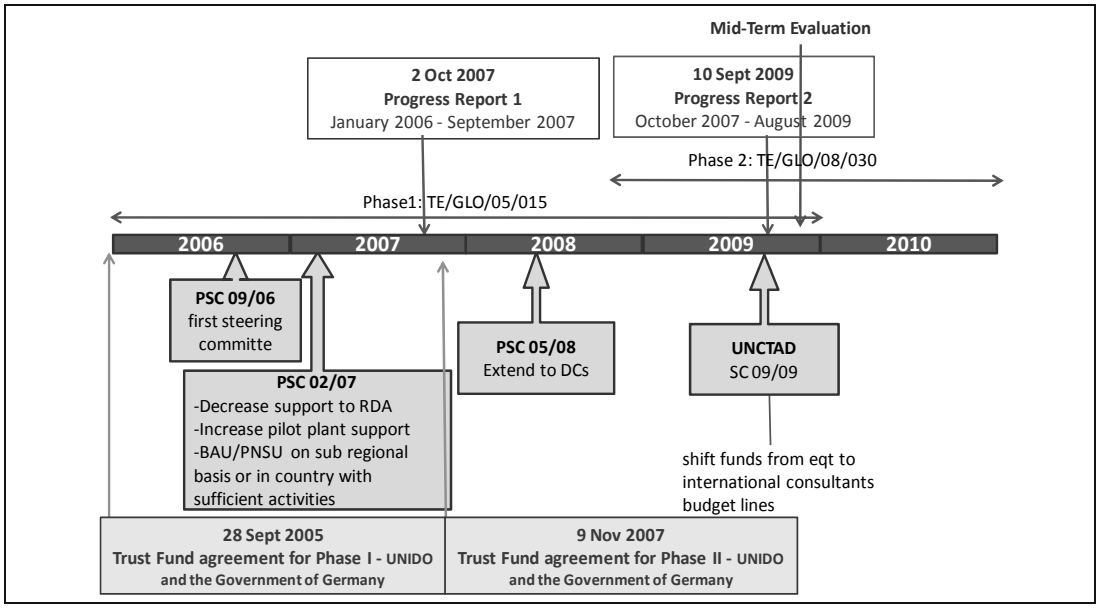
Box 1. The Ghana example.

In Ghana, the formulation of the draft strategic plan for the pharmaceutical industry was achieved in six months; from the time a national expert was hired as a Coordinator Industrial Pharmaceutical Sector Strategy Development and assigned to the Ministry of Trade and Industry (MOTI). Since then, the effectiveness and ownership of this project have largely improved in comparison with previous years. For instance, the national expert participated actively in the formulation of Ghana's industrial policy draft. The presence of the office in MOTI has increased the transparency of the project and the likelihood that the strengthening of SMEs for the local production of pharmaceuticals will be included in the Government's strategy for industrial policy that is currently being drafted.

At the global level, the overall coordination of the project is presently carried out by a Project Steering Committee (PSC), consisting of representatives from UNIDO (chairman), the Government of Germany (German Federal Ministry for Economic Cooperation and Development, BMZ), the United Nations Conference on Trade and Development (UNCTAD) and representatives of relevant bilateral organizations such as the Kreditanstalt für Wiederaufbau (KfW) and Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ). The committee is in charge of reviewing the implementation strategy, project modalities, project progress, and advice on adjustments on remaining actions when deemed necessary. Three meetings per year were planned in the initial project document; one meeting per year has been held.

In the project document for Phase I, it was also foreseen to create a Strategic Advisory Group (SAG) to monitor global developments, trends and policy issues pertaining to the pharmaceutical industry, with a focus on the production of essential generic medicines. The creation of this Group was put on hold and it is still not in place. Instead, the management team sought informal advice and assistance from short-term consultants and senior experts.

Figure 3. Main Milestones in the Project Management



The pharmaceutical sector profiles were developed through needs assessment exercises since 2007 and have been updated for Nigeria, Uganda, Zambia and Zimbabwe. One of the logical framework key outcome indicators is "*Export of essential medicines increases*". Even if this indicator was re-formulated, the baseline data of the export figures in each country would still be important in order to measure progress and hence, the project effectiveness. Among the nine pharmaceutical sector profiles reviewed, three studies do not mention the export value of essential generic medicines in the country, three studies mention the country's export amount in 2005 (Lesotho, Zambia and Laos (no export)), one mentions the export amount per month (Zimbabwe), two studies mention the export amount for the visited companies only (Senegal and Nigeria). Thus, the export figures are not comparable among these studies and the baseline data for this crucial indicator is available for only two countries. Because the project has been delayed, the baseline data can still be collected during the update of these studies.

The two available project progress reports cover the period from January 2006 to September 2007 and from October 2007 to August 2009. The documents follow the Phase I project document (planned activities) and give a clear update of the produced outputs and the achieved outcomes. The second progress report, issued while Phase II had already started does not follow the Phase II log frame because of the delay in implementation and is thus based on the Phase I logic. Nonetheless, both phases have been conducted in parallel in order to respect the different paces of achievement reached in the targeted countries.

The progress reports also include activities planned for the next reporting period and the required budget for their implementation.

D. Implementation

The strengths and weaknesses of project implementation are summarized in the table below.

Table 2. Strengths and Weaknesses of project implementation and management.

Strengths	Weaknesses
A fact finding phase is followed by the implementation phase in three to four selected countries.	Implementation delays
The project is based on careful needs assessments.	The project management has not performed any self-monitoring exercise.
The implementation has been tailored to the countries, taking into account other projects in the same area and the dynamic development of the environment.	OVI baseline data is not fully available.
The networking activities bring together the different actors around the production of medicines in (L)DCs and allow to coordinate the efforts and the creation of synergies.	The logical framework has not been updated.
The holistic approach including the goal to facilitate regional harmonization is an asset to reach sustainability.	Communication between the project management team and the national experts in participating countries is weak
Technical advisory support is effective at the plant level and well appraised in Ghana.	Understaffed management team until August 2009 yet activities in 14 countries.

The key reasons for the 18-month delay in the implementation of the project include:

1. It was difficult to identify an international expert familiar with pharmaceutical production, disposing of a multi-disciplinary expertise in industrial development, health and medicine policies in developing countries.
2. The management team which had to cover all the selected countries, was understaffed until August 2009.
3. UNIDO criteria that only enterprises that showed evidence for meeting the two main eligibility criteria - commercial viability and eventual compliance with international quality standards - would qualify for technical assistance made the identification of potential companies difficult and slowed down the implementation process.
4. Pharmaceutical sector profiles in the selected LDCs took more time than anticipated. The results obtained show that none of the eight scanned LDCs actually met the minimum eligibility criteria.
5. More time was required when the PSC recommended that the project should be extended to include DCs.
6. The networking activities are very relevant when one considers the position of UNIDO within the United Nations (UN) and the numerous agencies working on pharmaceutical development. Nonetheless, it is commonly agreed that these activities are time-consuming and take long to get results.
7. Delay to conclude contracts:

    - The need to hire an STA was agreed by the PSC. The first person identified for the STA position in early 2006 turned down the offer a few days before the planned start of the assignment. Thereafter, the STA recruitment was put on hold, giving way to a series of short-term international expert engagements. The eventual re-launch of the STA recruitment process was in October 2008, including advertising, interviews, reports, etc. and took ten months until the successful candidate's entry on duty.
    - UNIDO identified competent experts - retired seniors from pharmaceutical industries who had already worked for WHO. However, UNIDO rules prevented subcontracting these experts because a waiver from competitive bidding was initially not approved, resulting in a delay of about four months.
    - It took approximately eight months to subcontract the global market study to a reputable firm.

Another explanation cited during interviews was donor-induced strategic delay for a cost saving purposes. During the implementation of the first phase devoted to research and fact finding, there were a lot of uncertainties about the future of the project and it was a politically sensitive issue how to use the flexibilities enshrined in TRIPS. Therefore before the project could fully unfold, one needed to test the

waters—to be flexible on the approach and make a road map when enough supporting data was collected

In conclusion, the project encountered significant implementation delays of about 18 months. Nonetheless, after four years the project has achieved most of its planned objectives.

E. Efficiency

Efficiency is a measure of how economically inputs (funds, expertise, time, etc.) are converted to outputs.

Total Budget

The total budget is composed of (i) two German-funded projects supporting local pharmaceutical production in DCs/LDCs under implementation since January 2006 (TE/GLO/05/015) and strengthening the local production of essential generic medicines in DCs since November 2008 (TE/GLO/08/030); and (ii) UNIDO regular RPTC contributions (XP/GLO/07/026 and XP/GLO/09/016) towards TE/GLO/05/015 (see Table 3).

94.1% of the total amount allocated for project TE/GLO/05/015 (1.33 million Euros) or 1,249,433 Euros has been disbursed in a timely manner. UNIDO remaining part of 78,000 Euros will be released in January 2010. The final instalment of 881,908 Euros (996,556 Euros including support costs) was provided by Germany on 20 October 2009.

Table 3. Total project budget

Phase	Total budget EUR*	Project number	German contribution	UNIDO contribution
1	1,327,434	TE/GLO/05/015	973,451	
		XP/GLO/07/026		118,193
		XP/GLO/09/016		156,500
		XP/GLO/09/016-2010		78,947
2	1,592,920	TE/GLO/08/030	Initial Payment: 336,283 Final Payment: 881,908 Total 1,218,191*	
		XP/GLO/10/xxx		371,681

Source: Progress Reports and ToR

* excluding support costs

The implementation of the ongoing work plan will exhaust the first instalment (336,283 Euros for project TE/GLO/08/030 from Germany). The project budget and expenses are managed and authorized by UNIDO as stated in the financial agreement. Some 51.9% of the total project budget has not yet been disbursed.

The implementation of both the preparatory fact-finding and plant-level assessments was delayed due to the failure to identify and recruit a STA. To fill the gap, a larger number of short-term consultants than initially expected were required. Their recruitment, however, resulted in an increased demand on funds for short-term consultancies (see Table 4). A study on opportunities for generics producers in LDCs subcontracted to a reputed company, travel of project and UNIDO staff, and workshops/conferences required to network and disseminate results to potential stakeholders also took a big share of the expenditure. To meet the increased demands on the budget and for efficient use of funds, shifts were made in several project budget lines. The more substantive shifts were approved beforehand by the donor as per UNIDO rules and regulations. Specifically, funds from less urgently required budget lines, for example equipment were shifted to funds for recruiting short-term international consultants. The decreased equipment budget allocation did not affect implementation of Phase I which covered essentially research and fact-finding activities.

Table 4. Planned versus actual costs

BL	Description	Planned EUR*	Actual EUR	Unspent (overspent -)
1100	International experts		102,557	-102,557
1150	Short-term international consultants	351,130	499,493	-148,362
1300	Project administration assistants	60,606	10,069	50,537
1500	Project staff travel	22,607	46,574	-23,967
600	UNIDO staff travel	40,885	68,159	-27,274
1750	National experts	197,210	66,370	130,840
2100	Subcontracts	202,020	227,987	-25,967
3200	Exposure/study tours	53,315	41,208	12,107
3300	Training (in-country)	81,770	24,851	56,919
3500	Workshops/conferences	38,480	81,098	-42,618
4500	Equipment (pilot/demonstration plants)	336,700	956	335,744
5100	Sundries	17,967	19,359	-1,392
	Support costs	182,610	122,886	59,724
	TOTAL	**1,587,300**	**1,311,567**	**273,734**

Source: analysed data supplied by the project management team

* The total sum planned for each budget line in the project document was adjusted by a factor 0.481 since only 48.1% of the budget has been disbursed so far.

Expenditure according to outputs

The breakdown of expenditure according to outputs is shown in Table 5. Activities that were essential as building blocks for an efficient nascent manufacturing initiative understandably exhausted most of the funds. For example, outputs for the global market study and the national pharmaceutical sector profiles required as intelligence tools and for the preparation and/or assessment of individual plant-level business plans consumed up to 36% of the budget. When the required outputs needed more funds than anticipated or budgeted, funds from less urgent activities were re-allocated for the efficient implementation of priority activities as detailed above. Similarly, essential activities on institutional capacity building and identification of concrete opportunities including business partnerships consumed up to 17%. This was followed by inputs to disseminate and share the data obtained with all stakeholders. All in all, the funds were efficiently allocated and used for both the preparatory fact-finding and plant-level assessments as required.

Table 5. Expenditure according to output

	Output	**Expenditure in EUR**	**% of actual expenditure**
1	Development trends, operational challenges and policy issues related to the production of essential generic drugs in selected LDCs assessed.	423,641	36.2%
1.1	Global sector profiles of production of essential generic drugs	237,000	20.2%
1.2	National pharmaceutical sector profiles for 8-10 LDCs	173,475	14.8%
1.3	Identification and assessment of real case examples of business partnerships aimed at enhancing access to drugs in developing countries.	13,166	1.12%
1.4	Enlarged PSC meeting.	0	0%
2	Strategy and detailed project interventions for increased local manufacturing of essential generic drugs in 3-4 LDCs agreed upon.	113,188	9.6%
2.1	Initial networking with private business.	10,050	0.86%
2.2	In-depth constraints analysis and needs prioritization in target LDCs	99,447	8.48%
2.3	Exploration of scope for instruments to ensure markets for local producers	3,691	0.31%
2.4	Revision of output-activity schedule and final work plan.	0	0%
3	Overall project management and coordination mechanisms established	29,989	2.6%
3.1	Set up/first meeting of Project Steering Committee (PSC).	550	0.05%

	Output	Expenditure in EUR	% of actual expenditure
3.2	Set up/first meeting of National Project Steering Committees (NPSCs).	29,035	2.48%
3.3	Set up Strategic Advisory Group (SAG).	404	0.03%
4	Concrete opportunities including business partnerships identified and pilot local production of essential medicines put in place	200,569	17.1%
4.1	Establishment of business advisory, partnership promotion and matchmaking units (BAUs).	15,350	1.31%
4.2	Plant-level SWOT analyses and ad-hoc advice for local medicines-producing SMEs.	98,616	8.41%
4.3	Identification of concrete opportunities including business partnerships for the local production of essential medicines.	78,233	6.67%
4.4	Start-up support towards the local production of essential medicines.	7,070	0.60%
4.5	Dissemination of results.	1,300	0.11%
5	Institutional support capacities for the promotion and development of the local manufacturing by SMEs of essential generic drugs upgraded.	207,241	17.7%
5.1	Advice to public and private sector stakeholders institutions.	49,198	4.19%
5.2	Training of trainers, public classroom courses and/or on-the-job training activities (marketing, GMP, quality control/testing, etc.).	115,333	9.83%
5.3	Upgrading the drug testing/ laboratory facilities.	1,256	0.11%
5.4	Strengthening sector-specific BMOs and/or related local self-help bodies.	41,454	3.53%
6	Positive project results effectively communicated and potential for regional cooperation enhanced.	144,528	12.3%
6.1	Exchanges on experience and lessons learnt.	13,200	1.13%
6.2	Dissemination of successful project outcomes for replication.	3,569	0.30%
6.3	Exploration of potential for enhanced regional cooperation in promoting local generic drugs industries.	78,561	6.70%
	Project Staff	103,200	8.80%
	Total	**1,173,118**	**100%**

Source: analysed data supplied by the project management team

Direct and indirect beneficiaries

At the national level, the direct beneficiaries are the four selected SMEs (two companies in Ghana and one each in Botswana, Lesotho-(discontinued) and Cameroon) for local production of essential medicines. To three of these companies advice was provided on how to refine their business plan and to compile the necessary documentation for an investor search. Training and a study tour were implemented to enable production and managerial staff to acquire the necessary skills to satisfy WHO-prescribed standards in the production process. Altogether 25 persons from enterprises, MRAs and universities received training on state-of-the-art knowledge on GMP manufacturing and current medicine regulation. Also the training institution offering the course benefited from the publicity for the course and the sponsorship of participants. Furthermore, three institutions (Pharmaceutical Manufacturer Association of Ghana (PMAG) in Ghana, MRA in Kenya and the Tanzania Food and Drug Authority (TFDA)) received advisory and/or capacity-building assistance.

Fourteen governments have been made aware of the topic of local production and the importance of creating a business-friendly environment to allow a local production of pharmaceuticals.

At the regional level, the beneficiaries were workshop participants representing the private sector and government bodies and institutions, notably regulatory authorities for pharmaceuticals from the Association of Southeast Asian Nations (ASEAN), EAC, ECOWAS and SADC countries. Workshops provided platforms for public-private dialogue and exchange on the prospects of and prerequisites for creating a commercially viable pharmaceutical manufacturing base in the region.

Synergy with other projects

Potential for synergy with other projects was also sought. The cooperation with Deutsche Investitions- und Entwicklungsgesellschaft mbH (DEG, Germany) in supporting companies in Cameroon and Bangladesh proved, however, difficult. DEG was unable to share documents on the concrete nature of their collaboration with companies because of confidentiality clauses underlying the respective financial agreements. In the absence of this information, the originally envisaged UNIDO project interventions, i.e. supplementary technical assistance inputs, were difficult to define. However, synergy effects with DEG were reached as well as cost sharing in training of a quality manager of Cinpharm (Cameroon), through a WHO GMP training in Rabat and in relation to the study tour of eleven

key production managers to Cipla's facility in India (see chapter on Effectiveness).

In Ghana, the project is being implemented in parallel to a second UNIDO project "Trade Capacity Building for Ghana", managed by the PTC Trade Capacity Branch (TCB). The project is funded by the Swiss State Secretariat for Economic Affairs (SECO) with a comprehensive approach to strengthening Ghana's National Quality Infrastructure, including the Food and Drug Administration (FDA) Quality Control (QC) laboratory. There is also a proposal for a European Commission (EC) project to be implemented by UNIDO for upgrading and improving competitiveness of industries and related services in Ghana. When implemented, the new project could be an exit strategy for the project under evaluation. Last, but not least, another Swiss funded "Ghana Intellectual Property Project" has been implemented for three years in order to revise Ghana's patent law to make full use of the flexibilities enshrined in TRIPS and to support a local production of pharmaceuticals.

F. Effectiveness

Produced outputs and achieved outcomes

This chapter deals with the extent to which the main outputs have been produced and the outcomes achieved and the achievement of the specific objective defined in the Phase I project document: "*To support the establishment and/or the expansion and upgrading of SMEs in 3-4 target LDCs for the local manufacturing of essential generic drugs"*. A detailed table of produced outputs and achieved outcomes is found in Annex E.

Development trends, operational challenges and policy issues related to the production of essential generic drugs in selected LDCs assessed

OVI: Knowledge updated/info gaps closed on sector profile trends and pertinent policy environment issue

This outcome has been reached mainly through studies at the global and national levels.

The global market study[2] results were intended to be used i) as guidance for the management and fine-tuning of technical cooperation activities in support of sustainable, commercially viable pharmaceutical ventures in target LDCs, and ii)

[2] entitled "The Market for Selected Essential Generic Medicines: Opportunities for Producers in LDCs"

as an intelligence tool to be made available to project partners, particularly at LDC pharmaceutical company levels, for the preparation of business and/or investment plans towards the manufacturing of the selected generic medicines.

The two Ghanaian pharmaceutical companies that are the most advanced in this project have not yet received the final report of the global market study. Nonetheless, the results of the global market study were used by the project team in the revision and testing of assumptions of the business plans of both Ghanaian firms.

The conclusions from this study have facilitated the decision on the types of medicines that would be more efficient to manufacture, taking into account their clinical characteristics or "opportunity" and their manufacturing "feasibility".

Surely, when communicated, this global market study for production of essential medicines could help the pharmaceutical manufacturer institutions and SMEs in improving their strategy and medicine portfolio in order to focus on targeted medicines, with a global overview of the market.

At the national level, pharmaceutical sector profiles have been done in Cambodia, Lao People's Democratic Republic (PDR), Lesotho, Nigeria, Senegal/Mali, Uganda, Zambia and Zimbabwe. The structures of these studies are similar: policy, legal and regulatory environment impacting upon pharmaceutical sector development, the distribution of the institutions and market, constraints analysis of the access to essential medicines, and the entry points for improving access to essential generics. Unfortunately, the data obtained in these studies are generally not comparable (see subchapter on Coordination and Management). However, these surveys were useful in fine-tuning the future project interventions and in selecting the countries to be included in the project upon the following criteria (PSC, 4th September 2006), (UNIDO, Project Document Phase I):

- Record, performance and future potential of the pharmaceutical sector
- Proven interest and commitment of government and private sector
- Scope for exploitation of TRIPS flexibilities
- In-principle readiness of enterprises to join partnership-based efforts
- Potential for cross-border cooperation in increasing local manufacture of generics (regional/global)
- Complementarities with other donor activities
- Potential for synergies with other UNIDO interventions

One result of this assessment was the shift from LDCs to DCs as a lot of time and energy was spent on the analysis of LDC environments, which often did not result in activities due to low capacities at company and government level. This outcome has been substantially achieved. The knowledge has been updated,

and is still being updated through regular consultancies, and the info gaps on the sector-profile trends and the pertinent policy environment issues have been closed.

Strategy and detailed project interventions for increased local manufacturing of essential generic drugs in three-four LDCs agreed upon

OVI: all the project parameters for phase two defined

At the national levels, awareness for the project and UNIDO engagement in the pharmaceutical sector's development has been raised through organizing and participating in workshops and roundtable discussions. Four workshops have been conducted of which two were regional workshops in Dakar (Senegal, 2007), Lusaka (Zambia, 2008) and two were national workshops in Phnom Penh (Cambodia, 2007), Vientiane (Lao PDR, 2007). They offered opportunities for manufacturers of pharmaceuticals, representatives of the governments, representatives from regional and international organizations, and civil society and academics to come together and talk to each other. Pharmaceutical sector profiles results have been presented and companies were informed on how they could apply to participate in the project. The workshop in Tanzania (October 2006) marked the first opportunity for a comprehensive dialogue among all stakeholders on the "*Strategies for the promotion of the local pharmaceutical in Tanzania*", prepared by the TFDA.

Activities have been defined in the countries that were most receptive of UNIDO support, roundtables have been held, resulting in the preparation of a draft strategic plan for Ghana and the plan to prepare a strategy document for Kenya by the first quarter of 2010 (UNIDO, IPC meeting, November 2009). Furthermore, coordination with other UN agencies working in the same area was started to define possible areas of collaboration.

Box 2: Results of roundtables in Ghana

In Ghana, the first roundtable was chaired by the Minister of Trade and Industry in July 2009 and led to i) Definition of the three levels of the project's interventions and the respective counterparts; ii) Creation of sub-committees to draft the strategic plan for pharmaceutical industries in Ghana.

Then, an early draft was shared with the MOTI in December 2009. Consultations are ongoing as is the work on a full-fledged strategy paper. Submission for multi-stakeholder approval would appear unlikely before the second quarter of 2010.

Formal and informal interactions with local players have enabled the project management to develop a deeper understanding of the challenges they face and the context within which these entities operate.

One future scenario is that WHO could refer promising candidates for prequalification that require technical assistance to UNIDO. UNIDO would then

assign an international expert to help with the preparation of the required documentation. Similarly, the WHO team could give priority to firms in the prequalification process that have received technical assistance through UNIDO.

The proposed collaboration with Interagency Pharmaceutical Coordination Group (IPC) consists of i) exchange of information on existing local production activities, on support tools related, for instance, to norms and standards, financing, IPR, lists of products and approved local suppliers, ii) concrete collaboration on training and sharing of information, and iii) working towards a common UN agencies/IPC position on local production (IPC, September 2009).

This outcome two has been achieved significantly and the indicator is verified. All project parameters for Phase II have been defined. The Phase II document was prepared and approved both by UNIDO and the Government of Germany on 9th November 2007. Furthermore, draft interventions for increased local manufacturing of essential generic medicines have been decided in Ghana, Kenya, Lesotho, Botswana, Cameroon, and Uganda. The Lesotho project was discontinued in January 2009 and the company in Uganda declined UNIDO offer to participate in the project. Today, four targeted countries are already involved in the project Phase II.

Overall project management and coordination mechanisms established

OVI: Membership and terms of reference/work plan agreed; inaugural meeting successfully held.

As described in the subchapter on Coordination and Management, at the global level, the evaluation team did not find any ToR for the PSC and only one of the three project management mechanisms has been established. Nonetheless, national experts are in place in countries with more than minimum activity. At the national level, neither national counterparts' ToRs nor formalized national work plans were available. Tools to conduct an effective coordination were not implemented (work plan at national level, ToR for counterparts).

Concrete opportunities including business partnerships identified and pilot local production of essential medicines put in place

OVI: Local production of essential medicines with local SME involvement operational.

A feasibility study was performed after the pharmaceutical sector profile, in Lesotho, and the verification of business plans took place in Ghana, Cameroon

and Uganda (two companies in Ghana, in Cameroon the verification was carried out by DEG). In Botswana, a preliminary assessment was done and a tender will be closed mid-January 2010 for a conceptual design and a feasibility study on Gemi Pharmacure Ltd.

The above-mentioned activities (pharmaceutical sector profiles, and verification of business plans) have been implemented at the existing plants that had expressed interest in being supported by submitting a completed Company Project Profile (CPP) to this project after the workshops or other networking activities. The plant-level Strengths, Weaknesses, Opportunities and Threats (SWOT) analyses examined eligibility of the companies based on the following five criteria:

- The company has a business plan that realistically predicts a commercially viable and sustainable production in the longer term.
- The local production increases access to medicines through local availability at current market price or lower than current market price.
- The products will meet the highest quality standards of international GMP.
- Key personnel are familiar with GMP and ideally have experience in running a GMP-compliant facility.
- Staff is fully committed to support the efforts of consultants/experts and carry out assigned tasks in a self-reliant manner.

All along the project implementation, the relationships with pharmaceutical manufacturers from the North and from the South gave birth to the concept of a UNIDO Pharmaceutical Production Partnership Platform (U4P). The relationship differs from other types of cooperation in that that the driving factor is cooperation of interested players (SMEs, business partners and investors). U4P is being designed as a platform promoting partnerships between producers from both industrialized and developing countries to produce medicines against HIV/AIDS, malaria, TB, neglected tropical diseases and national EML. It is a mechanism for brokering mutually beneficial business partnerships. The aims of the partnerships are to set up domestic pharmaceutical production using GMP standards to increase access to affordable and high quality medicines in (L)DCs. Four meetings have already brought together five companies from Germany, Kenya and Vietnam from which the U4P idea emerged. This initiative is foreseen to be further developed and implemented during the first quarter of 2010.

The outcome was only partially achieved because upgrading of the SMEs has not yet occurred. The selected SMEs were already operational before the

implementation of this project. Nonetheless, three CPPs, two in Ghana and one in Botswana, have been completed and a search for business partnerships is being supported in Ghana. This can be seen as the starting point in promoting the local production by SMEs of high quality essential medicines.

Institutional support capacities for the promotion and development of the local manufacturing by SMEs of essential generic drugs upgraded

OVI: improved performance of selected support entities.

According to the second progress report, at least 26 people from the African continent have participated in training activities - a WHO GMP training in Rabat (the quality manager from Cinpharm Cameroon), study tour to Cipla's facility in India (eleven Cinpharm production personnel) and 14 people have participated in the first two courses of the Industrial Pharmacy Advanced Training programme at the Kilimanjaro school of pharmacy, St Luke Foundation, Moshi, Tanzania (seven participants from the private sector (enterprises) and seven from the public sector (MRAs and universities)). The choice of participants was made with a view to increasing the publicity of the course in a number of countries and reacting to the willingness of the private sector participants to pay 50% of the fees themselves and hence to contribute to the future sustainability of the course.

The latter course is made up of four modules spread over two years (KSP, 2009): i) Medicine Development and Regulatory and Quality Compliance, ii) Medicine Manufacturing Process (GMP); iii) Regulatory Documents and Generic Medicine Approval Submissions, iv) Medicine Discovery.

The content of the modules focused on the GMP and was in line with the capacity building needs of the attendants.

From the Lusaka workshop in 2008, organized by UNIDO/BMZ/SADC, companies and business associations from various countries in the Southern African region identified the need for a sub-regional advocacy and service provision in the generic medicines manufacturing sector. A private-sector-driven initiative emerged for establishing the Southern African Generics Medicines Association (SAGMA). The project seized the opportunity to provide advisory and capacity building support towards the establishment of this regional association, through international expertise including a lawyer. Cost sharing and facilitation of meetings has allowed the birth of an organizing committee with members from seven countries and the preparation of the statutes of this association. On 4 December 2009 the inauguration of SAGMA proved the success of this UNIDO supported initiative.

In West Africa, the West African Pharmaceutical Manufacturers Association (WAPMA) already exists and has around 120 members. As part of their efforts towards the attainment of harmonization of policies, practices and elimination of trade barriers in the West African region, WAPMA is organizing a conference for medicine regulatory bodies and pharmaceutical manufacturers in the region in Accra, Ghana. UNIDO will co-sponsor this conference, which had initially been planned for January 2010.

In conclusion the achievement of this objective is satisfactory.

Positive project results effectively communicated and potential for regional cooperation enhanced.

OVI: international dialogue underway

An international dialogue was initiated within SADC to support the SADC secretariat in the implementation of the SADC Pharmaceutical Business Plan 2007 – 2013. While the latter was instrumental for co-opting the SADC Secretariat as co-host of the Lusaka workshop in November 2008, the UNIDO support to SADC stalled in view of the latter's inability to make the requisite funding available. This activity has been deferred.

A UNIDO consultant attended the second meeting of the technical committee on the Pharmaceutical Manufacturing Plan for Africa (PMPA), organized by the African Union Ministers of Health in Johannesburg, February 2008. During this meeting, the possible contribution of the UNIDO project to the PMPA was assessed (Walter, 18-19 February 2008).

The contribution to the potential regional cooperation in promoting local generic medicine industries is an ambitious outcome. In parallel, UNIDO has engaged with WHO/New Partnership for Africa's Development (NEPAD) /DFID/Gates and the Clinton Foundation initiative on drug regulatory harmonization for Africa's regional economic communities.

Outputs have started to be produced from the Phase I of this project but concrete results are still lacking. There is a tremendous momentum currently focused on pharmaceutical innovation in Africa. Collective and concerted efforts to help countries harness these energies for the advancement of public health and socio-economic development are both timely and useful (Berger, M., 2009). Recent examples of the increased activities include the IPC sub-group meeting on local production that was attended by 12 agencies in Geneva in September 2009, and

a special meeting of the African Union's Extended Technical Committee on the PMPA that was convened in Pretoria, South Africa, February 18-20, 2010.

Stakeholders' perceived quality of the project outcomes

At the plant level, the inputs of the experts have been judged to be very efficient and professional, useful for the preparation of the documents required for the WHO prequalification and for seeking investment. In Ghana, the recommendations of the consultants and experts have been implemented by some companies.

During our interviews in the field, the following information has been requested:

"In order to assess the stakeholders' perception of the quality of outcomes of UNIDO project we would like to request you to give a score between one to five (one being the lowest and five the highest)".

In Ghana, the results show clearly that there is a very good perception at the macro and the micro level, whereas at the meso level, the benefit from the project is perceived as weak. This is probably due to the delays in the implementation and the change of the counterpart function from PMAG to the MOTI.

« Things have jumped up when national experts arrived »

Table 6. Stakeholders perception of the quality of UNIDO project outcomes in Ghana and in Lesotho

	Ghana			Lesotho
	Macro	**Meso**	**Micro**	**Micro level**
Number of respondents	7	2	3	14
Not answered	1	1	0	1
Average	4	2,5	4,3	1,38

In Lesotho, the project has been discontinued, and of course, the perception is very negative. The main reasons for malfunctioning and finally discontinuing this project have been identified as:

- The Lesotho National Development Corporation (LNDC) is the main investment gateway into Lesotho. The corporation is therefore the only potential candidate counterpart for any project that wants to establish a niche in Lesotho. Unfortunately, at the start of the implementation of this project, the chosen counterparts have been the three concerned Ministries: Ministry of Trade, the Ministry of Health and the Ministry of Finances.

- The proposed business partnership model required the Government of Lesotho to make a commitment of paying 3 to 4 million US$ for shareholding. It appears that the Ministry of Finance (MoF) was not given enough time to get the requested funds approved by parliament (from May 08, when the amount was determined, until November 08).
- Despite efforts of UNIDO consultant, the local private investors were not able to prepare the required business plan. In the absence of such a detailed business plan, the MoF could not issue a letter of intent that was required by UNIDO and the other private sector partners in order to take the project further. The result was a catch-22 situation.

Conclusion on effectiveness

The delay in the implementation has not compromised the effectiveness of this project. Outputs have been produced in 14 countries (see Table 7) and four countries have been identified to support the establishment and/or the expansion and upgrading of the SMEs. In Lao PDR and Cambodia, pharmaceutical sector profiles and plant level assessments were developed. The results show that the targeted medicines were not perceived as being of great relevance for Lao and Cambodia and activities have been put on hold.

Table 7. Summary of countries' and regions' activities

Country	Policy	Institutions	Plants
Ghana	Draft strategy	PMAG	LaGray and Danadams
Botswana	Other UNIDO project	MRA visited	Gemi Pharmacure
Kenya	Draft strategy	Ongoing	Ongoing
Cameroon			Cinpharm coperation with DEG
Uganda			Quality Chemical Industries declined UNIDO offer at the plant-level in Jan. 2009
Lesotho			discontinued in Feb. 2009
Zambia	Regional workshop 2008		Pharmaceutical sector profile
Senegal	Regional workshop 2007		Pharmaceutical sector profile
Tanzania	National Dialogue	Support Training Institution SLF/Kilimanjaro School of Pharmacy in	

Country	Policy	Institutions	Plants
		Moshi	
Cambodia	National workshop		Pharmaceutical sector profile Plant-level assessments
Lao PDR	National workshop		Pharmaceutical sector profile, Plant-level assessments
Zimbabwe			Pharmaceutical sector profile
Nigeria			Pharmaceutical sector profile
Bangladesh			Some fact finding

Regional institutions support	
West Africa	WAPMA
Southern Africa	SAGMA

Source: information collected by evaluators

Outcome one of Phase II "*Strategies and policies for increased local manufacturing of essential generic drugs in project DCs implemented*" has progressed in two countries as described above. Outcome three "*Institutions offer demand-oriented support services to SMEs in the pharmaceutical sector*" and Outcome five "*project examples are accessible and can be used for replication*" can build on the activities of the first phase. The other outcomes of the Phase II have not been achieved yet but are likely to be reached in countries where activities have taken off. However, the time frame needed for these achievements to materialize is difficult to anticipate and the third phase will require at least three years. But more importantly, the project should focus on assisting SMEs, where it is economically and technically feasible to upgrade their facilities to become GMP compliant and WHO pre-qualified so that they can begin manufacturing good quality medicines at low cost that can compete in the international market.

In order to achieve the new outcome in Phase II "Export opportunities provide extended market for generic drugs", emphasis must be put on the medicines' regulatory regional harmonization activities.

G. Sustainability

The project is putting in place essential building blocks required for the production of high quality pharmaceuticals. For this purpose, the project has a supportive policy advice, a basic human skill set training programme and a technical

assistance at the enterprise for upgrading the production plants to become compliant to GMP accreditation and WHO prequalification. In parallel, the project offers policy advice for the harmonization of the medicine regulation in the regions. It also offers training in GMP and the preparation of documentation required for the GMP and WHO prequalification. These activities are critical for a shift to sustainability and country ownership of local production of pharmaceuticals.

An essential aspect in the WHO prequalification process of generic medicines is the determination of the bio-equivalence status of the produced medicine. To be compliant with the WHO prequalification, manufacturers must conduct studies to determine whether their version is bio-equivalent to the original medicine. It means that certified laboratory and clinical services (bio-equivalence centre) must be available and affordable to the manufacturers. The present project has a small budget. It could also seek support from other donors, on a modular approach, to meet the costs of additional activities that would strengthen the sustainability of this project. Any additional fund could be used for carrying out feasibility studies on the setting up a bio-equivalence centre and to support national quality infrastructures or procurement of relevant equipment (see Annex F).

As mentioned above, the project offered specific training of selected individuals from both public and private sector in medicine regulation in Tanzania and similar courses are foreseen to be offered also in the West African region. The ongoing efforts on interregional harmonization of medicine regulation, sharing of information and procurement of Active Pharmaceutical Ingredients (APIs) will surely contribute to the sustainable supply of affordable, efficacious and high quality medicines in the region. The recent inauguration of the Southern African Generic Medicines Association (SAGMA)[3], a platform to discuss these issues, is one of the success stories of the present project.

Box 3: SAGMA

The mission of SAGMA is to achieve self-sufficiency and reliability in the local production and/or promotion of affordable, efficacious, quality generic medicines in SADC. Even when it is still a long way to achieve a full interregional harmonization of drug regulation in Sub-Saharan African countries, the birth of SAGMA is a step in the right direction. SAGMA could offer a setting for sharing of information, manufacturing tools and for the joint procurement of API. Hence, the support the project provides to this association is timely because the association could be the force that makes local manufacturing achieves international standards to become competitive and sustainable.

[3] Press release: Regional Generic Medicines Association for SADC Inaugurated. Accessed December 30, 2009 at http://www.tralac.org/cgi-bin/giga.cgi?cmd=cause_dir_news_item&cause_id=1694&news_id=79607&cat_id=1043

The choice of the MOTI as the counterpart, has given the project a good chance to succeed because ownership is clearly defined and the strategies for sustainability of local production of pharmaceuticals can be aligned with the Government's priorities and policies for development. The project has provided a private-public dialogue forum which is helping to identify specific constraints that hinder local pharmaceutical production. The roundtable is a platform to build a joint vision and to discuss and design incentives that promote the development of a sustainable pharmaceutical industry. The ongoing strengthening of PMAG in Ghana can also contribute in a sustainable manner to making the institution more proactive in identifying and analyzing factors that limit the ability of pharmaceutical manufacturers to play an important role in their domestic and regional markets.

In short, local production of pharmaceuticals in today's modern world does not only require that medicines produced are of high quality. Local producers must be competitive, too. The focus is therefore to build a sustaining culture that supports improved manufacturing processes and productivity whilst being unflinching in their attention to detail when making medicines. This project is making the participating countries invest in new technology, develop new skills, and maximize the efficiency of the output from their existing manufacturing facilities.

H. Conclusions

Since 2006 the project is being implemented in 14 countries to explore ways of encouraging nascent pharmaceutical manufacturers in LDCs and to strengthen and upgrade SMEs in DCs to become GMP certified and WHO prequalified. The project has spread the relatively weak budget too thinly over an optimistic programme and undertaken activities in many countries. Many LDCs require not only advisory technical assistance but also need tangible inputs, such as equipment to allow them upgrade their manufacturing facilities, to support R&D activities, quality infrastructures and operational pharmaceutical manufacturers associations. Nonetheless, attempts to strengthen pharmaceutical production without directly supporting related quality infrastructures could become counterproductive in the achievement of the explicit goals and objectives—to supply high quality medicines produced locally at the GMP and WHO prequalified standards in a sustainable manner.

The project design, through its three-pronged approach (policy, institutional and enterprise level), offered a good opportunity to form an economically viable backbone of a pharmaceutical manufacturing value chain in LDCs and DCs. The project draws on industrial policy advice to create a conducive business

environment for the pharmaceutical sector. At the same time, the institutional infrastructure is strengthened through training and mentoring. Finally, direct technical assistance is offered to SMEs for their upgrade to GMP certification and WHO prequalification status and in identifying potential investors. The flexibility which allows the project to respond according to the ever changing environment is a crucial element for the relevance, effectiveness and sustainability of the project.

In Ghana, this holistic approach has united private and public stakeholders to engage on a common vision for the sector's development, and, hopefully, this will be enshrined in a mutually agreed sector development strategy of the MOTI. At the same time, the PMAG is being supported to be pro-active and to engage effectively in this public-private dialogue process. In parallel, needs identification and verification of business plans at the company level have indirectly informed the strategy-building process. It has also allowed to check back on the relevance of the support measures required for the preparation of the trainings and documentation required for upgrading the selected SMEs for GMP and WHO prequalification status.

The project was considerably delayed due to, amongst other things, understaffing of the management team. The implementation of phase I relied heavily on international consultants. Collaboration with the national counterparts was not formalized and a National Steering Committee (NSC) was not created. Offices of national experts in countries where the project is being implemented remain operational but suffer from weak communication with UNIDO headquarters. At the global level, a PSC is managing the project but the set up of the SAG has been postponed. Most of the objectives for Phase I were achieved after four years of implementation. The results of this fact-finding phase were used to select four countries (Botswana, Ghana, Kenya and Cameroon) where support measures at the enterprises level were defined.

At the interregional level, workshops and training were used to promote effective public-private dialogue and exchange on the prospects of and pre-requisites for creating a commercially viable pharmaceutical manufacturing base. A key outcome of these initiatives in the SADC region was awareness of the need for *subregional* advocacy and service provision to the generic medicines manufacturing sector. Since then, a private-sector-driven initiative spearheaded by UNIDO emerged for establishing SAGMA. This subregional association will be instrumental in promoting the interests of the Southern African pharmaceutical industry. It will also provide a forum for harmonization and setting up a strategy for the pharmaceutical industry sector for the sustainable supply of locally manufactured life-saving medicines and for creating jobs in a knowledge-intensive industry. Efforts to support other interregional pharmaceutical manufacturers associations will potentially reinforce the regional harmonization of trade and pharmaceutical regulations.

III

Recommendations

To UNIDO

1. The existence of project documents defining clearly the expected roles of the counterparts would facilitate communication between the national teams and their government. At the international level, a revision of the logical framework should facilitate the tasks of all the stakeholders including the PSC in the future management and monitoring of the project.
2. A “light” NSC including at least Ministry of Health and Trade/Industry (or any national mandated by law corporation) and national experts should define with UNIDO the specific national log frames and work plans, continuously monitor the project without compromising the presence of sub regional PNSU if needed.
3. The inclusion of impact OVIs in a specific country’s log frame that would be in accordance with the national strategy indicators (from national drug policy, health policy or other national texts) will improve the harmonization and managing for results commitment of the Paris declaration on aid effectiveness.
4. There are insufficient funds to cover the costs of stand-alone activity such as equipment, support to quality infrastructures, bio-equivalence centre setup and R&D activities. For this reason, it could be worth considering a modular approach where additional donors could fund related modules.
5. Currently, there is a dearth of case studies on DCs and LDCs that have entered technology transfer arrangements to manufacture essential medicines locally. This gap may be filled by the ongoing WHO/UNCTAD/ICTSD Initiative that is working on case studies on technology transfer in (L)DCs. The project management should look for ways to collaborate with this initiative and to harness the benefits from the results to be generated therefrom.

   Similarly, there is no information on whether or not and under what conditions domestic production of pharmaceuticals actually make a meaningful contribution to access and affordability of essential medicines to patients who need them most.

6. Support the early setup of the SAG, to take place as soon as possible, including representatives of such institutions as pharmaceutical companies, WHO, Global Fund to Fight Aids, Tuberculosis and Malaria (GFATM) and key NGOs involved in advocating for the maximum use of TRIPS flexibility as Médecins Sans Frontières.

<u>To the donor</u>

7. The third phase, expected to start in 2011 for two to three years, with a budget of around two million Euros should follow the same holistic strategy but focus on:
   - Phase II achievements and, specifically, the pharmaceutical and trade regional harmonization in COMESA, ECOWAS, EAC and SADC through the support of regional pharmaceutical manufacturers associations and networking activities. UNIDO role should be to facilitate meetings and to provide international consultants to advise on the definition of the regional regulation and on action plans.
   - Achieving convincing results in Ghana, Kenya, Cameroon, and Botswana and suspending any activities in Asia until models and increased funds are available.
   - Consider undertaking a feasibility study to facilitate setting up of a regional bio-equivalence centre and upgrading reference laboratories for prequalification monitoring (in collaboration with WHO) required in every economic region. GTZ is already building up a bio-equivalence centre for Ethiopia and Kenya. No such centre is available in the ECOWAS region. At least one WHO pre-qualified laboratory per region would be enough to support needs in the four selected countries in Africa.

IV

Lessons learned

The challenges that local manufacturers of essential medicines in LDCs and DCs face are formidable. A comprehensive approach that addresses the constraints at the policy, institutional and enterprise level at the same time offers the best chance of success. This holistic approach is feasible, enhances sustainability and ownership as in the Ghana model.

It is necessary to put in place a national management mechanism at the start of the implementation of a project. In Ghana, the project made a significant progress from the time the national expert was hired.

Annex A. Terms of Reference

22 October 2009

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

TERMS OF REFERENCE

Independent Mid-term Evaluation of

UNIDO global project TG/GLO/05/015 and TG/GLO/08/030

'Strengthening the local production of essential generic drugs in Least Developed/Developing Countries'

I. Background

According to the World Health Organization (WHO), 30% of the world's population lacks access to life-saving medicines. In some countries in Asia and Africa, the number may be as high as 50%[4]. 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.

Project objectives. The project 'Strengthening the local production of essential generic drugs' aims at enhancing the poors' access to affordable generic drugs in Least Developed and Developing Countries (LDCs and DCs). To reach this objective, the project intends to promote the establishment and/or expansion and upgrading of Small and Medium Enterprise (SMEs) in three or four selected LDC or DCs for local production of essential generic drugs. This enterprise-oriented approach was to be complemented by interventions at marco and meso levels to remove constraints in the policy and business environment. The project has been implemented at three levels:

- ***Macro level***: *Policy advice* towards improving the business, legal and regulatory environment for local production of generic drugs. This includes national strategy formulation and support to regional harmonisation efforts.
- ***Meso level***: *Institutional capacity building* of support entities of the pharmaceutical-sector SMEs, such as Medicine Regulatory Authorities, pharmaceutical manufacturers associations, or quality infrastructure bodies.
- ***Micro level***: *Direct support to enterprises*, such as technical and managerial assistance to achieve international standards, preparing feasibility analysis or matching partnerships between local and foreign drug producers.

The project is jointly funded by the Government of Germany (GOG) and UNIDO and is divided into two phases. The project started in January 2006 and is scheduled to complete in December 2010.

Project budget. The total budget of the project (including support costs) is Euro 3.3 million with the majority of the funding coming from the GOG. So far, 55% of the allotment has been committed and/or spent.

[4] **WHO, 2004, *Equitable Access to Essential Medicines: A Framework for Collective Actions.***

Table 1. Project budget

	Phase 1	Phase 2	Total
Total allotment	1,319,951	336,283	1,656,234
from GOG	*973,451*	*336,283*	*1,309,734*
from UNIDO	*346,500*		*346,500*
Total expenditure so far	873,058	35,813	908,871
Rate of expenditure (%)			55
Total budget (including support cost)	**1,500,000**	**1,800,000**	**3,300,000**

Source: UNIDO INFOBASE as of 5 August 2009 and project documents

Project duration. The implementation of phase 1 started in January 2006 and was expected to last 30 months. There have, however, been delays in the project implementation and phase 1 is now expected to complete in December 2009. Phase 2, which closely follows the approach of phase 1, started in November 2008 with a planned duration of18 months, till June 2010.

II. Purpose of the evaluation

In accordance with the UNIDO Evaluation Policy and the Guidelines for the Technical Cooperation Programmes and Projects and in line with the project document, the UNIDO Evaluation Group (OSL/EVA) will conduct an independent evaluation of the project tentatively in October-November 2009. Given the actual implementation time frame and duration, the evaluation will be carried out as an independent mid-term evaluation.

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;
- Identify strengths and weaknesses of the project implementation 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.).

III. Evaluation approach and methodology

The evaluation will assess the project's continued relevance, efficiency, effectiveness and sustainability.

In this context, the evaluation will examine the following aspects:

Relevance

- How relevant is the project 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 thematic priorities
  - ✓ Government of Germany's policies and priorities
- Is the project's design adequate to address the problem(s) at hand? Does the project remain relevant taking into account the changing environment? Is there a need to reformulate project design and log frame given changes in the country and operational context?

Efficiency

The extent to which:

- The donor, UNIDO and Government/counterpart inputs have been provided as planned and were adequate to meet requirements.
- The quality of UNIDO inputs and services was as planned and timely
- The interventions were cost-effective
- There was coordination with other UNIDO and other donors' projects and possible synergy effects
- Has the project reached the expected number of beneficiaries (institutions, targeted companies etc.) within the expected time frame? Are the project's activities in line with the schedule of activities as defined by the project team and annual work plans? Are the disbursements and project expenditures in line with budgets?

Effectiveness

- To what extent have the expected outputs and outcomes been achieved or are likely to be achieved? How do the stakeholders perceive their quality? Were the targeted beneficiary groups actually reached?
- What outputs and outcomes has the project achieved so far (both qualitative and quantitative results)? Has the project generated any results that could lead to changes of the assisted institutions' operations? Have there been any unplanned effects?

Sustainability

- To what extend are the benefits from the project likely to continue after the project completion in terms of financial, institutional, technical and environmental sustainability and local ownership?
- Does the project have an exit strategy? Is it accurate and realistic?

Project coordination and management

The extent to which:

- The national management and overall coordination mechanisms have been efficient and effective. Did each partner have specific roles and responsibilities from the beginning? Did each partner fulfill its role and

responsibilities (e.g. providing strategic support, monitoring and reviewing performance, allocating funds, providing technical support, following up agreed/corrective actions…)?

- The UNIDO HQ based management, coordination, quality control and technical inputs have been efficient and effective.
- 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?

Evaluation steps

The evaluation will encompass the following steps:

Desk review and interviews at UNIDO HQ

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, tools and training guidelines…). Relevant documents from the Government of Germany, selected countries and other development organizations will also be consulted. Interviews will be conducted at UNIDO HQ. The evaluation team will prepare an evaluation plan after the desk review and HQ interviews.

Field visits and interviews

So far the project has implemented activities/interventions at three levels in a number of LDCs and DCs as follow:

Levels	Interventions
Macro – Policy advice	• 8 sector profiles and a Global Market study prepared in collaboration with IMS Health • National dialogue: Cambodia, Lao PDR, Ghana and Tanzania, • Regional workshops: Senegal and Zambia
Meso – Institutional capacity building	• Working with associations and institutions in: Ghana, Tanzania, Southern Africa
Micro – Enterprise support	• Direct support to enterprises in: Botswana, Cambodia, Cameroon, Ghana, Lao PDR, Lesotho and Uganda

Given the wide geographical coverage of the project of 11 countries (see the table above) and few concrete results, so far, at the micro level, it is recommended that the evaluation team should visit three countries where there are either broad project activities at all three levels or in-depth interventions at enterprise level. Ghana, Botswana and Lesotho appear to meet these criteria. The project has activities at all three levels in Ghana and has provided intensive

support to local companies in Botswana and Lesotho. Although the interventions at the enterprise level in Lesotho did not lead to a complete success, the analyses and lessons from the evaluation will provide information on the challenges encountered by the project, on what actually went right/wrong and what could have been done differently, if at all. As the project has a similar intervention in Botswana, the field visits will harness the learning from the evaluation through a comparative review of the two cases.

More specifically, the evaluation team will:

- Interview the UNIDO project manager/s, Chief Technical Advisor, the unit chief and Director of the Private Sector Development Branch in Vienna prior to the field visit to Botswana, Ghana and Lesotho;
- Interview a sample of consultants and/or institutions that were hired by UNIDO to support the project in the countries.
- Visit Botswana, Ghana and Lesotho 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.

For each type of the interviews, the evaluation team will develop their ideas for the coverage and interview guidelines will be used to capture the information required. Field interviews can take place either in the form of focus-group discussions or one-to-one consultations.

Reporting

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. A presentation of preliminary findings will take place at HQ after the field visits. The length of the 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 Government of Botswana, Ghana and Lesotho and Germany for factual validation and comments. On the basis of this feedback, the evaluation team will prepare the final report.

Quality Assessment of the Evaluation Report: All UNIDO evaluations are subject to quality assessments by 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 (Annex 1).

IV. Evaluation team and timing

Expertise required. The evaluation team will include: 1) an International Evaluation Consultant, preferably with knowledge of enterprise development issues and 2) an International Pharmaceutical Consultant with extensive

knowledge and experience in the field of pharmaceutical or generic drugs production or public health in developing countries. The profiles and duties of the international consultants are specified in the job descriptions attached to this TOR.

The UNIDO Field Offices in Ghana and in South Africa, and the project management in Vienna will provide support to the field missions.

Timing. The evaluation is tentatively scheduled to take place in November-December 2009. The final draft report will be prepared within six weeks of completion of the field missions and will be submitted to UNIDO, the Governments of Germany and all the participating countries.

Annex B. List of persons met

Attendance list for debriefing held on January 11, 2010

Name	Job title/Position in company/organization	Name of company/organization
Margareta De Goys	Director	OSL/EVA
Peter Loewe	Senior Evaluation Officer	OSL/EVA
Johannes Dobinger	Evaluation Officer	OSL/EVA
Sophie Zimm	Consultant	OSL/EVA
Agnes Moser	Intern	OSL/EVA
Ricardo Seidl da Fonseca	Officer in Charge	PTC/PSD/BEP
Juergen Reinhardt	Industrial Development Officer	PTC/PSD/BEP
Alastair West	Senior Technical Advisor	PTC/PSD/BEP
Nadine Vohrer	Associate Expert	PTC/PSD/BEP
Bashir Conde	Field Operations Officer	RFO/AFR
Matilda Muweme	Field Operations Officer	Africa Programme

In Lesotho

Name	Job title/Position in company/organization	Name of company/organization
Mr. R. Sefako	Director	GlobaPharm
Mrs. Mothibe	Former CEO, LPC	NUL
Ms. Qenehelo Tsokeli	Former First Secretary, LEB	MoF
Mrs M Matšoara	Pharmacist	MRU/DRU
Mr G. Van Montfort	Deputy Resident Representative	UNDP
Mrs M Ntšekhe	Director, Pharmaceutical Services	MoHSW
Mrs T. Khetsi	President	LPS
Mr Hlabana	Advisor, Essential Medicines	WHO

Name	Job title/Position in company/organization	Name of company/organization
Ms M Khabele	Deputy Principle Secretary	MoHSW
Dr M. Moteetee	Director General Health Services	MoHSW
Mrs Mathabo Klass	Head, Investment Services	LNDC
Mr. M. Makumane	Project Officer	LNDC
Ms. Fumane Maema	Project Manager	LNDC
Mr. M. T. Ramotšoari	Principal Secretary	MoTICM

In Ghana

Name	Job title/Position in company/organization	Name of company/organization
Francois D'Adeseky	UNIDO Representative in Ghana	UNIDO
Louis Nortey	Coordinator Industrial Pharmaceutical Sector Strategy Development	UNIDO/MoTI
Frank Boateng	Chairman, CCM	The Global Fund to fight AIDS, Tuberculosis and Malaria
Edward Larbi-Slaw	Tax Policy Advisor	Ministry of Finance, Economic Planning
Robert Tandor	Deputy Director, SMEs	MoTI
Mike Addo	President, PMAG	Pharmaceutical Manufacturer Association of Ghana
Kwabena Asante	Executive Secretary, PMAG	Pharmaceutical Manufacturer Association of Ghana
Joseph KN Nyoagbe	Registrar	Pharmacy Council, Ghana
Stephen Kwabena Opuni	CEO	Food & Drug Board
John Odame-Darkwah	Ag. Dep. Chief Executive	Food & Drug Board

Name	Job title/Position in company/organization	Name of company/organization
	(Food)	
Ben Botwe	Director Special duties	MoH – *met on the 1st Dec, he didn't inform us he has been interdicted*
T. C. Corquaye	Senior Advisor Pharmaceutical Sector Strategy, Ghana	UNIDO
Paul Lartey	CEO	LaGray Chemical Company, Inc.
Edith Annan	Essential drugs	WHO

List of persons interviewed through Skype- or Teleconference

Name	Job title/Position in company/organization	Name of company/organization
Mr. Frank Schmiedchen	Responsible officer	BMZ
Mr. S. Bologna	Director	UNIDO REP, SA Phone: +27 12 3945 463 Skype: Dec 18, 2009, 12.00 hr
Mr. F. Von Massow	Consultant (strategic advisor, partnership matchmaking in Lesotho and concept of a Network—U4P)	UNIDO Phone: +49 6661 43 99 51 Teleconference: Dec 23, 2009, 10.00 hr
Mr. L. Ehrhardt	Consultant (Match-maker in Lesotho and in Botswana)	UNIDO Phone: +27 218 828 692 Skype: Dec 23, 2009, 15.00 hr
Mr. G. Proctor	CEO	Gemi Pharmacure (PTY) Ltd -Phone: +26 774 714 422 Teleconference Jan 8, 2010, 9.00 hr

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Annex D. Chronology of mission

November 2009

	24	25	26	27	28	29	30
Contract signature	X						
Briefing							
Review project documentation							
Ghana mission							
Lesotho mission							
Interview - Mr F. von Massow expert							
Interview - Mr L. Ehrardt expert							
Interview - Mr F. Schmiedchen - Donor rep							
Interview - Mr Proctor - Gemi Pharmacure Bsw							
Interview - Mr Bologna SA UNIDO's rep							
Deliverables							
Inception report - eval plan & chronology					X		
Aide mémoire - main field findings							
Debriefing in Vienna - ppt							
Draft final report							
Reception of consolidated UNIDO's comments							
Final report							

December 2009

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Contract signature																															
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Review project documentation																															
Ghana mission				X																											
Lesotho mission											X																				
Interview - Mr F. von Massow expert																							X								
Interview - Mr L. Ehrardt expert																							X								
Interview - Mr F. Schmiedchen - Donor rep																															
Interview - Mr Proctor - Gemi Pharmacure Bsw																															
Interview - Mr Bologna SA UNIDO's rep																					X										
Deliverables																						Christmas time									
Inception report - eval plan & chronology																															
Aide mémoire - main field findings				X											X																
Debriefing in Vienna - ppt																															
Draft final report																															
Reception of consolidated UNIDO's comments																															
Final report																															

January 2010

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
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Inception report - eval plan & chronology																															
Aide mémoire - main field findings					X																										
Debriefing in Vienna - ppt											X																				
Draft final report															X																
Reception of consolidated UNIDO's comments																						X									
Final report																													X		

Annex E. Detailed effectiveness

	Activities and Produced Output	Achieved Outcome
1	**Development trends, operational challenges and policy issues related to the production of essential generic drugs in selected LDCs assessed**	
11	Global market study "The market for selected essential medicines: Opportunities for producers in Least Developed Countries" – Procurement process has been launched since July 2007. – It has been commissioned to IMS in October 2007 (PSC P. S., Meeting minutes, 15 May 2008).	First version of the survey has been available in April 2008, a first update has been provided in March 2009 and a second update is expected for the end of 2009. Results have been presented at the regional workshop on Pharmaceutical Production in Southern Africa, in November 2008 and used when reviewing and preparing business plans..
12	International and national consultancies for studies in Senegal/Mali, Nigeria, Cambodia, Lao PR, Lesotho, Uganda, Zambia, Zimbabwe. (Ghana sector profile has been performed by GTZ in 2007)	8 pharmaceutical sector profiles completed. Updates of 4 Scans (Nigeria, Uganda, Zambia, Zimbabwe) are on going Kenya (since Oct 2009) and South Africa sector profiles are planned to be finalised by 2009 year end (UNIDO, Progress Report Covering October 2007 to August 2009, 10th September 2009)
13	Identification of real case examples of business partnerships- with a focus on South-South cooperation – aimed at enhancing access to drugs in developing countries, and assessment of their potential for replication in Phase 2.	4 examples of business partnership identified: – Shelys/Tanzania and Emcure/India – Cipla/India and Quality Chemicals/Uganda – Cipla/India and Cinpharm/Cameroon – Cipla/ Medpro South Africa
14	Holding of enlarged Project Steering Committee Meeting "PSC Plus"	Not held, budget not spent
2	**Strategy and detailed project interventions for increased local manufacturing of essential generic drugs in 3-4 LDCs agreed upon**	
21	Identification of and initial networking with private business from LDCs, other developing countries and developed countries showing an interest in cooperation with LDCs to improve access to essential drugs – Networking with a lot of UN entities	Companies informed of the project and the way to apply Collaboration on the way to be defined and/or effective with WHO, IPC, UCSSIC Contact established and partnership started with private sector, NGO and assessment of actual cooperation

	Activities and Produced Output	Achieved Outcome
	(WHO, IPC, UCSSIC) – Networking with private partners including German Medicines Manufacturer's Association (BAH), Pro-Generica – Workshops at regional levels in Africa (Dakar and Lusaka) and national workshops in Asia (Lao PDR and Cambodia)	potential
22	In-depth constraints analysis and needs prioritisation in each of the selected target LDCs. – Consultation and inception missions in selected countries (Uganda, Zimbabwe, Zambia, Lesotho, Tanzania and Thailand, Lao PDR, Cambodia)	Scope of desirable future project identified
23	Explore scope for access of local LDC producers to international markets	See 21
24	Preparation of and agreement on revised output-activity schedule and ensuing final work plan phase 2	Phase 2 document detailing the interventions and arrangement between the donor and UNIDO signed in Nov 2007.
3	**Overall project management and coordination mechanisms established**	
31	Set up and regularly hold meetings of Project Steering Committee	Effectively done. 4 meetings within 4 years
32	Set up/first meeting of National Project Steering Committees (NPSCs)	Has been modified, see subchapter on "project coordination and management" 3.2 National experts have been put in place in few countries. No formal NPSC in place.
33	Set-up Strategy Advisory Group	Postponed, see subchapter on "project coordination and management " 3.2
4	**Concrete opportunities including business partnerships identified and pilot local production of essential medicines put in place**	
41	Establishment of business advisory, partnership promotion and matchmaking units (BAUs in target countries) – Repeated short term contracts to national experts, with concrete ToR have been implemented	see subchapter on "project coordination and management " 3.2 National Experts have been hired in countries with a minimum level of activity Lesotho, Ghana, Kenya.
42	Plant level SWOT analysis and ad-hoc advice for local medicines-producing SMEs (international consultancies)	Despite few selected plant analysis field missions, that didn't lead to concrete adherence from the local plants (Lao PDR, Cambodia, Uganda), positive

	Activities and Produced Output	Achieved Outcome
		analysis have permit the project to progress in at least 4 countries (Lesotho, Ghana, Kenya, Botswana, Cameroon) – 3 company profiles have been done so far (2 in Ghana and 1 in Botswana) – Pre-feasibility studies at company level have been performed in Lesotho and in Ghana. – Verification of the business plan in Cameroon had been carried out under the leadership of DEG.
43	Identification of concrete opportunities including business partnership for the local production of essential medicines: – Matchmaking consultations – Invitations to submit CPP	– Active facilitation of a search for investors (Ghana, for 1 company) and contacts established – Accompanying the DEG loan through training to Cinpharm Cameroon – Lesotho – Birth of the "UNIDO Pharmaceutical Production Partnership Platform" concept
44	Provision of start-up support towards the local production of essential medicines	– Preliminary assessment in Botswana on green field investment, – Collaboration with AfDB by comments on feasibility study ToR for the Ivory Cost
45	Dissemination of results – Networking described above	– Publication in DIVA magazine – Publication "UNIDO in Africa" presented during the General conference in Nov 2009 – Briefing on the project activities at the UNCTAD/WHO/UNIDO/ ICTSD Ministerial roundtable at ECOSOC in July 2009
5	**Institutional support capacities for the promotion and development of the local manufacturing by SMEs of essential generic drugs upgraded**	
51	Advising public and private sector stakeholders/institutions on improvements of business, legal and regulatory environment. – Through workshops and round tables (included in activity 2.2)	Kenya: approval received for the pharmaceutical sector scan study and support at the 3 levels (Reinhardt, Back to office mission report - Kenya, South Africa, Lesotho, Botswana, 17 march - 2 April 2009) see also 2.2
52	Training of trainers public classroom courses and/or on-the-job training activities	– Cost sharing of training of quality manager of Cinpharm at WHO GMP

	Activities and Produced Output	Achieved Outcome
	(marketing, GMP, quality control/testing) - Funding participants	training in Rabat (July 2008) – Cost sharing of study tour of 11 key production personnel to Cipla's facility in India including 2 weeks training on production, Quality Control, Engineering and Maintenance. – Sponsorship of 14 participants from companies and public institutions from Kenya, Lesotho, Nigeria, Tanzania, Uganda at the Industrial Pharmacy advanced training programme (Kilimanjaro school of pharmacy, St Luke Foundation, Moshi)
53	Upgrading of drug testing/laboratory facilities	Activity cancelled, budget line reallocated (PSC P. S., Meeting minutes, 27 Feb 2007)
54	Strengthen sector specific BMOs and/or related local self-help bodies – Part time Senior adviser recruited to strengthen PMAG – International expert advisory and capacity building support towards the set up of the Southern African Generics medicines Association(SAGMA), including a lawyer and cost sharing of preparing meetings	Ghana – Advocacy from PMAG in the roundtables – Strengthening of PMAG is on going SADC – SAGMA has been inaugurated and the Board is operational
6	**Positive project results effectively communicated and potential for regional cooperation enhanced**	
61	Organize exchanges on experiences and lesson learnt among project counterparts and beyond – Participation in the UNDP/UNAIDS/WHO interagency meeting on intellectual property innovation and access to essential medicines	Follow up on the action plan where UNIDO is mentioned as the stakeholder for promoting transfer technology and the production of health products in developing countries. Decision for a once a year meeting on IPRs See also outcomes under activities 2.1
62	Disseminate successful project outcomes for replication – Concept note sent to UNITAID (International Drug Purchase Facility) in response of a call for proposal – Consultation on possible UNIDO support towards the implementation of the SADC pharmaceutical	Determination of the SADC secretariat to rely on UNIDO as main technical partner for the SADC pharmaceutical business plan 2007-2013. Cooperation modalities still to be finalized

	Activities and Produced Output	Achieved Outcome
	Business plan	
63	Explore potential for enhanced regional cooperation in promoting local generic drug industries – See outputs 2.1 West and Southern Africa workshop – A consultant attended the second meeting of the technical committee on the Pharmaceutical Manufacturing Plan for Africa (PMPA), implemented by the African Union Ministers of Health, in Johannesburg, February 2008. – Participation in WHO/DFID/GF/CF workshop on Drug Registration Harmonisation across regional economic communities, SA Feb 2009	Compatibility and contribution of the UNIDO project into the PMPA are identified in most tasks of this technical committee(Walter, 18-19 February 2008) Lusaka workshop resulted in the set up of SAGMA and plant level support to Botswana.

Annex F. Potential donors

The Netherlands Foreign Trade Agency, EVD, carries out the Private Sector Investment Programme (PSI) for the Dutch Ministry of Foreign Affairs/Development Cooperation. The PSI stimulates and supports private and public sector organizations and supports innovative investment projects in emerging markets in Africa, Asia, Central and Eastern Europe and Latin America. A PSI project is an investment project, implemented by foreign company together with a local company, in one of the eligible developing countries. If this investment meets the criteria, it can be eligible for a grant by PSI. This grant consists of a financial contribution to the costs of the investment. Ghana and Kenya are among the list of eligible countries.

Medicines Transparency Alliance (MeTA) work through national and international partners (including but not limited to DFID, the World Health Organization and Health Action International) to support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management. The added value of this initiative would entail explicit commitments from international actors in support of national efforts, coupled with focused technical and financial support to strengthen transparency and accountability. Such national efforts would seek to improve access to information about medicine quality, availability and pricing, with strong civil society and consumer involvement in scrutiny and debate.

MeTA has been launched as a global alliance in mid-2007, with pilots running in four countries. Among the possible activities of MeTA, the following could match with the outcomes and objectives of the project under evaluation:

- helping countries establish and maintain a multi-stakeholder working group or forum, engaging the public, private and non-profit sectors,
- working with countries to produce country-specific MeTA reports, which would bring data together and further analyse and contexualise issues related to quality, availability and price, and to disseminate these reports through the media and public interest groups;
- with support from a dedicated research 'observatory', developing and building awareness of guidelines and case studies on good practice, as appropriate and pooling information from different countries to build a global resource.

UNITAID's mission is to contribute to scaling up access to treatment for HIV/AIDS, malaria and tuberculosis, primarily for people in low-income countries, by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available. Recently, UNITAID's Executive Board made a landmark decision to establish a Patent Pool for AIDS medicines. The pool, scheduled to start operating in mid-2010, aims to make newer medicines available in patient-adapted form, at lower prices, for low- and middle-income countries. "UNITAID has now put in place a mechanism that will make medical advances work for the poor, while compensating companies for sharing their technology."

The Patent Pool will allow generic companies to make lower cost versions of widely patented new medicines by creating a common space for patent holders to license their technology in exchange for royalties. This will spur competition and further bring down the price of vital new and effective medicines, giving hope to millions of patients.
UNIDO has already applied to UNITAID but didn't win the tender (UNIDO, Concept note, 27 Feb 2008). Surely, a new proposal would be worth to be developed one more time to UNITAID, now.

The Finland Ministry of Health and Ministry of Foreign Affairs, as well as the Norway Government could be also a good track to explore in order to include this project into their ongoing programs.

International Finance Corporation is a member of the World Bank group; it fosters sustainable economic growth in developing countries by financing private sector investment, mobilizing capital in the international financial markets, and providing advisory services to businesses and governments. IFC helps companies and financial institutions in emerging markets create jobs, generate tax revenues, improve corporate governance and environmental performance, and contribute to their local communities. The goal is to improve lives, especially for the people who most need the benefits of growth. IFC invests in enterprises majority-owned by the private sector throughout most developing countries in the world including Sub-Saharan Africa.

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