



PROMOTING LOCAL **PHARMACEUTICAL** PRODUCTION IN UGANDA

Challenges facing local pharmaceutical firms

Report of A Survey conducted June 2013



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ABBREVIATIONS AND ACRONYMS

ACTs	Artemisinin Combination Therapies
APDL	Abacus Parenteral Drugs Limited
APIs	Active pharmaceutical ingredients
ARVs	Anti-retroviral (medicines)
CEHURD	Center for Health Human Rights and Development
cGMP	Current Good Manufacturing Practice
EMHS	Essential Medicines and Health Supplies
GDP	Gross domestic product
GMP	Good Manufacturing Practice
HSSIP	Health Sector Strategic and Investment Plan
KPI	Kampala Pharmaceutical Industries
MDGs	Millennium Development Goals
MoH	Ministry of Health
NDP	National Drug Policy
NMS	National Medical Stores
NPSSP	National Pharmaceutical Sector Strategic Plan II
PSU	Pharmaceutical Society of Uganda
QCIL	Quality Chemical Industries Limited
R&D	Research and Development
UIA	Uganda Investment Authority
UMA	Uganda Manufacturers Association
UNDP	United Nations Development Programme
US\$	United States Dollar
VPP	Voluntary Pooled Procurement
WHO	World Health Organisation
WTO	World Trade Organisation

EXECUTIVE SUMMARY

This work assessed the capacity of selected pharmaceutical manufacturing firms in Uganda and identified the challenges they face in increasing and maximising their supply and contribution to access to essential medicines.

The World Health Organisation (WHO) Framework for Collective Action on Equitable Access to Essential Medicines envisages cooperation of pharmaceutical companies in maximising access to affordable, essential drugs on a sustainable basis, and in progress toward achievement of the United Nations Millennium Development Goals (MDGs).

The need for local production of essential medicines has been recognised internationally, and in Uganda, it has been on an upward growth over the recent years. This has been facilitated by tax exemptions for imports of raw materials and machinery used in pharmaceutical production; the improving infrastructure (information technology and water supply); and the country's open market economy and the untapped regional pharmaceutical market.¹

However, the pharmaceutical industry is still generally at infancy, and barely accounts for one tenth of the country's medicine market share. Basing on an assessment of five local pharmaceutical manufacturing firms, this survey identified the following challenges:

- **Gaps in government support to the pharmaceutical firms**

Respondents reported that support from government in terms of investment incentives is far from adequate. They indicated that tax waivers and concessions are meagre and barely enough to reduce the costs of production. They expressed concern about the ad hoc nature of accessing certain incentives in the sector, particularly land.

- **Market-related challenges**

Market access still remains a major challenge for the local pharmaceutical manufacturing industry. The Ugandan pharmaceutical market is dominated by Asian imports, which supply up to 90 percent of the country's medicine needs. Local manufacturers account for a paltry 10 percent of the medicine supply needs of the country. Respondents reported that they have difficulties supplying drugs to the public sector, which is by far the largest single market for medicines. A major concern relates to the practice of donor countries and agencies whose procurement policies do not favour local pharmaceutical producers

- **High costs of production**

All pharmaceutical manufacturers in Uganda process imported active pharmaceutical ingredients (APIs). They also use imported packaging materials, and run costly alternative energy provisions. Because of the small market they serve, and the fact that they operate below

1 Rugumambaju and Kutwabami, 2010.

capacity, they are not in position to purchase inputs in bulk and hence do not benefit from economies of scale.

- **Limited access to affordable business financing**

The pharmaceutical manufacturing is typically a high capital venture that requires a lot of financial investment for one to establish a plant that meets Good Manufacturing Practice (GMP). There is no special financing facility for pharmaceutical investments, and yet the commercial borrowing market is too expensive and offers only short-term financing.

- **The pharmaceutical market is still indeterminate**

There is a lack of credible basic information on the pharmaceutical industry and market, including the types and volumes of medicines produced in the country, on imported medicines as well as on the medicine needs of the country. Without this kind of baseline information, respondents indicated it was difficult to have guided investment plans.

- **Insufficient capacity of NDA to control quality of medicines**

NDA is primarily mandated under the National Drugs Act to regulate the production, importation and supply of medicines in the country. However, due to various challenges the NDA has not effectively regulated the manufacture and importation of pharmaceutical products in Uganda. Respondents questioned NDA's capacity to check foreign manufacturers to ensure that they are complying with manufacturing standards, and that competition in the market is fair

- **Weakness of the Uganda Pharmaceutical Manufacturers' Association**

Uganda Pharmaceutical Manufacturers Association (UPMA) has not succeeded in winning over all local pharmaceutical manufacturers into its membership. At the time of this survey, the Association had an active membership of six companies – KPI, QCIL, APDL, Medipharm Industries, Rene Industries, and Quality-Afro Asia – fewer than half the country's known pharmaceutical producers. The limited membership has undermined the ability of UPMA to be a vehicle for collective lobbying.

- **Limited investment in research and development**

The pharmaceutical industry has not invested in R&D, which is necessary for keeping track of diseases, improving efficiency and improving product quality, among others. QCIL is the only producer with a formal Research and Development (R&D) Division, but it is still in its infancy. Universities are involved in some form of R&D, but collaboration with pharmaceutical firms is limited.

- **Inadequate human resources**

Skilled technical personnel with sufficient know-how of the highly sensitive pharmaceutical producing technology and to undertake R&D is in short supply. The supply of pharmacists in the country is far below demand. The quality of the available labour force is therefore relatively low to meet the requirement of investors in the pharmaceutical industry. This has led to dependence on relatively more expensive expatriates largely from Asia, and on interns who are usually fresh graduates who must be trained at a high cost.

Recommendations

- Respondents in this survey urged government to adopt a policy of restricting importation of all medicines that are produced locally
- EAC member states should consider taking concerted measures to protect the regional pharmaceutical production.
- Civil society organisations and other players with a neutral voice should carry out sensitisation campaigns and policy advocacy to support the ability of local manufacturers to compete in the local market.
- Government should expand and streamline the incentives scheme, and set up a pharmaceutical manufacturing zone, with preferential tariffs, joint R&D initiatives, and access to essential facilities like water, electricity and transport infrastructure.
- Government should work with the banking sector to provide a financing facility specifically for the pharmaceutical sector similar to those provided for agriculture, and a technology fund established to facilitate R&D
- NDA should collect and share routine information on the pharmaceutical market and medicine needs.
- NDA should re-orient its inspection and approval processes to encourage the local manufacturers grow while also maintaining the robustness of the process to guarantee product quality
- Government should increase investment in specialised training, particularly in the science fields, in order to increase supply of skilled workers to the manufacturing sector and the R&D field. UPMA should undertake a resource need assessment of the pharmaceutical manufacturing industry
- Government should seek the support of the World Trade Organisation (WTO) and other multilateral bodies to promote mutually beneficial partnerships between local and foreign manufacturers in order to acquire technological capacity for local producers.

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The survey was conducted by Mr Denis Kibira, Mr Moses Mulumba, Ms Primah Kwagala and Mr James Zeere. The report has been edited and designed by Mr Richard Hasunira.

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The cover image was obtained from www.constructionweekonline.com.

INTRODUCTION

This section presents an overview of the background to the survey, the situation of access to medicines in Uganda, the role of local pharmaceutical production in improving access to essential medicines, and the objectives of the survey.

Background

Lack of access to essential medicines is one of the most serious global health problems.¹ When medicines are not available, affordable, of assured quality and properly used, health is compromised and lives are lost. The World Health Organisation (WHO) estimates that more than one third of the world's people – most of them in Africa and Asia – do not have regular access to full and effective treatments with the medicines they need.

The WHO framework for collective action on equitable access to essential medicines envisages cooperation of pharmaceutical companies in maximising access to affordable, essential drugs on a sustainable basis, and in progress toward achievement of the United Nations Millennium Development Goals (MDGs).

According to WHO, medicine production is highly concentrated in industrialised countries. Only five countries – United States, Japan, Germany, France and United Kingdom worldwide – account for two-thirds of the value of all medicines produced worldwide. In addition, large-volume production of lower-price medicines only exists in the highly competitive domestic markets of China and India.²

In 2004, WHO undertook a classification of countries, according to their medicines production capability. Of 188 countries classified, 10 industrialised countries had “sophisticated industry with significant research”; a further 16 countries, including India and China, were grouped as having “innovative capability”, with India described as having a rapidly growing pharmaceuticals biotechnology market. Ninety-seven countries had a domestic medicines industry based on reproducer firms, manufacturing branded or generics; although the majority (84) of these countries manufacture finished products from imported ingredients, 13 countries (including Brazil, Egypt, Norway, Turkey and Indonesia) were considered to have industries that make both active ingredients and finished products.

The need for local production of essential medicines has been recognised internationally. The International Conference on Primary Health Care, held in Alma-Ata in 1978, stated: “In developing a supply system, consideration has to be given both to cost and to national and local production as part of overall development. For example, it may be cheaper to buy certain items

1 DFID, 2004, Increasing access to essential medicines in the developing world: UK government policy and plans

2 WHO, 2011. Local production for access to medical products: Developing a framework to improve public health

abroad, but economically more productive in the long run to produce them within the country.”

Encouraging and promoting local production of pharmaceuticals serves to bring the price of drugs down in host countries, and thereby increase access. Local production might serve this purpose in a variety of ways: it could lower transportation costs and hence overall costs; it could increase the number of producers in a local market, increasing both supply and competition, which over the long term should drive drug prices down and hence increase access. Local production can also increase employment; and increase domestic expertise in the production of medicines for key local diseases and cut dependence on foreign suppliers. For these reasons, promoting local pharmaceutical production in developing countries is not only seen as a potential solution to the problem of public access to medicines, but is also seen as having other valuable socioeconomic benefits as well.

Industrial and innovation policy advocates argue that static costs of developing production capacity can be offset by the dynamic gains that accrue from reasonably priced products that are locally produced in the mid- or long term, provided countries ensure a policy environment that secures increasing financial returns to local enterprises over time. Other arguments in favour of local production in small developing countries include reliability of supply, foreign import savings, and the potential impact on the global market by increased competitive pricing. The indirect benefits of promoting local production on national economies have also been identified as including employment generation, foreign export earnings through export of medical products, and spill-over effects in other sectors of the economy. The need for government support, however, is also emphasized in these arguments.

Increasing access to essential, efficacious, safe, good quality and affordable medicines and other health supplies is one of the major priorities of Uganda’s health sector³. One of the strategies for ensuring access to essential medicines is through strengthening the policy and legal environment governing the production, procurement and distribution of pharmaceuticals.

Whilst still at infancy, Uganda’s pharmaceutical industry has been on an upward growth over the recent years. The pharmaceutical sector in Uganda has evolved over the last 15 years from two large manufacturing plants registered in the mid-1990s, to 15 companies of varying sizes. In early 2010, the country’s largest pharmaceutical manufacturer, Quality Chemicals Ltd., received the WHO Good Manufacturing Practices (GMP) certification for production of anti-retroviral medicines (ARVs) and artemisinin-based combination therapies (ACTs) for treatment of HIV/AIDS and malaria, respectively.

As of December 2009, Uganda had a total of 19 sites licensed for the manufacture of medicines and health supplies, although only 11 of these were involved in commercial production of pharmaceuticals.⁴ Using the

3 Government of Uganda, Ministry of Health (2009). Health Sector Strategic Plan III 2010/11-2014/15, Para 6.13 (b), p.102

4 Rugumambaju, S. and Kutwabami, P. 2010. Pharmaceutical Sector Profile: Uganda.

Söderbom and Teal 2003 classification of African manufacturing firms, based on the number of employees, four of the 11 manufacturers operate on a large scale (100 or more employees), six on a medium scale (between 31 and 99 employees), and one operates on a small scale (between six and 30 employees). The local pharmaceutical industry contributes about 0.18 per cent of GDP and employs about 1,216 people. In 2008, exports of medicines and other health supplies were estimated at some US\$ 3.1 million.⁵

There are several factors that have supported local manufacture of pharmaceuticals and these, according to a 2010 survey by the United Nations Industrial Development Organisation (UNIDO), include, among others: tax exemptions for imports of raw materials and machinery used in pharmaceutical production; the improving infrastructure (information technology and water supply); and the country's open market economy and the untapped regional pharmaceutical market.⁶

Whilst the local pharmaceutical industry has developed significantly over the last 10 years, Uganda still imports 90 percent of its Essential Medicines and Health Supplies (EMHS).

According to the Health Sector Strategic and Investment Plan (HSSIP), about 90 percent of EMHS are imported from India and China and about 60 percent are distributed by the private sector. Only 7 percent of the local drugs are branded medicines and the remaining 93-95 percent is generic medicines.

Local manufacturers face major challenges that are not only undermining their contribution to access to essential medicines in Uganda, but are also likely to affect their long-term commercial viability. The second National Pharmaceutical Sector Strategic Plan (NPSSP II) recognises that there was an increase in the local productions of medicines especially of ARV and artemether/lumefantrine (AL) and parenterals⁷ in the preceding few years. It However, it also recognised that the low number of pharmacists and dispensers in the country are limiting access to quality pharmaceuticals services.

The bulk of the medicines provided by the government are not locally funded but have been funded through global initiatives which ultimately determine the source and destination of the medicines whose supply they fund. Only 30 percent of the Essential Medicines and Health Supplies (EMHS) are provided for in the national budget. In 2006/7 for example global initiatives finance USD 2.39 per capita out of the USD 4.06 per capita spent on EMHS.⁸

United Nations Industrial Development Organisation (UNIDO), Vienna.

5 Rugumambaju and Kutyabami 2010.

6 Rugumambaju and Kutyabami, 2010.

7 Parenteral preparations are sterile, pyrogen-free liquids (solutions, emulsions, or suspensions) or solid dosage forms containing one or more active ingredients, packaged in either single-dose or multidose containers. They are intended for administration by injection, infusion, or implantation into the body. There are four main forms of parenteral preparations: injections, intravenous infusions (large volume parenterals), powders for injections, and implants.

8 Government of Uganda, Ministry of Health (2009). Health Sector Strategic Plan III 2010/11-2014/15, p.22

While financing for EMHS shows that there has been increase in per capita expenditure from US\$0.5, 2010/11 to \$0.9, 2012/13,⁹ the demand for essential medicines continues to outstrip supply.

In partnership with the United Nations Development Programme (UNDP), Center for Health Human Rights and Development (CEHURD), undertook an assessment of the capacity of selected pharmaceutical manufacturing firms in Uganda in order to identify challenges they may be facing in increasing and maximising their supply and contribution to access to essential medicines. this report summarised the findings of the survey.

Objective

This survey attempts to identify challenges facing selected pharmaceutical producers in Uganda by:

- α) Assessing the operating environment of local pharmaceutical manufacturers;
- β) Examining the internal capacities to produce pharmaceutical products and to compete effectively with imports;
- χ) Identifying firm-level and industrial needs for competitive production of pharmaceutical products for the local market;
- δ) To identify areas of policy gaps that need to be filled to effectively promote local pharmaceutical manufacturing.

9 Government of Uganda, Ministry of Health, Health Sector Strategic Investment Plan (HSSIP) (2010), Mid Term Review Report on Medicines Management

METHODOLOGY

This section outlines the methodology used in this survey, including the design, scope, population, data collection methods, as well as the data analysis methods.

Survey design

The survey employed a descriptive design in order to capture the views and perspectives of people involved in the pharmaceutical industry and to explore the state of affairs in the pharmaceutical manufacturing sector using qualitative approaches.

Scope

The study was conducted in Kampala district where most of the pharmaceutical manufacturers are concentrated. The subject scope of the study was to primarily inquire into the challenges faced by the pharmaceutical companies.

Population and sample selection

The population of the survey was the 15 pharmaceutical industries listed by National Drug Authority (NDA) on its website. A sample of five local pharmaceutical manufacturers was purposively selected to represent the large and the small-medium size manufacturers. Kampala Pharmaceutical Industries (KPI), Quality Chemical Industries Limited (QCIL), and were Abacus Parenteral Drugs Limited (APDL) were selected to represent the large manufacturers, while Mavid Pharmaceuticals Limited (MPL) and GKO medicines Limited were selected from the small and medium category. The respondents were the entrepreneurs and top management.

Data collection

Data collection was conducted in June 2013. Key informant interview questionnaires were used to guide the data collection. Key members of the data collection team were a pharmacist and lawyers who had good knowledge of the industry as well as the legal and policy frameworks that govern it.

Data management and analysis

The qualitative data collected was subjected to thematic content analysis in accordance with the themes set out in the data collection instrument. The data collected was extracted and analysed into appropriate themes which best highlighted the challenges of the pharmaceutical manufacturers from whom the data was collected. These themes were then further analysed to identify and extract the challenges.

POLICY AND LEGAL FRAMEWORK FOR PHARMACEUTICAL MANUFACTURING IN UGANDA

This section reviews the policy framework governing pharmaceutical production in Uganda.

The Policy Framework

The policy framework governing the production of pharmaceuticals in Uganda consists of the second National Health Policy (NHP II); the Uganda Health Sector Strategic Investment Plan (2010/11-2014/15); the National Drug Policy (NDP, 2002); the National Pharmaceutical Sector Strategic Plan (NPSSP II) 2009/10-2013/14; and National Development Plan (2010/11-2014/15),

National Health Policy

The National Health Policy (2009) recognises that adequate quantities of affordable, good quality essential medicines and health supplies should be accessible to all who need them. As a policy, the government undertakes to ensure availability and affordability of safe, good quality medicines and health supplies to the population of Uganda.

The policy however, also acknowledges that the public sector has been unable to fulfil its mandate to provide medicines to those who need it because of inadequate financial and human resources, capital investment and related management issues. The policy cites, as part of the explanation, shortfalls in the regulatory framework, and highlights the Pharmacy Profession and Practice Bill; Uganda Medicines Control Authority Bill; National Health Insurance Bill, and the Traditional and Complimentary Regulatory Bill as some of the laws that are pending enactment/review to fill the gap.

In the policy, government pledges to encourage local production of medicines and ensure compliance with Standards of Good Manufacturing Practices.

Uganda Health Sector Strategic and Investment Plan

The Uganda Health Sector Strategic Investment Plan (2010/11-2014/15) identifies the major stakeholders involved in national medicines as National Medical Stores, Joint Medical Stores, and NDA.

As a strategy to increase the supply of medicines and essential health services, the plan undertakes to strengthen the policy and legal environmental governing the production, procurement and distribution of pharmaceuticals in Uganda. To this end the plan undertakes to work with local companies and encourage them to produce medicines local in compliance with Standards of Current Good Manufacturing Practices.

National Drug Policy

The National Drug Policy (NDP) (2002) was drawn to contribute to the attainment of a good standard of health by the population of Uganda, through ensuring the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy, and by promoting their rational use. Under the policy, government commits to boosting local production through creation of a conducive environment for building national capacity to produce essential drugs and to ensure that local production follows recommended standards, namely the current Good Manufacturing Practice (cGMP), as well as the statutory requirements.

To realise these objectives, the policy promises to create a system of incentives for the local manufacture of essential drugs (such as tax incentives, tender preference, reduced import tariffs, reduced rates for electricity and water consumption); to institute regular and systematic inspection of premises and processes to ensure full adherence to licensing requirements and cGMP; to improve local pharmaceutical technical capacity by encouraging and assisting in the training of sufficient numbers of human resources in pharmaceutical production techniques, quality assurance and cGMP; and to institute a system of monitoring and support supervision to ensure maintenance of required standards.

The policy also undertakes to ensure that appropriate information on the correct use and storage of drugs is readily available, widely disseminated and used accordingly. To achieve this it undertakes to establish a drug information infrastructure/system, including a National Drug and Poisons Information Centre, to provide on request and actively disseminate objective, relevant, practical and up-to-date information to health workers and consumers. It also promises to establish a suitable body, representing all agencies involved in production and dissemination of drug and therapeutics and rational drug use information and including relevant consumer bodies to ensure the relevance, appropriateness, harmonisation and coordination of the information to be provided and to avoid conflicting messages and duplication of effort and expense.

National Pharmaceutical Sector Strategic Plan

The second National Pharmaceutical Sector Strategic Plan (NPSSP II) 2009/10-2013/14 sets out strategies to prioritise and streamline the pharmaceutical sector by providing for policy guidelines and to ensure availability and rational use of essential, efficacious, safe, good quality and affordable medicines.

As part of the policy strategies, government commits to supporting the local production of pharmaceuticals through among other strategies, facilitating acquisition of appropriate manufacturing facilities/equipment to comply with GMP; enable acquisition of improved technology; encourage R&D; build human resource capacity; facilitate reduced operational costs; and strengthen regulatory capacity.

Government further undertakes to commission a pharmaceutical development research fund; develop a comprehensive protocol for industrial training; develop a list of products that can be manufactured or prepared economically in a hospital; and ensure that pharmaceutical manufacturers take part in ministerial trips abroad.

National Development Plan

The National Development Plan (2010/11-2014/15) recognises the pharmaceutical industry as one of the key manufacturing industries in Uganda. Under the Plan, government commits to ensuring that local pharmaceutical production follows recommended procedures (current Good Manufacturing Practice (cGMP) and statutory requirements), the plan undertakes to ensure that local production follows recommended procedures and to strengthen the existing regulation and its enforcement in the pharmaceutical sector.

The Legal and Regulatory Framework

The legal and regulatory framework consists of the Uganda Investment Code Act; the National Drug Authority and Policy Act; the Food and Drugs Act; and the Public Procurement and Disposal of Public Assets Act.

Uganda Investment Code Act

The Uganda Investment Code Act, which went into effect in 1991, regulates local and foreign investments in Uganda and establishes the Uganda Investment Authority (UIA), whose functions are to, among others, promote and regulate the investment sector.

The Act creates incentives for investors importing any plant, machinery, equipment, vehicles or construction materials for an investment project in form of concessional rates of import duty and other taxes.

An investor commencing operation also qualifies for an incentive if their business enterprise contributes to the generation of new earnings or savings of foreign exchange through exports, resource-based import substitution or service activities; utilisation of local materials, supplies and services; the creation of employment opportunities; introduction of advanced technology or upgrading of indigenous technology; or contribution to locally or regionally balanced socioeconomic development. The Act lists the pharmaceutical industry as one of the priority areas, and hence, investors in this industry are entitled to extra incentives from government.

National Drug Authority and Policy Act

The National Drug Authority and Policy Act, which went into force in December 1993, establishes the national drug authority (NDA) to generally regulate the local circulation of pharmaceutical products, and to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

The Act sets rules for regulation of the importation, production, distribution, marketing, exportation and use of pharmaceuticals in the public as well as in the private sector.

The Act imposes restrictions on manufacturing of drugs not included on the national formulary or speciality unless the drug or preparation is approved by the authority, and drugs can also only be imported or exported under licenses granted by NDA. Classified drugs should also be manufactured under supervision of a pharmacist unless in some instances they are under supervision of a medical practitioner.

NDA is mandated to encourage research by persons carrying on research and development in herbal and other medicines and where appropriate take such medicines into production as a component of the drug supply.

National Drug Policy and Authority Regulations

The National Drug Policy and Authority (Certificate of Suitability of Premises) Regulations provide for the application for inspection and approval of premises to be used in the manufacturing and sale of pharmaceutical products.

The National Drug Policy and Authority (Issue of Licences) Regulations provide for the application and issuance of licenses to sell Class C drugs¹⁰, to operate pharmacies, to manufacture drugs and to import drugs.

The National Drug Policy and Authority (Prescription of Forms) Regulations provide for the forms to be used in application for the several pharmaceutical approvals and licensing.

The National Drug Policy and Authority Regulations amplify the provisions of the Act and provides for the procedural measures to be taken in the implementation of the Act.

¹⁰ Class C licensed drugs are specified in the National Drug Authority and Policy Act as drugs that in a form suitable for sale by retail only by a person or company operating a licensed pharmacy or a licensed drug seller, but in the case of the latter, only in accordance with the terms of his or her licence.

Food and Drugs Act

The Food and Drugs Act, which has been in effect since 1959, provides for the prevention of adulteration of food and drugs and related matters. The Act makes it an offence to add any substance to, or abstract any constituent from, a drug so as to affect injuriously the quality, constitution or potency of the drug, with intent that the drug shall be sold in that state. It is also an offence to sell any drug which is not of the nature, or not of the substance, or not of the quality, of the food or drug demanded by the purchaser.

Public Procurement and Disposal of Public Assets Act

The Public Procurement and Disposal of Public Assets Act 2003 established the Public Procurement and Disposal of Public Assets Authority to regulate public procurement and disposal of public assets. The Act sets principles governing public procurement and disposal of public assets as: non-discrimination, transparency, accountability and fairness, competition, confidentiality, economy and efficiency, ethics, preservation and reservation, open competitive bidding, best evaluated bids, public accessibility and publication of information and opportunities (Part IV). The Act requires government entities involved in procurement to use the open domestic bidding method of procurement.

FINDINGS

This section summarises the key results from the survey and outlines the issues inhibiting the pharmaceutical sector in Uganda

Gaps in government support to the pharmaceutical firms

The government of Uganda has a policy strategy to encourage local production of medicines through: facilitating acquisition of appropriate manufacturing facilities/equipment to comply with GMP; enabling acquisition of improved technology; encouraging research and development (R&D); building human resource capacity; facilitating reduced operational costs and strengthening regulatory capacity.¹¹

Under the Uganda Investment Code Act, investors importing any plant, machinery, equipment, vehicles or construction materials for an investment project are offered incentives in form of concessional rates of import duty and other taxes. The pharmaceutical industry is listed as one of the priority areas, and hence, investors in this industry are entitled to extra incentives from government. In addition, in 2012, government announced a price preference policy that favours local manufacturers by giving them a 15 percent price advantage in National Medical Stores (NMS) procurements.

Respondents however, reported that this and other support from government is far from adequate. They indicated that tax waivers and concessions are meagre and barely enough to reduce the costs of production. For example, APIs and equipment can be imported free of tax but spare parts for the same equipment, packaging material and other accessories like air handling systems are not tax exempt which is a lacuna in the tax laws.

Some players in the pharmaceutical sector also expressed dissatisfaction with the ad hoc nature of accessing certain incentives in the sector, citing the case of Quality Chemical Industry Limited (QCIL) acquired the land on which it is located in Luzira, got a tax holiday of ten years, and was able to negotiate an arrangement to supply government with Anti Retrovirals (ARVs) and Artemisinin Combination Therapies (ACTs). Government provided these incentives on special request from QCIL and have been crucial in the company's survival. Some respondents reported that such opportunities were minimal or unavailable, especially to the smaller manufacturers who do not have as much clout and influence over government.

Respondents in other companies reported that they had not accessed any incentives through such an ad hoc arrangement. Respondents at Abacus Parenteral Drugs Limited (APDL) reported that they had requested Uganda Investment Authority (UIA) for land in the Industrial Park in Luzira but its request was reportedly not granted until the proprietors mobilised resources to purchase their own land in Mukono.

**B.S. RAMESH BABU,
APCL:**

“...except the regulation which has a few problems for example we were planning to bring an air handling system on which we were expected to pay tax and yet it is a requirement for the pharmaceutical industry to have an air handling system. It's a requirement to have the air handling system as part of the GMP requirements but they tax it.”

¹¹ Government of Uganda, Ministry of Health (2008), National Pharmaceutical Sector Strategic Plan for Uganda (NPSSP) II 2009/10-2013/14

Respondents recommended that the existing incentive structure for the pharmaceutical industry should be expanded given the sector's importance in improving access to essential medicines and improving the health of the citizens; and to set clear, predictable guidelines for accessing them equitably for a level playing field in the industry.

Market-related challenges

G.W.BAGUMA, QCIL:

"...land we are on was given to us on condition that we put up the plant. For us we requested for that incentive but it is not written anywhere. There is no policy that the government will give you land. You have to ask for an incentive."

DR. GILBERT OHAIWE, GKO PHARMACEUTICALS:

"...why our factories are closing? (It is) because they cannot compete with the Indians, Chinese and Pakistanis because their manufacturing costs are very low for reasons well known to them so when you make something here and you do your pricing you can't compete with them because of their prices..."

G.W. BAGUMA, QCIL:

"There is another big problem of dumping. Many donors like now through this VPP...Voluntary Pooled Procurement...they pool drugs from all over the area then negotiate the price, buy from there and then they give you. So they have been giving NMS a lot of drugs rendering this place useless. Why would they buy from us if they have drugs but international circles are just killing off the facility?"

Market access still remains a major challenge for the local pharmaceutical manufacturing industry. The Ugandan pharmaceutical market is dominated by Asian imports, which supply up to 90 percent of the country's medicine needs. Local manufacturers account for a paltry 10 percent of the medicine supply needs of the country. Respondents reported that the collective market share of local manufacturers needs to expand significantly beyond this paltry proportion if the industry and individual firms are to achieve commercial viability. They cited the case of Uganda Pharmaceuticals Limited, one of the oldest pharmaceutical manufacturers in Uganda closed shop as it became increasingly difficult to sustain operations.

Respondents also reported that they have difficulties supplying drugs to the public sector, which is by far the largest single market for medicines. They reported that it is extremely difficult for local manufacturers, particularly the small and medium producers, to meet the stringent bidding requirements of NMS, the national medicine procurement and distribution agency. Respondents reported that the 15 percent price preference policy for local pharmaceutical producers that was announced in 2012 was yet to be effected.

As a result a small market, the relatively large manufacturers, such as APDL and QCIL are producing far below capacity. APDL reported producing at only 50 percent capacity because of market limitations. Respondents at APDL reported that they are trying to expand their market to South Sudan and Rwanda as a way of broadening the existing market. They reported that they had found challenges penetrating the Tanzanian and Kenyan markets despite being under a regional integration arrangement with Uganda.

Another factor that respondents cited is the practice of donor countries and agencies whose procurement policies do not favour local pharmaceutical producers. The bulk of the medicines for HIV/AIDS, reproductive health and malaria are supplied by donors who source supplies internationally, sometimes through pooled procurement but also sometimes through favouring their home producers.

Global Fund, UNITAID and other global health initiatives use the Voluntary Pooled Procurement (VPP), an international bulk purchasing mechanism to procure medicines at least prices as a way of improving access to essential medicines. This pooled procurement does not favour Ugandan manufacturers whose prices may not be competitive at the international level, and many of who do not have WHO prequalification, and produce limited volumes. QCIL, the only facility with WHO approval in Uganda,

has reported also not been successful in this international bidding arrangement. Respondents reported that they had limited knowledge of the qualifications required to win international medicine supply tenders under the donor pooled procurement.

High costs of production

One of the major factors making locally produced pharmaceuticals uncompetitive is high costs of production. All pharmaceutical manufacturers in Uganda process imported active pharmaceutical ingredients (APIs). This is in addition to technology, packaging material and other inputs which are not manufactured in Uganda and have to be imported. Respondents at APDL reported that they require bottles for packaging of the parenteral medicines and good packaging material requires to be imported with a Drug Master File available with only two suppliers in the world. This material reportedly costs three times the normal cost and has to be competed for with other manufacturers, hence it is not readily available. For local manufacturers who have to purchase in small volumes due to small markets and low production, negotiating power for the purchase of APIs and other materials is highly fettered.

Uganda being a landlocked country makes importation very expensive. KPI for example pays between US\$ 800 to US\$1000 to import material from Mumbai, India to Mombasa, Kenya. However, it costs between US\$ 2500 and US\$ 3000 to move the material from Mombasa to the KPI premises in Kampala. The transportation infrastructure from Mombasa to Kampala is also a challenge; it takes between 12-14 days to transport raw materials into the country which is too expensive in terms of time.

The cost of production has further been aggravated by the expensive and unreliable cost of power in the country which has compelled the local manufacturers to employ alternative sources of power which also unreliable and immensely expensive. The unreliable power supply is mainly characterised by ever increasing power tariffs and rampant load shedding which has made Uganda a very difficult and expensive place to invest in being one of the countries with the most expensive electricity in the world. QCIL for example has two standby electricity generators which are turned on at a huge cost every time power goes off. APDL on a daily average gets power interruptions of two hours and the cost of running generators is three times that provided by national power grid.

These factors have therefore heightened the cost of production for pharmaceutical products in the country and coupled with the minimal government support of the sector have collectively pushed the prices of the medicines up thereby making them unable to compete domestically, regionally and internationally against the highly subsidised Chinese, Indian and Pakistani products. Government proposed preferential tariff rates on electricity and water¹² have not been implemented. The cost of production is therefore a significant non-tariff barrier which has inhibited the development of local pharmaceutical manufacturers.

G.W. BAGUMA, QCIL:

“If you are producing for Uganda it is a very small market. But you find companies in India manufacturing for the whole world. So when you are negotiating for the purchase of APIs or other raw materials the volume of the load will increase costs and as we have low quantities.”

B.S. RAMESH BABU, APCL:

“...it is too expensive for us because the cost of running generators is too high for us compared to the normal power. If you look at it in a month, on average we are running about 60 hours which is so much without power yet I need about 100 litres per hour. It is very expensive so if you compare it, it is three times the cost of the fuel.”

¹² Government of Uganda, Ministry of Health (2008), National Pharmaceutical Sector Strategic Plan for Uganda (NPSSP) II 2009/10-2013/14

Limited access to affordable business financing

G.W. BAGUMA, QCIL:

“First of all to set up a plant which is WHO GMS compliant is a very expensive venture and there is no funding available to this extent except you going to get from commercial banks. This means that you will pay high interest rates and you have short repayment periods (5yrs). So that makes it a very expensive venture. So when people are arguing about price they forget that the investment is very high for you to get that medicine.”

RESPONDENT AT MAVID PHARMACEUTICALS:

“...we are not supported as manufacturers because the interest is minimal...financially banks even alter interest rates on existing loans which makes it difficult for us to pay back. The government doesn't even protect us from such errant banks and financial institutions.”

The pharmaceutical manufacturing is typically a high capital venture that requires a lot of financial investment for one to establish a plant that meets Good Manufacturing Practice (GMP). Unfortunately, the people interested in engaging in local pharmaceutical production do not have the necessary financial capital required to venture into such an investment and even those who start eventually fail along the way because they run out of finances. Responses in this survey indicated even large investors need business financing to set up and or run their operations.

Borrowing interest rates are as high as 22 percent or more, and the depreciating value of the shilling which is estimated at 8-10 percent per annum makes the cost of foreign currency-denominated loans prohibitive and unaffordable.

Respondents at QCIL reported that they acquired loans from banks in order to start up, which put the company in a terrible financial situation and yet the money had to be repaid over very short period of five years. KPI on the other hand is only able to get preferential finance rates because of being part of the Aga Khan Group, which also owns financial institutions. It is difficult to access affordable finance since there are no financial concessions being made for pharmaceutical producers as was envisaged in the NPSSPII compared for example to the agricultural industry where the Uganda Development Bank avails farmers with finance at relatively more reasonable interest rates of about 10 percent per annum.

Access to affordable long-term business finance is needed not only to start up pharmaceutical manufacturing plants, but also to expand and upgrade existing ones to global standards.

The pharmaceutical market is still indeterminate

NAZEEM, KPI:

“I am not sure of what area I should go into...if we should develop a product for cancer, am not sure of what cancer. If we go for cholesterol, blood pressure...there are so many diseases which we know are there but If we can't quantify it, we cannot know how much opportunity is there commercially.”

One of the guiding factors in making a decision to engage in any kind of investment is the availability of demand. To this end, for effective investment to be made in Uganda, it is important that the size of the pharmaceutical market is assessed on a regular basis. This should include the information on the types and volumes of medicines entering the country as well as those being manufactured.

Without this kind of baseline information, respondents indicated it was difficult to have guided investment plans on the part of pharmaceutical investors, and almost impossible for government to streamline the policy and legal framework, as well as the incentive strategy for the sector. Respondents reported that they are not in position to clearly define the market potential, to facilitate informed investment decision-making.

KPI for example makes a range of products, including anti-malarial medicines, pain killers, medicines for coughs, colds and allergies, and others. Respondents reported that the company had also recognised that the disease pattern in Uganda is continuously changing and lifestyle diseases like hypertension and diabetes were on the rise. With this

knowledge, they have been able to launch a new line of treatments for diabetes and blood pressure to meet the new demand. QCIL on the other hand are fast-tracking plans to develop a new range of treatments for tuberculosis.

Respondents felt that NDA, which routinely verifies medicines entering the Ugandan market, is best placed to synthesise this information for prospective users. One respondent cited the case of the information that NDA exclusively holds regarding the pharmaceutical industry which can be used to promote the local manufacturing of pharmaceuticals if shared strategically by enabling local manufacturers to expand product ranges.

Insufficient capacity of NDA to control quality of medicines

NDA is primarily mandated under the National Drugs Act to regulate the production, importation and supply of medicines in the country. However, due to various challenges the NDA has not effectively regulated the manufacture and importation of pharmaceutical products in Uganda. While it is mandated to carry out inspection of pharmaceutical manufacturers to ensure that the quality of medicines being produced meets the set standards, respondents reported that NDA makes inspection visits to their plants only a year and sometimes one in three years, which is considered too infrequent to assure quality. Respondents blamed weaknesses in inspection, including of medicine imports, for reported increase in substandard and counterfeit medicines on the market. Respondents questioned NDA's capacity to check foreign manufacturers to ensure that they are complying with manufacturing standards.

Local pharmaceutical manufacturers are at different levels of development. For example whereas QCIL is operating a WHO GMP compliant pharmaceutical plant, some companies are running small scale manufacturing plants. However, it was reported that NDA uses a uniform checklist to conduct their inspections which although respondents felt was the professional thing to do, but complained about the "policing" nature in which it is conducted in total disregard of providing support to facilitate corrective action. One respondent described NDA officers as "fault seekers" during their inspections and do not support local producers of pharmaceuticals to develop beyond their shortfalls. This inhibits the growth of the industry which is still at a significantly premature stage.

Furthermore, the period it takes for NDA to approve pharmaceutical products is considered too long and this frustrates the development and production of new products for the local market.

With the NDA which plays the primary role in administration and regulation of the local pharmaceutical sector failing to implement its obligations and in some instances frustrating local manufacturers, there is no way the local industry can grow.

G.W. BAGUMA, QCIL:

"NDA is supposed to be giving information to guide us on planning but now we just invest blindly...Now that should be part of your advocacy. That we need information on drugs, their content and what is there... That is why I told you there must be an assessment of the local capacity. Nobody has done that."

RESPONDENT AT MAVID PHARMACEUTICALS:

"Every year NDA does annual inspection for compliance of local producers however they never act on the findings of the inspection. If you asked for inspection reports you will find that firms which failed the inspection still have licenses and have not been disqualified. This negates the whole purpose and puts into discredit the local manufacturing sector since inspection and approval mechanisms are not effectively being implemented"

B.S. RAMESH BABU, APCL:

First of all a stability study is done for between 6-7 months, then the product is submitted for market authorisation which also takes a very long time. We submitted some medicines for market authorisation some nine months ago but have not yet received market authorisation from the NDA. This period totals to 15 months which is too long and kills the enthusiasm of local manufacturers to produce new products."

Weakness of the Uganda Pharmaceutical Manufacturers' Association

RESPONDENT AT MAVID PHARMACEUTICALS:

The Uganda Pharmaceutical Manufacturers Association (UPMA) is just a tea party which does not help their members and performs no action. This is the reason we take all these trips on our own volition so that we can network which is something they are supposed to be doing for us.”

Uganda Pharmaceutical Manufacturers Association (UPMA) was created as an umbrella organisation bringing together different pharmaceutical manufacturers for joint lobbying, information-sharing, networking, and promotion of harmonious competition in the market. It was registered with a vision of creating a vibrant industry to move the country from dependency to self-reliance in the provision of essential drugs¹³.

However, UPMA has not succeeded in winning over all local pharmaceutical manufacturers into its membership. At the time of this survey, the Association had an active membership of six companies – KPI, QCIL, APDL, Medipharm Industries, Rene Industries, and Quality-Afro Asia – fewer than half the country’s known pharmaceutical producers. Mavid Pharmaceuticals and Uganda Pharmaceutical Company Limited recently pulled out of the Association.

Respondents said the Association was not effective in furthering the interests of its members. One respondent cited the case of Mavid Pharmaceuticals Limited which lost a protracted legal battle against its landlord who unfairly shut down the company’s plant. The Association reportedly did not do enough to defend their member. Instead, the Uganda Manufacturers Association (UMA), which is the umbrella association for all manufacturers in Uganda, actively protested the actions against Mavid and lobbied for the reopening of its plant.

According to respondents, UPMA’s weakness also relates to lack of effective structures through which to streamline its objectives and attract more manufacturers into the association. The limited membership has undermined the ability of UPMA to be a vehicle for collective lobbying.

Limited investment in research and development

B.S. RAMESH BABU, APCL:

“These (our products) are not research products though they are imported to the country and are new to the country. So what we register is the new products we want to bring in.”

The pharmaceutical industry continuously evolves with the ever changing and emerging diseases that it seeks to combat. It is therefore expected that pharmaceutical manufacturers continuously conduct research into the ability of their products to deal with the continuously evolving nature of diseases. While the majority of drugs made in Uganda are generic products, including anti-malarials, antibiotics, pain killers, cough, cold and allergy products, there is very little being done by pharmaceutical manufacturers to improve or expand the range of these products. QCIL is the only producer with a formal Research and Development (R&D) Division, but it is still in its infancy. Universities are involved in some form of R&D, but collaboration with pharmaceutical firms is limited.

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R&D is a very expensive venture because it is by nature a trial and error exercise, and local manufacturers lack access to funds to finance it. In addition, research increases the cost of production which has already been noted to be prohibitive for local manufacturers to compete with the imported medicines. The growth of the pharmaceutical industry has been inhibited by the low levels of R&D, which has restricted local producers to production of off-patent and generic medicines that do not fetch a premium on the market.

Inadequate human resources

Skilled technical personnel with sufficient know-how of the highly sensitive pharmaceutical producing technology and to undertake R&D is in short supply. The supply of pharmacists in the country is far below demand. The quality of the available labour force is therefore relatively low to meet the requirement of investors in the pharmaceutical industry. This has led to dependence on relatively more expensive expatriates largely from Asia, and on interns who are usually fresh graduates who must be trained at a high cost. QCIL reported that it had so far recruited and trained up to 250 interns.

The second human resource challenge is the high turnover of the few available skilled personnel. Respondents reported a major challenge in retaining skilled staff even after training them at a high cost due to their limited numbers and the willingness of other employers to pay them more highly.

G.W. BAGUMA, QCIL:

“You can’t get money from the government that you are going to do research because universities are also getting money for research.”

NAZEEM , PI:

“Our guys here are not trained enough. They don’t work hard enough... Ugandans don’t work hard...I can’t find a Ugandan pharmacist who wants to work hard enough. There was a time I had interns from Makerere...extremely intelligent, they came here.. poor guys had no practical experience... some of them were seeing the machines for the very first time.”

B.S. RAMESH BABU, APCL):

“So right now we are still struggling to train these people especially in the quality control and quality assurance departments so they have been hijacked by the government by paying higher salaries. So we cannot sustain the people we have been training here; you train them and after one year they have been hijacked. This is very difficult for us.”

TACKLING THE CHALLENGES

Regardless of all the many challenges that the industry faces, some pharmaceutical companies have found ways of working around them to keep their operations going. This section provides suggestions for the various issues that still need to be addressed for pharmaceutical producers to optimise their operations.

Imposing restrictions on pharmaceuticals imports

Trade restrictions are standard measures that many countries have used to prop-up high-cost infant producers. In the case of the pharmaceutical industry, Uganda is yet to utilise this option. Players within the industry say the tax regime governing importation of medicines has frustrated the local manufacture of medicines by levying what they consider to be low taxes on imported medicines. Respondents in this survey urged government to adopt the “Ghana Model” of trade restrictions on imports.

In 1989, Ghana started implementing a policy that restricted importation of all medicines that are produced locally; encouraged importation of products in which local production capacity is lacking; and set regulations on importation of products in which local production capacity is partial.¹⁴ This model is ideal in balancing protection of local pharmaceutical manufacturers with the need to have sufficient supply of medicines from both local and foreign manufacturers.

Regional mobilisation to protect local market for local pharmaceutical manufacturers

One of the key objectives of East African Community (EAC) is to create a regional market for goods and services produced by member states. In as far as pharmaceuticals are concerned, as is the case with many other categories of goods, this objective is yet to be fully achieved. There is fierce competition in the regional market created by cheap generic medicines from China, India and Pakistan. Across the region, pharmaceutical producers do not have the capacity to compete with Asian producers who are highly subsidised by their respective governments. EAC member states should therefore consider taking concerted measures to protect the regional pharmaceutical production.

¹⁴ FEAPM Position Paper: Supporting Local Pharmaceutical Manufacturing.

Promoting local pharmaceutical manufacturers

While most of the products made by local manufacturers are more costly than most of the imported medicines, regard should be paid to the long term benefits of supporting the local manufacturers. While these products are expensive in the short run, development of their capacity in the long run will see the reduction of their costs as the scale of production increases. For example QCIL insist they did not set up to compete on the existing medicines but are rather looking at the newer generation of drugs in which they will be able to compete favourably against the already established manufacturers. Respondents at QCIL cited the anti-retroviral Tenofovir, which still has patent restrictions but NDA has approved its manufacture by QCIL under license from Cipla India. It is therefore imperative that civil society organisations and other players with a neutral voice be facilitated to carry out sensitisation campaigns and policy advocacy to support the ability of local manufacturers to compete in the local market.

Streamlining the implementation of government incentives

While the government has a well-documented intention to support local manufacturers of pharmaceutical products, the implementation of the incentive structure has not been standardised. Government should expand the range of incentives offered for local pharmaceutical production. Some start-up incentives are already in place but the procedures for implementing their realisation are not clearly defined. A streamlined guideline through which incentives such as access to land should be put in place to encourage investment in the sector. The government should set aside a pharmaceutical manufacturing zone, preferential tariffs, joint R&D initiatives, and access to essential facilities like water, electricity and transport infrastructure.

The Tax policy should also be streamlined to clarify on the items which are subject to tax exemptions. While the government has undertaken to waive taxes on machinery and equipment necessary to set up manufacturing plants in all phases, the scope of these waivers has not been properly defined and some manufacturers have had to pay taxes on accessories, packaging material, spare parts of equipment and air-handling systems which are essential to the running of pharmaceutical plants. It is therefore important that the local policy in relation to subsidies and incentives is clearly defined by the government and this could be through the commissioning of a comprehensive guidelines tool on the incentives available to local manufacturers and on what they are available for.

Provision of affordable business finance

Government should work with the banking sector to provide a financing facility specifically for the pharmaceutical sector similar to those provided for agriculture. A technology fund should be set up at a preferential rate to enable the pharmaceutical manufacturers who have the capacity to undertake R&D to borrow at friendly rates. Such funding will facilitate pharmaceutical producers to expand and grow to meet the WHO medicine manufacturing standards which are needed in accessing foreign markets.

Assessment of Local pharmaceutical capacity and routine collection of data on the market

One of the primary challenges inhibiting the ability of pharmaceutical manufacturers to invest in the local industry is the lack of baseline data on which to base investment decisions. Respondents intimated that it is for this reason that there are many “redundant” pharmaceutical products on the market. NDA should collect and share routine information on the pharmaceutical market and medicine needs. It is also necessary to determine the capacity of local manufacturers to manage the disease burden in the country and the scope of drugs which are domestically being manufactured. This can also form the basis on which national policy on import restriction and the government’s provision of incentives and subsidies can be carried out to protect the local manufacturing capacity. One of ways in which government can support investments in local manufacturing is through facilitating access to information.

Strengthening regulation of the pharmaceutical sector

NDA has the mandate to undertake inspection, approval, verification and approval of local manufacturers of pharmaceutical products, to guarantee that the quality of medicines on the market from both local and foreign producers. The process of inspection and approval should be streamlined to fast-track the process through which pharmaceutical products can be authorised for marketing while also ensuring that the review is robust enough to guarantee quality. This is necessary to encourage the local manufacturers to lay out new lines of medicines and this encourages R&D into new medicines. Also the regional level, harmonisation of regulation should improve inspection and market approvals in the regional market.

Development of local human resource capacity

Government should increase investment in specialised training, particularly in the science fields, in order to increase supply of skilled workers to the manufacturing sector and the R&D field. There is therefore a need to modify the training structure of the local human resource to introduce a practical component through which they can be empowered with the practical skills necessary in the pharmaceutical industry. UPMA should undertake a resource need assessment of the pharmaceutical manufacturing industry and work with the Pharmaceutical Society of Uganda (PSU) and other professional bodies to design training programmes for further and higher education.

Promotion of partnerships and collaborations

One of the principles outlined under agreements of the World Trade Organisation (WTO) is the promotion of the local technological base through transfer of technology between countries to their mutual advantage. The WTO and other multilateral bodies have an obligation to promote the transfer of technology to least developed countries. Government should seek the support of such bodies to promote mutually beneficial partnerships between local and foreign manufacturers in order to acquire technological capacity for local producers. QCIL is the only pharmaceutical manufacturer in the country already benefitting from a partnership with Indian giant Cipla, and partly because of this collaboration, it has been able to achieve the WHO GMP compliance certification. Similar benefits could be realised by other local manufacturers if such partnerships are further exploited and promoted and this will ultimately facilitate the development of the local pharmaceutical base.

The UPMA in collaboration with government should reach out to manufacturers in countries like India and Brazil (South-to-south) or other western countries (North-to-south) and lobby for partnership initiatives with local manufacturers. UPMA can also foster collaboration of manufacturers to address the impact of economies of scale related to bulk purchases of raw materials. Such collaborations could extend to anti-competition agreements through which market quarters are allocated to various local manufacturers to ensure fair competition in the pharmaceutical markets.

Pharmaceutical manufacturers should carry out self-audits to determine their capacity and technological needs to inform the search for partnerships and collaborations for technological transfer, quality improvement, and cost minimisation.

CONCLUSION

Local production of medicines reduces the length of the procurement cycle and is in the long-run more sustainable. In the short-term however, it is costly and less efficient. Uganda's pharmaceutical industry has made significant progress in developing its capacity to manufacture pharmaceutical products locally. However, a range of challenges need to be addressed at the firm, industry and national levels to unlock the industry's full potential. Manufacturers need to appreciate the value of joint advocacy and lobbying through networking and strong collaboration through a national association. Government has a central role to play in nurturing the infant pharmaceutical industry through support supervision, facilitating access to technology and business finance, and promoting market access at the national, regional and international levels.

Selected references

Department for International Development, June 2004. Increasing access to essential medicines in the developing world: UK Government policy and plans.

FEAPM, Position Paper: Supporting local pharmaceutical manufacturing Government of Uganda (2010), National Development Plan (2010/11 – 2014/15)

MoH (2002), National Drug Policy (NDP)

MoH, 2008, Pharmaceutical situation assessment: Level II Health facility survey. Kampala.

MoH (2009), National Health Policy (NHP)

MoH, (2010), National Pharmaceutical Sector Strategic Plan (NPSSP II) 2009/10-2013/14

MoH, 2010, Health Sector Strategic Investment Plan (HSSIP) 2010/11 – 2014/15

MoH, 2013, Health Sector Strategic Investment Plan (HSSIP) Mid Term Review Report on Medicines Management. Kampala.

National Drug Policy and Authority Regulations, 2003

UPMA Position Paper: A case for local manufacturing of pharmaceuticals

Sylvester Rugumambaju and Paul Kutwabami, 2010. Pharmaceutical Sector Profile: Uganda. United Nations Industrial Development Organisation (UNIDO), Vienna.

The Food and Drugs Act, Cap. 278, Laws of Uganda

The National Drug Authority and Policy Act Cap. 206, Laws of Uganda

The Public Procurement and Disposal of Public Assets Act, 2003

The Uganda Investment Code Act Cap. 92, Laws of Uganda

WHO, 2004. Equitable access to essential medicines: A framework for collective action (March 2004)

WHO, 2011. Local Production for Access to Medical Products: Developing a Framework to Improve Public Health. Available at http://ictsd.org/downloads/2011/12/local_production_policy_framework1.pdf

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