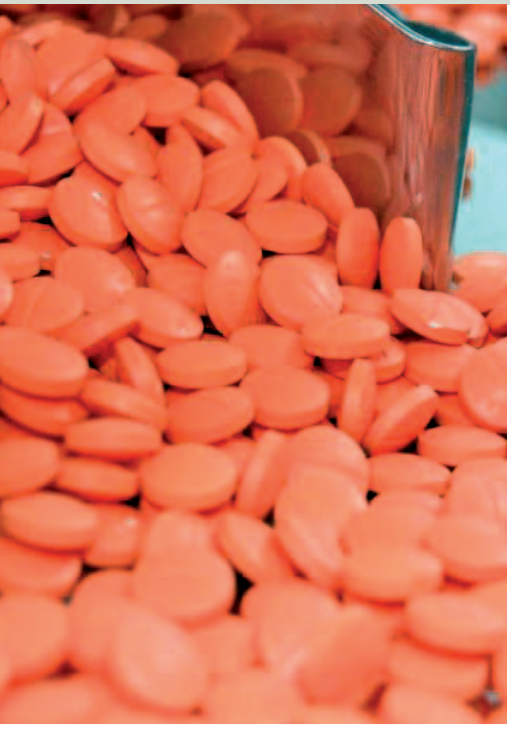

Pharmaceutical Sector Profile: Uganda

Global UNIDO Project: Strengthening the local production of essential generic drugs in the least developed and developing countries

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Cover photographs

Left and middle images—Cinpharm, Cameroon;
Right image—Medipharm industries (E,A) Ltd., Uganda

PHARMACEUTICAL SECTOR PROFILE
Uganda

Global UNIDO Project:
Strengthening the local production of
essential generic drugs in least developed and
developing countries

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna, 2010

This study was prepared by UNIDO consultants, Sylvester Rugumambaju and Paul Kutyabami, and is an update of a report originally prepared in 2007 by Thomas Walter and Sylvester Rugumambaju. The work was carried out under the supervision of Juergen Reinhardt, Project Manager, assisted by Alastair West, Senior Technical Adviser and Nadine Vohrer, Associate Expert. The Editor was Diana Hubbard.

Foreword

Providing adequate health care to their populations remains a major challenge for governments in Africa. Unsatisfactory and inadequate access to essential drugs and other healthcare commodities is a key limitation that impacts on people's health in most developing and Least Developed Countries (LDCs).

The increased funds now available for the procurement of medicines to treat the three pandemics (HIV/AIDS, malaria and tuberculosis) are a very valuable development and have reduced the suffering and extended the lives of millions of people in developing regions. However, reliance on donor funds is clearly not sustainable in the long term and there are many other diseases for which pharmaceuticals are key treatments and for which access to quality medicines is much less advanced. In response to these considerations, the African Union, subregional organizations such as the Southern African Development Community (SADC), and various individual countries in Africa have identified the local production of essential drugs as an important component of a long term solution to the provision of adequate healthcare in developing countries.

Adequate access to drugs is dependent on both the affordability and quality of the products. Unaffordable drugs are clearly not the solution but, equally, affordable low quality products are not the answer either. Therefore, an industry that produces high quality drugs at competitive prices must be the target when developing local manufacture of pharmaceuticals in Africa.

The pharmaceutical sector is a complex one, involving many different stakeholders such as the manufacturers themselves, national regulators, government ministries, wholesalers and others. Developing the industry requires concerted action across these stakeholders to create the environment in which that industry can flourish and realize its full potential as an asset to economic and social development. An example of the role of different stakeholders can be seen with regard to the scourge of counterfeit drugs, which cause huge health problems and also represent a threat to legitimate manufacturers who effectively have to compete with these substandard products.

In the face of this situation, actions by, for example, regulators to reduce the penetration of these counterfeit products would, as well as being important from a health perspective, also benefit the local pharmaceutical industry. Furthermore, quality requires upgraded skills and equipment, so how can high quality products be produced at affordable prices? This challenge requires various government ministries to work together to establish the support to the industry that will enable efficient local companies to invest in high quality production. However, those companies that do invest in upgrading will need some form of protection from those that wish to produce products at a lower standard. Consequently, the establishment and enforcement of quality standards by regulators is a critical element in solving the conundrum.

Since 2006, UNIDO, with funding from the Government of Germany, has been conducting a project on strengthening the local production of essential generic drugs in developing and least developed countries. The objective is to help the pharmaceutical sectors in developing countries to realise their potential role of acting as a pillar of public health and contributing to economic and social development.

The project has conducted a number of different initiatives and will be continuing and expanding on this work in the future. This series of reports, which describe the local pharmaceutical industry in individual countries is one such initiative. They provide a comprehensive picture of the status and operating environment of the pharmaceutical sector and are designed to assist national level stakeholders and inform discussions on how local production fits into the strategy for improved supply of medicines. In parallel, this information will inform the ongoing debate among the international development community on the local manufacturing of generic medicines in closer proximity to where they are actually needed.

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Acronyms

ACTs	Artemesinin-based Combination Therapies
AfHRF	Africa Health Research Forum
AIDS	Acquired Immune Deficiency Syndrome
AKDN	Aga Khan Development Network
AMFm	Affordable Medicines Facility for malaria
APDL	Abacus Parenterals Drugs Limited
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Organization
ARV	Anti-Retroviral
BL	Betalactam Line
BOU	Bank of Uganda
CBO	Community Based Organization
cGMP	Current Good Manufacturing Practices
COMESA	Common Market for Eastern and Southern Africa
DMMP	District Medicines Management Programme
DOTS	Direct Observed Treatment, Short-Course
EAC	East African Community
EDA	Essential Drugs Account
EDLU	Essential Drugs List of Uganda
EMHS	Essential Medicines and Health Supplies
GDP	Gross Domestic Product
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HSSP	Health Sector Strategic Plan
ICCM	Inter-agency Coordination Committee for Malaria
IoP-M	Index of Production—Manufacturing
IPR	Investment Policy Review
IPT	Intermittent Presumptive Treatment
ITN	Insecticide Treated Nets
JMS	Joint Medical Store
KPI	Kampala Pharmaceuticals Industries (1996) Limited
LDC	Least Developed Country
LVP	Large Volume Parenterals
MDGs	Millennium Development Goals
MoFPED	Ministry of Finance, Planning and Economic Development
MIS	Management Information System
MoH	Ministry of Health
MoLG	Ministry of Local Government
MTTI	Ministry of Tourism, Trade and Industry
MVA	Manufacturing Value Added
NBL	Non Betalactam Line

NCD	Non Communicable Diseases
NCRL	National Chemotherapeutics Research Laboratory
NDA	National Drug Authority
NDQCL	National Drug Quality Control Laboratory
NDP	National Development Programme
NDP	National Drug Policy
NHP	National Health Policy
NGO	Non-Governmental Organization
NIP	National Industrialization Policy
NIP	National Investment Policy
NIMES	National Integrated Monitoring and Evaluation Strategy
NMS	National Medical Stores
NPSSP	National Pharmaceutical Sector Strategic Plan
NTG	National Treatment Guidelines
NTLP	National Tuberculosis and Leprosy control Programme
OPD	Out Patients Department
ORS	Oral Rehydration Salts
PEAP	Poverty Eradication Action Plan
PEPFAR (US)	President's Emergency Plan for Aids Relief
PIBI	Presidential Initiative on the Banana Industry
PLT	Patent Law Treaty
PMCT	Prevention of Mother to Child Transmission
PPDA	Public Procurement and Disposal of Public Assets Authority
PPM	Public Private Mix
PSU	Pharmaceutical Society of Uganda
QC	Quality Control
R&D	Research and Development
SME	Small and Medium Size Enterprise
SVP	Small Volume Parenterals
SWAp	Sector Wide Approach
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UBOS	Uganda Bureau of Statistics
UCG	Uganda Clinical Guidelines
UNCST	Uganda National Council for Science and Technology
UGX	Uganda Shilling
UIA	Uganda Investment Authority
UIP	Uganda Integrated Programme
UIRI	Uganda Industrial Research Institute
UMA	Uganda Manufacturers Association
UNBS	Uganda National Bureau of Standards
UNCCI	Uganda National Chamber of Commerce and Industry
UNCST	Uganda National Council for Science and Technology
UNCTAD	United Nations Conference on Trade and Development
UNHRO	Uganda National Health Research Organization

UNIDO	United Nations Industrial Development Organization
UNMHCP	Uganda National Minimum Health Care Package
UPL	Uganda Pharmaceuticals (1996) Limited
UPMA	Uganda Pharmaceutical Manufacturers Association
UPPA	Uganda Pharmaceutical Promoters Association
URA	Uganda Revenue Authority
USSIA	Uganda Small Scale Industries Association
UVRI	Uganda Virus Research Institute
VC	Value Chain
VCT	Voluntary Counselling and Testing
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

This report is an update of the pharmaceutical sector scan on Uganda originally prepared in March 2007 as part of project TE/GLO/08/030[1] funded by Germany and formulated and implemented by the United Nations Industrial Development Organization (UNIDO). The objective is to strengthen the local production of essential generic drugs in developing countries. The report focuses primarily on essential generic drugs, although particular attention is given to medicines for priority health diseases, that is HIV/AIDS, malaria and tuberculosis.

According to the annual health sector performance report for 2008/2009 issued by the Ministry of Health (MoH):

- The HIV epidemic in Uganda is again on the rise and the country's HIV prevalence in 2007/2008 was estimated at 6.2 per cent, with 1.1 million Ugandans living with HIV and AIDs. There are currently some 110,000 new HIV infections and some 60,000 AIDS-related deaths annually
- Malaria remains the most common and leading killer disease in Uganda and over 10 million malaria cases are seen in Out Patients Departments (OPD) annually
- Although there has been improvement in case detection rates for tuberculosis and the treatment success rate increased to 75.1 per cent in 2008/2009, the World Health Organization (WHO) Global Tuberculosis Control Report of 2009 still ranked Uganda 15th out of the 22 high burden countries

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. Using the 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).

Whilst the local pharmaceutical industry has developed significantly over the last 10 years, Uganda still imports 90 per cent of its Essential Medicines and Health Supplies (EMHS) needs. Nonetheless, a positive development was the news that, early in 2010, one manufacturing site, which is manufacturing Anti-Retrovirals (ARVs) and Artemesinin-based Combination Therapies (ACTs), received the WHO Good Manufacturing Practices (GMP) certification. The local pharmaceutical industry contributes about 0.18 per cent of GDP, employs about 1,216 people and exported medicines and health supplies worth about US$ 3.1 million in 2008.

[1] In this report, the terms "essential drug" and "essential medicines" are used interchangeably but essential medicines is used mainly as per WHO recommendations.

The local industry faces a number of challenges that include, but are not limited to:

- Technology, machinery and the associated high skilled expertise are still sourced from outside Uganda
- The need to import Active Pharmaceutical Ingredients (APIs) and almost all excipients and some packaging materials
- Reliance on step-by-step manual manufacturing processes although a few manufacturers have automated production processes
- Unreliable supply of utilities, especially electricity, which compels all manufacturers to operate backup power generators

These challenges, among others, increase the cost of local production of generic essential medicines, especially oral solid preparations, and tend to make locally produced medicines less competitive than imported products. However, this is not a general trend for all medicines. It has been demonstrated that local production of unique essential medicines, such as intravenous fluids, is more economical than importing them. For example, the recent local production of intravenous fluids by one of the local manufacturers, Abacus Parenterals Drugs Limited (APDL), has led to a fall in the wholesale price from UGX 1200 to UGX 850 per 500 ml bottle, almost a 30 per cent reduction in price in the first five months of local production.

There are several factors that support local manufacture of pharmaceuticals and these, according to manufacturers, include but are not limited to:

- Tax exemptions for imports of raw materials and machinery used in pharmaceutical production
- The growing number of pharmacy training schools will increase the number of qualified pharmacists and foster universities' and manufacturers' collaboration in pharmaceutical research and development
- The improving infrastructure (information technology and water supply)
- The open market economy in Uganda and the untapped regional pharmaceutical market

At policy level, local production of pharmaceuticals is governed by the National Health Policy (NHP) and the National Drug Policy (NDP). However, given the commercial nature of this activity, it is also governed by the National Investment Policy (NIP) and the National Industrialization Policy (NIP). It is important to note that all policies are aligned to complement and support the overall objectives of the Poverty Eradication Action Plan (PEAP) and the Millennium Development Goals (MDGs).

There is significant progress in the local production of pharmaceuticals but if interventions are to strengthen the industry and increase the percentage market share of locally manufactured essential generic medicines from the current estimated 10 per cent, Uganda will have to address challenges at policy, institutional, and firm levels.

At policy level, interventions should focus on the harmonisation of the policy strategies of line ministries to ensure that existing government subsidies and incentives are accessible to and utilized by local pharmaceutical manufacturers.

At institutional level, attention should be given to the National Drug Authority (NDA) and the three pharmacists' training universities. Particular attention should be given to:

- Training for NDA staff and improvement of NDA's infrastructure, particularly technological upgrading of the National Quality Control Laboratory (NQCL)
- Promoting collaboration between the Pharmaceutical Society of Uganda (PSU), the Uganda Pharmaceutical Manufacturers Association (UPMA) and national universities in introducing industrial pharmacy into their curricula, as well as organizing pharmacy students' industrial attachments

At firm level, there is a need for businesses to be financially viable and sustainable. As such, interventions should focus on:

- Improving production and quality management capacity and enabling local manufacturers to improve their Good Manufacturing Practices (GMP) and, in due course, to compete for national and international tenders
- Improving operational performance (mainly through cost reduction); this can be achieved through international business partnerships which would facilitate technology, knowledge, and skills transfer to local pharmaceutical industries

It is important to note that, for interventions to be successful, tailor made technical assistance is required. This assistance should be at the request of local stakeholders and should focus on the locally identified needs and not the needs perceived by the provider of technical assistance. For this arrangement to work, local pharmaceutical manufacturers have to be committed to working with development partners in the development and implementation of sustainable business plans.

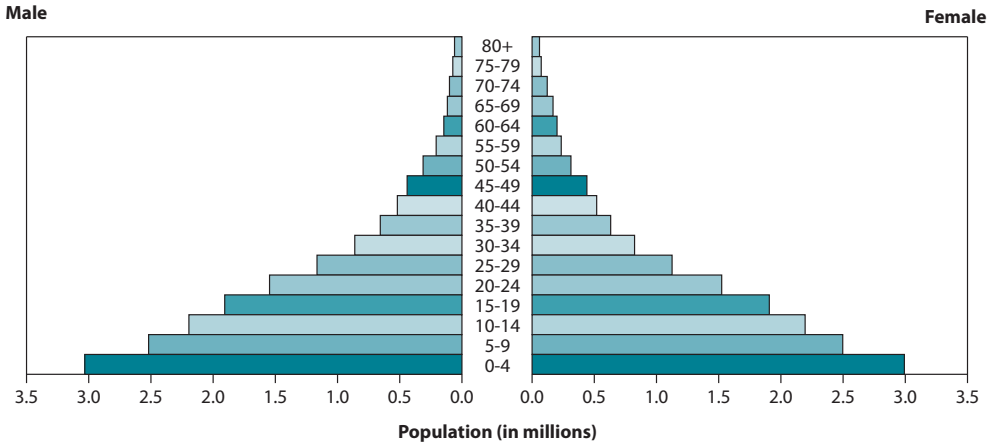
INTRODUCTION

Uganda is a land locked country (Figure 1), with a total surface area of 241,551 km^2 (land covers 197,323 km^2 and water and swamps cover 44,228 km^2). The altitude varies between 620 metres (minimum) and 5,110 metres (maximum) above sea level, and temperatures range from 15°C to 30°C, with an average annual rainfall of between 600 mm and 2,000 mm.

The total population (mid-2009) was estimated at 30.7 million, of whom 15.65 million or 51 per cent were female, with 23.8 million (87 per cent) living in rural areas. The population growth rate over the last five years averaged 3.2 per cent, and over half of the population is below 14 years of age. With a total GDP (current market prices) of UGX 29.824 trillion (US$15.29 billion) and a per capita GDP of UGX 990,314, Uganda is among the low income countries in the world. The GDP growth rate is currently around 6.3 per cent per annum, with GDP per capita growing at some 2.9 per cent and inflation at around 8.5 per cent. According to the 2002 Census, the infant mortality rate was 8.3 per cent and life expectancy was below 50 years.[2]

The census also showed that the population of Uganda is getting progressively younger (figure 1), with the proportion of children under 18 years having increased from 51 per cent in 1969 to 56 per cent in 2002. In contrast, the proportion of elderly persons, (60 years and above), decreased from 5.9 per cent in 1969 to 4.6 per cent in 2002.

Figure 1. Projected age and sex distribution of Uganda's population in 2010



Source: U.S. Census Bureau, International Data Base.

Data from the Uganda Bureau of Statistics (UBOS) indicate that malaria remained the leading killer disease over the period 2006 to 2008 and HIV prevalence was reportedly higher among women in the age group 15-49 years, at 7.5 per cent, than the rate of 5.0 per cent among their male counterparts in the same age group.

[2]Uganda Bureau of Statistics, 2009.

The pharmaceutical sector in Uganda has evolved over the last 15 years from two large[3] manufacturing plants registered in the mid 1990s to the current four large, six medium, and one small scale manufacturer.[4]

Although the sector continues to expand, with the establishment of two new large pharmaceutical manufacturers (Quality Chemical Industries Limited, QCIL, and Abacus Parenterals Drugs Limited, APDL) in the last two years, the country still imports over 90 per cent of its essential medicines and health supplies. Consequently, local manufacturers face significant challenges that are likely to affect their long-term commercial viability and thus the overall access of the population to essential medicines and health supplies in Uganda.

This report presents a review of the pharmaceutical sector in Uganda as part of the UNIDO project: "Strengthening the local production of essential generic drugs in developing countries" (TE/GLO/08/030). It builds on an initial study entitled "Strengthening the local production of essential generic drugs in least developed countries through the promotion of SMEs, business partnerships, investment promotion and south-south cooperation" under project TE/GLO/05/015 implemented in 2006/2007. The report assesses the capacity of Uganda's local pharmaceutical industry to meet the population's need for generic essential medicines and explores the industry's potential contribution to the country's development.

The report has six chapters. Chapter 1 provides an overview of the pharmaceutical sector in Uganda; chapter 2 focuses on the importance of local pharmaceutical production, the overall importance of the sector, and the pharmaceutical value chain. The policy, legal and regulatory framework for the pharmaceutical industry is discussed in chapter 3, while the institutional environment is discussed in chapter 4. The challenges of accessing essential medicines and health supplies and possible interventions to improve access to essential medicines are presented in chapter 5. Chapter 6 presents the conclusions of this study and proposed entry points to strengthen local production of essential generic medicines.

[3]This report uses Söderbom and Teal 2003 for the classification of African manufacturing firms based on size and efficiency. Large in this context refers to manufacturers employing more than 100 people, medium to enterprises employing between 31 and 99 people, and small to manufacturers who employ six to 30 people.

[4]Information from the NDA indicates that, as of December 2009, there were 19 sites licensed for local production of medicines and health supplies in Uganda and activities at these sites vary from actual production to secondary packaging of imported medicines and health supplies.

1. THE PHARMACEUTICAL SECTOR IN UGANDA

1.1 Overview of demand for medicines and health supplies

The demand for medicines and health supplies in Uganda has been increasing steadily over the last two decades. While this is to some extent a natural consequence of the country's population growth, the increase in the number of local pharmaceutical manufacturers and the rapid increase in the number of pharmacies and chemist shops across the country (although these are predominantly located in urban areas)[5] indicate that there is a growing market and that the population's ability to purchase medicines and health supplies has generally improved.

In addition, statistics from the Uganda Investment Authority (UIA) show an increase in the annual index of local production for the chemical and pharmaceutical sectors, with an annual average growth rate of 4.7 per cent from 2004 to 2008 although there was a slight decline from 190 in 2007 to 181 in 2008.[6] This increase in production has also been accompanied by an increase in chemical and pharmaceutical exports, which grew from US$ 1.5 million in 2005 to US$ 3.1 million in 2008. However, it should be borne in mind that these figures combine both the chemical and pharmaceutical sectors and this makes it difficult to know with precision the portion of growth and exports that can be attributed to pharmaceuticals alone.

Over the last 12 years, the Government of Uganda has developed two comprehensive National Health Policies (NHP), National Health Policy I (NHP I) in 1999, and National Health Policy II (NHP II) in 2009. Both these policies aimed at increasing access to essential medicines as part of national efforts to deliver the Uganda National Minimum Healthcare Package (UNMHCP), which puts particular emphasis on management of communicable diseases, especially HIV/AIDs, malaria and tuberculosis. The focus on these three priority diseases is in line with the broader country strategy outlined in the Poverty Eradication Action Plan (PEAP) and with efforts to meet targets set in the Millennium Development Goals (MDGs).

Demand for generic essential medicines is driven by the absolute size of the disease burden and interventions to reduce this burden. At 6.4 per cent, Uganda's HIV prevalence, although stable, is still high compared with many other countries and the number of people requiring HIV/AIDS treatment and care is increasing. There are interventions to scale up HIV/AIDS treatment and care services and, according to the Ministry of Health (MoH), at the end of June 2009, the number of people on anti-retroviral drugs (ARVs) stood at 187,974, of whom 18,000 were children.

[5] According to NDA records, all but one of the 11 local pharmaceutical manufacturers are located in Kampala and the nearby Mukono Districts. Of the registered wholesale and retail pharmacies, 73 per cent are located in the central urban parts of the country.

[6] The Uganda Bureau of Statistics (UBOS) uses the Index of Production—Manufacturing (IoP-M) to measure monthly trends in the output of the manufacturing sector.

The HIV/AIDS burden also impacts on the burden of tuberculosis. According to the WHO 2009 Global Tuberculosis Control Report, Uganda is ranked 15th out of the 22 high burden countries in the world. Today, there are annually 136 new tuberculosis cases for every 100,000 Ugandans and TB is the cause of death of some 30 per cent of people living with HIV/AIDs (MoH 2009). Today, the National Tuberculosis and Leprosy control Programme (NTLP) strategic plan gives particular attention to expanding quality Direct-Observed-Treatment, Short-Course (DOTS) therapy country-wide as the best option to control the disease.

Malaria remains the leading killer disease and the demand for malaria medicines continues to grow both in the public and private sectors. In 2008/2009, in order to assess demand in the private sector and explore ways of responding, the Ministry of Health, in collaboration with private sector partners and with funding from the Affordable Medicines Facility for malaria (AMFm), piloted the procurement, distribution and use of subsidized Artemesinin-based Combination Therapies (ACTS) in the private sector. The results of the pilot will be used to roll out the supply of ACTs country wide and may provide a market for locally manufactured ACTs.

1.2 Supply of medicines and health supplies

According to the Uganda Pharmaceutical Manufacturers Association (UPMA), Uganda's pharmaceutical market has an estimated value of US$ 276 million, of which 90 per cent of the medicines are imported, mainly from India and China, and 10 per cent produced by local manufacturers. The imported medicines and health supplies account for 5.4 per cent of Uganda's total imports.[7]

Medicines are supplied through both the public and the private sectors and there are also non-governmental organizations (NGOs), faith-based organizations (FBOs) and international aid agencies involved in the procurement and distribution of medicines and health supplies. Uganda has a total of 11 licensed local pharmaceutical manufacturers, 477 registered pharmacies and over 4,370 chemist shops.[8] As of 2006, the country had 114 hospitals, 60 of which were public, 46 private not for profit or FBO, and eight private.[9] The National Medical Stores (NMS) are responsible for the procurement, storage and distribution of medicines and health supplies for the public sector, while the private sector is served through a chain of wholesale and/or retail pharmacies, chemist shops, and private clinics.

The supply of essential medicines for HIV/AIDs, malaria and tuberculosis depends on the funding mechanism. All the donor and development partners' funded procurements for ARVs, ACTs, and TB medicines source their medicines outside Uganda. This is mainly because of the requirement that the suppliers should have World Health Organization (WHO) product prequalification. This situation will probably change in the near future as the local pharmaceutical industry, which produces ACTs and ARVs, acquires international certification. Although these locally produced ACTs and ARVs are not WHO prequalified at the moment, in January 2010, Quality Chemical Industries Limited (QCIL) received the WHO Good Manufacturing Practices (GMP) certification and the firm is working on the product prequalification process for ARVs and ACTs.

[7] Uganda Investment Agency, 2009.

[8] National Drug Authority, 2009.

[9] Uganda Bureau of Statistics, 2009.

As of December 2009, procurement of locally manufactured ACTs and ARVs was funded solely through Government of Uganda resources. UGX 60 billion of government funds have been allocated for these purchases as part of government efforts to increase the availability of ACTs and ARVs and to support the local pharmaceutical industry.

1.3 Cost of and funding for medicines and health supplies

In the public sector, medicines and health supplies are available free of charge. Nonetheless, given budget constraints, stock outs often mean that patients have no choice but to purchase medicines prescribed in public hospitals from the private sector.[10] According to the MoH, there has been an increase in the budget allocation for the health sector. The 2007/2008 financial year saw an increase of 12.1 per cent (from UGX 381.85 billion to UGX 428.26 billion), followed by a 46.7 per cent rise (to UGX 628.46 billion) in 2008/2009. However, in relation to the overall national budget, the percentage allocation to the health sector dropped from 9.3 per cent in 2006/2007 and 9.0 per cent in 2007/2008 to 8.3 per cent in 2008/2009. Moreover, this government funding is still below the Health Sector Strategic Plan II (HSSP II) target of 13.2 per cent of the national budget. It also falls short of the 15 per cent target agreed by African leaders during a special summit on AIDS, malaria and tuberculosis in Abuja, Nigeria in 2001. On that occasion, African leaders committed themselves to allocate 15 per cent of their domestic budgets to health.

Nonetheless, per capita spending on health in the national budget grew from US$ 7.84 in 2006/2007 to US$ 10.4 in 2008/2009 although funding for essential medicines, estimated at US$ 0.93 per capita for 2008/2009, clearly remains insufficient and represents only a very small fraction of the US$ 5.86 projected per capita spending in HSSP II.

With the exception of the allocations of UGX 60 billion for purchases of locally manufactured ACTs and ARVs, funding of medicines for priority diseases (malaria, HIV/AIDS and tuberculosis) continues to come mainly from donor agencies and global initiatives. Table 1 shows public funding for essential medicines by the government. The table reflects only the budgetary allocation through Primary Health Care (PHC) grants and credit lines for districts, general hospitals and regional referral hospitals. The figures do not include the additional UGX 60 billion 2008/2009 allocation from the government.

Table 1. Financing for essential medicines and health supplies in Uganda from 2006 to 2009

Financial Year	*2006/2007*	*2007/2008*	*2008/2009*
Funding in billions UGX	31.40	36.50	34.60
Funding estimate in million US$ at a rate of US$ 1.00 = UGX 2,000.	15.70	18.25	17.30

Source: MoH 2009.

[10] According to a MoH 2008/2009 report, only 26 per cent of sampled health units had continuous availability of all indicator essential medicines. This shortfall was attributed to the increasing cost of medicines and the poor management of medicines and health supplies at health units.

Health care in Uganda is funded through government revenue, development assistance and private sources, with 14.4 per cent coming from the government, 35.6 per cent from development partners and 50 per cent from household incomes.

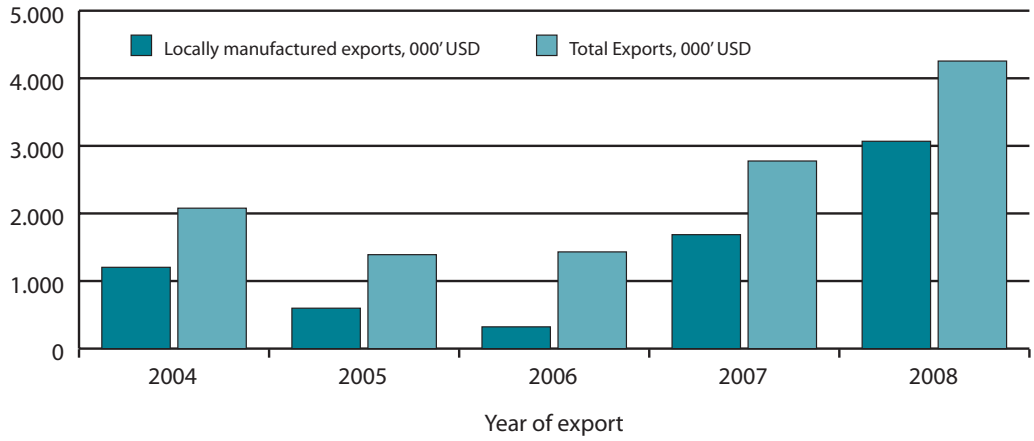
2. DOMESTIC PHARMACEUTICAL PRODUCTION

2.1 Overall importance

As of June 2009, domestic pharmaceutical production had an estimated annual value of US$ 27.6 million, constituted approximately 0.18 per cent of Uganda's GDP at current market prices, and generated exports worth US$ 1.023 million in 2004/2005, increasing to US$ 3.068 million in 2008/2009. These exports are destined mainly to the neighbouring countries of Democratic Republic of Congo (DRC), Rwanda, Southern Sudan, and the United Republic of Tanzania.

Figure 2 below shows the trend in exports of locally manufactured pharmaceuticals and health supplies from 2004 to 2008. The red bars represent the total volume of exports of all pharmaceuticals and medical supplies and the blue bars represent the proportion of locally manufactured pharmaceuticals and medical supplies within that total. The "gap" between the two bars represents re-exports since there are no barriers in Uganda to trade involving the import and subsequent re-export of pharmaceuticals, the only requirement being that these are accompanied by valid import and export licences.

Figure 2. Pharmaceutical and medical supplies exports by value 2004 to 2008



Source: UBOS 2009

At the end of 2006, no local pharmaceutical manufacturer was producing ACTs, ARVs or tuberculosis medicines. Today, there are two local producers of ACTs and one of ARVs, with two more planning to move into ACTs and ARVs. Only one company has plans to produce fixed dose combination medicines for tuberculosis. As of end January 2010, out of the 11 local pharmaceutical manufacturers, only Quality Chemical Industries Limited (QCIL) was WHO GMP certified and no locally produced ACTs and ARVs were WHO prequalified. Nonetheless, it is hoped that prequalification will eventually expand the potential for exporting to neighbouring countries.

In terms of job creation, the local pharmaceutical industry employs about 1,216 people out of an estimated national labour force of 10.9 million in 2006. Most of these employees, some 1,010 or around 83 per cent, were with the five large scale manufacturers, and the remainder (206) with the six medium scale manufacturers. Although these figures are not very significant, the Pharmaceutical Society of Uganda (PSU) points out that, as manufacturers expand and upgrade their production lines, there will be a growing need for skilled personnel. Consequently, it is hoped that the subject of industrial pharmacy will progressively be incorporated into pharmacy training at Uganda's three universities. This will be a welcome development and should contribute to strengthening collaboration between local pharmaceutical manufacturers and the universities, especially in pharmaceutical research and formulation development.

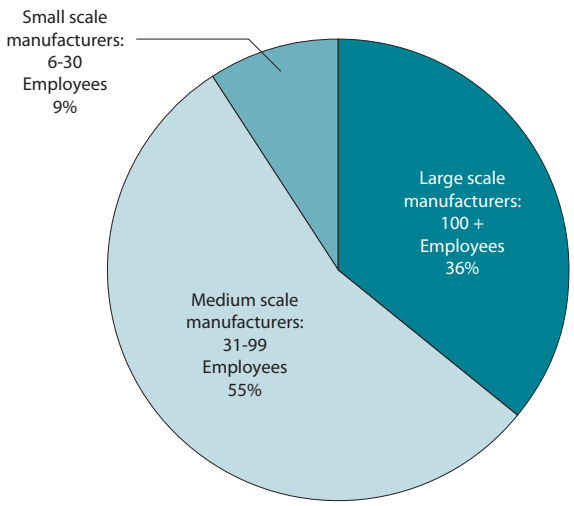
Most importantly, locally manufactured medicines can greatly improve the population's access to essential medicines. Initial indications from the local manufacture of intravenous fluids show that the local industry has the potential to lower the price of medicines and thereby facilitate accessibility.

The local manufacture of intravenous fluids by Abacus Parenterals Drugs Limited (APDL) has already reduced their price from UGX 1200 to UGX 850 per 500ml bottle, almost a 30 per cent reduction in wholesale price in the first five months of local production.

2.2 Structural characteristics

According to the National Drugs Authority (NDA), there were 19 different sites licensed for local production of medicines and health supplies in Uganda as of December 2009. Of the 19 sites, 11 were engaged in commercial production of pharmaceuticals and these can be categorized into large and medium scale, using the number of employees as indicated in figure 3 below. Using this categorization, there are four large, six medium and one small scale local pharmaceutical manufacturer. Of the large manufacturers, two are new (established in 2007/2008) and one of the two (QCIL) produces only ACTs and ARVs.

Figure 3. Large, medium and small scale pharmaceutical manufacturers in Uganda



It is important to note that not all NDA licensed sites are actively producing medicines and health supplies and interviews with manufacturers found that some of these sites have no products on the market, while a number of licensed sites handle medicines and supplies for veterinary use.

Table 2 shows that there are about 15 different production lines and that the majority of local manufacturers specialize in oral and topical liquid preparations. Given the similarity in manufacturers' production lines, it is not surprising that their product range is limited. The table also shows that that there is hospital based production of medicines but it should be noted that this is not for commercial purposes.

Table 2. Sites licensed by the NDA for local production of medicines and health supplies as of December 2009

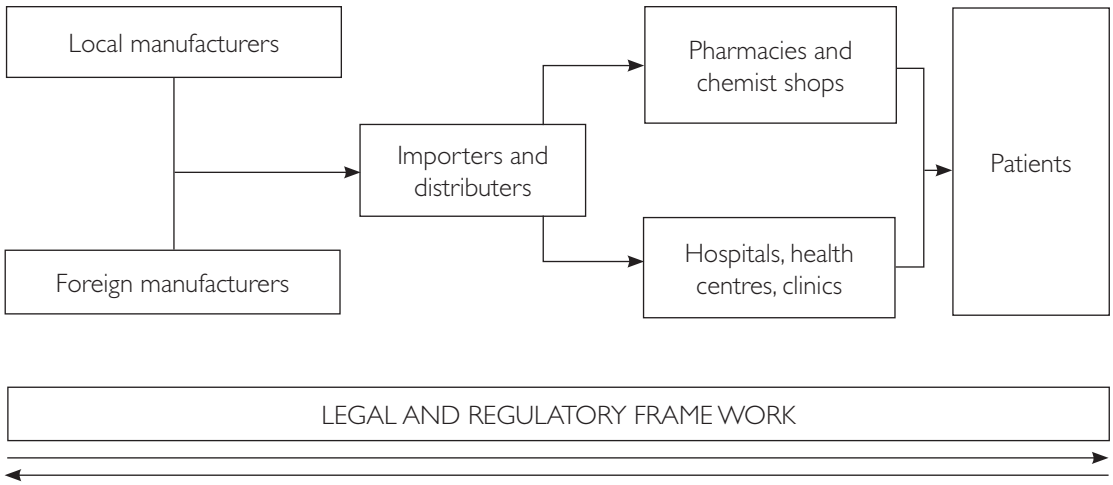
	Site/manufacturer's name	*Production lines*
1	Abacus Parenterals Drugs Ltd.	Large Volume Parenterals (LVP), Small Volume Parenterals (SVP) and eye drops
2	Astel Diagnostics	Diagnostic kits
3	Brentec Investments Ltd.	Newcastle disease—vaccine for veterinary use
4	Charms (U) Limited	Secondary packaging for condoms
5	Kampala Pharmaceutical Industries (1996) Limited	Oral liquids, tablets, capsules and creams
6	Kisakye Industries Ltd.	Oral liquid and topical liquid preparations
7	Kwality Afro Asia Ltd.	Oral and external liquids
8	Mavid Pharmaceuticals Ltd.	Oral and topical liquid preparations
9	Medipharm Industries Ltd.	Oral Rehydration Salts (ORS), oral powders for reconstitution and oral liquid preparations
10	Mengo Hospital Eye production unit	Eye drops
11	Mulago Hospital	Large Volume Parenterals (LVP)
12	NEC Health World Pharmaceuticals Ltd.	Tablets
13	Phenix Logistics	Cotton surgical gauze
14	Population Services International	Secondary packaging for condoms and oral contraceptive pills
15	Quality Chemical Industries Limited	Tablets
16	Rene Industries Ltd.	Non Betalactam Line (NBL): tablets, hard gelatine capsules, and oral liquids Betalactam Line (BL): hard gelatine capsules, powders for oral suspension
17	SEV Pharmaceuticals Ltd.	Oral and external liquid preparations
18	Uganda Kwefuga African Industries	Topical ointments
19	Uganda Pharmaceuticals (1996) Limited	Tablets, hard gelatine capsules, oral liquid preparations, dry powders

Source: NDA December 2009.

2.3 Pharmaceutical value chain

A value chain (VC) describes the full range/sequence of discrete value-added activities needed to bring a specific product/service from its conception through the different stages of production to its use and final disposal after use (UNIDO, 2004). Sections 2.3.1 to 2.3.4 focus on the supply of inputs, production and distribution of outputs for Uganda's pharmaceutical sector value chain, which is summarized in figure 4.

Figure 4. Uganda's pharmaceutical sector value chain



2.3.1 Supply of inputs

Inputs to the manufacture of pharmaceuticals can be broken down into four broad categories—human resources; pharmaceutical raw materials; plant and equipment; and electric power and water.

Human resources

There are about 350 registered pharmacists in Uganda.[11] Although this is a small number given the country's population of 30.7 million, for local manufacturers, the human resource challenge is not the number of pharmacists and other professionals (such as pharmacy technicians and chemists) but their limited or non-existent industrial pharmaceutical knowledge and skills.

This shortcoming can be traced back to the curricula and training at universities and the limited collaboration between the pharmaceutical industry and the training institutions.

[11] According to the Pharmaceutical Society of Uganda (PSU), there were 348 registered pharmacists in Uganda as at 7 December 2009. The majority of these are trained in the three universities in Uganda and are not trained to work in industries but in clinical settings. However, there are initiatives for collaboration between the PSU, NDA, and UPMA to work with the universities in facilitating industrial training and attachments to enterprises during the pharmacists' internship programmes.

Most manufacturers, therefore, rely on expatriates for highly skilled operations, training, and supervision of local staff. This is expensive and a number of local pharmaceutical manufacturers have observed that the problem is exacerbated by "job hopping" by both expatriates and trained local staff in order to obtain higher pay. It should be noted that all manufacturers agree that there is an abundant supply of low cost casual labour.

Pharmaceutical raw materials

Pharmaceutical raw materials, especially Active Pharmaceutical Ingredients (APIs), are imported mainly from India, China and a number of European countries. According to information emerging from interviews, the import process is long and may take more than six months. In addition, local pharmaceutical manufacturers observed that raw materials' prices fluctuate at will depending on demand from other countries.

Most packaging materials are available on the local market with the exception of glass bottles and aluminium. However, a number of manufacturers prefer to import most of the primary packaging materials for their pharmaceuticals as the locally available materials may not be of the desired quality. An associated cost of this problem noted by some manufacturers is that, in order to keep their production lines running, they have to maintain very high raw material inventories and this depletes their working capital.

Plant and equipment

Pharmaceutical manufacturing equipment and technology are not available on the Ugandan market and consequently manufacturers must import both equipment and replacement and spare parts. Although manufacturers have maintenance workshops, maintenance activities for critical machinery are dependent on sourcing of replacement and spare parts and, on occasion, specialized technical personnel from abroad. In addition to the often lengthy import process, the immediate hurdle faced by some manufacturers is taxation on equipment and machinery. As part of government incentives to the industry, such taxes are to be refunded, provided that manufacturers can prove that the equipment is for use in the manufacture of medicines and health supplies. However, the approval process involves many different offices, takes too long and the outcome may not be positive. This discourages a number of local manufacturers from even claiming the refunds.

Electric power and water

According to the Ministry of Tourism, Trade and Industry (MTTI), non-existent or poorly functioning utilities, especially electricity, are the biggest threat to Uganda's industrialization. To solve this problem and to promote local industries, the government agreed to contribute to all local manufacturers' electricity costs. Unfortunately, interviews carried out in the framework of this report indicate that this incentive was not fairly applied and is now under review with the objective of minimizing abuse.[12] On a positive note, over the last two years, electricity generation and supply have improved and government projections show that the problem should be solved in 2011 when a hydro dam starts feeding into the national electricity grid. Meanwhile, manufacturers must continue to invest in back up power generating equipment and this requires extensive capital investment.

[12]The Government of Uganda has been subsidizing the cost of fuel, such as diesel, needed by local industries for their large generators. However, a number of manufacturers abused this incentive by declaring higher than actual fuel consumption.

Although there have been significant improvements, water supply is still not reliable and manufacturers have had to invest heavily in water production and treatment. In view of these inadequacies, the high cost of utilities has a significant impact on overall production costs and this, in turn, translates into high prices for some locally manufactured products, impacting on their competitiveness against imported pharmaceuticals.

2.3.2 Production

Large scale pharmaceutical manufacturers (with the exception of Abacus Parenterals Drugs Limited (APDL) and Quality Chemical Industries Limited (QCIL), who have almost all processes automated depending on the production line) mainly operate step by step automated manufacturing processes. Medium scale manufacturers' processes are mostly manual.

Information gathered in interviews indicates that all these manufacturers are planning to increase the level of their automation in order to achieve higher capacity utilization and therefore increase output. Manufacturers point out that, with increased automation, they will be able to raise their installed capacity utilization from the current average of between 30 per centand 55 per cent, benefit from economies of scale, and consequently be in a position to lower costs and compete on favourable terms in the expanding regional market for essential medicines and health supplies. It should be noted that the process of automation requires adequate planning and resources and will take time. Results will, therefore, vary depending on the individual firm's financial resources and technical capabilities.

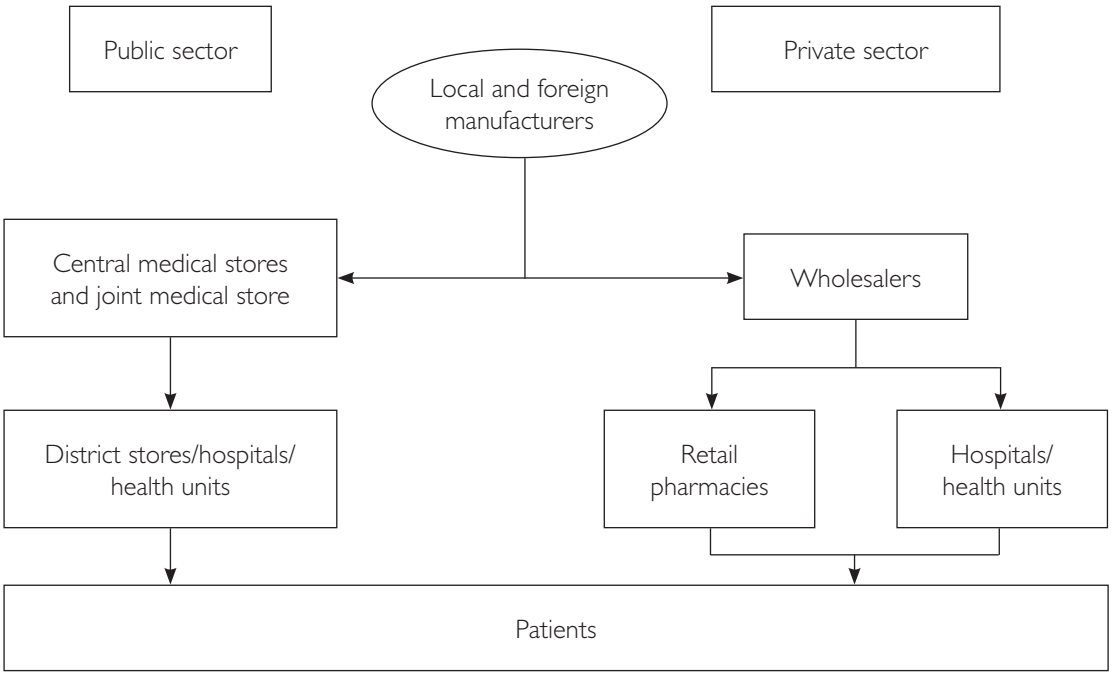
2.3.3 Distribution of medicines and health supplies in Uganda

The National Drug Policy (NDP) of 2002 provides for a medicines and health supplies distribution system for both the public and private sectors in Uganda and also assigns responsibilities to different institutions in order to facilitate distribution throughout the country. The policy defines strategies to ensure that the supply, selling and distribution of medicines is regulated effectively and that the contribution of manufacturing, wholesale and retailing activities within the medicines distribution chain is monitored.

The medicines distribution system in Uganda is summarized in figure 5. It is important to note, however, that this is the ideal structure whereas, in practice, there is often overlap between the public and private sectors at different levels within the system, depending on the nature of the medicines being distributed.

Both private and public distribution is constrained by rising fuel costs, the poor state of the roads and the resulting high truck maintenance costs. According to the MoH, there is also a major problem of pilferage of public medicines and health supplies which is very difficult to quantify. However, it is hoped that the problem will be reduced since all public medicines must now carry the GoU logo. Local manufacturers have also welcomed this measure since they acknowledge that their private market was being undermined by medicines diverted from the public sector distribution system.

Figure 5. Distribution of medicines and health supplies in Uganda's public and private sectors



Source: Adapted from NDP 2002 and interviews with MoH, NDA and local manufacturers.

Most imported medicines (about 90 per cent of consumption within the public health sector, including NGOs and/or faith based health units and hospitals) are distributed through the National Medical Stores (NMS) and the Joint Medical Store (JMS) as wholesalers. Local manufacturers also sell medicines to NMS and JMS. In addition, the larger manufacturers either manage their own distribution systems or contract licensed private sector subsidiaries as wholesalers. Distribution to end-users is through over 477 pharmacies, about 5,263 registered chemist shops, 1,500 clinics, and 114 hospitals (in 94 districts).[13]

Currently, there are 477 registered/licensed pharmacies in Uganda (wholesalers and retailers). Table 3 shows the trend in the number of pharmaceutical manufacturers and pharmacies (wholesale, wholesale and/or retail, and retail) between 2004 and 2009.

[13]Not all districts have hospitals but, as new districts are created, some health centre IVs (which function as sub-hospitals) are elevated to district hospital level although this does not immediately translate into hospital level infrastructure and services.

Table 3. Number of registered/licensed pharmaceutical distributors

Region	*Year*					
	2004	***2005***	***2006***	***2007***	***2008***	***2009***
Central	216	244	251	260	315	346
South West	38	36	43	35	38	32
West	04	09	08	22	26	24
East		09	11	14	17	18
South East	15	15	23	24	32	35
North		10	13	19	24	15
West Nile						07
Total	**273**	**323**	**349**	**374**	**452**	**477**
	Chemist shops					
All regions	3,061	3,711	4,046	4,812	4,910	5,263

Source: NDA Statistics, December 2009.

The number of non-registered/non-licensed pharmaceutical outlets, especially chemist shops and clinics in rural areas, is unknown. However, even if the public health sector clearly dominates the distribution of medicines, informal activities, including cross border trade, should not be underestimated in Uganda.

According to the Uganda Investment Authority (UIA) and manufacturers, some locally manufactured pharmaceuticals are exported to nearby countries and it is hoped that further integration of the East African Community (EAC) market will provide a considerable market opportunity. The five member countries of the EAC had a total population of about 138 million and a combined GNI of US$ 70.4 billion in 2008 and, consequently, this regional economic grouping represents an extremely large potential market. Moreover, they have almost similar disease patterns.

However, for Ugandan manufacturers already exporting to neighbouring countries, there are a number of bureaucratic procedures involved, including:

- Registration in EAC countries
- Inspections and dossier preparation
- Import duties (United Republic of Tanzania)

Registration and inspection processes currently have to be repeated for each member country of the EAC and this takes time and money. It is hoped that EAC integration will provide an opportunity to minimize these repeated and costly activities thus making locally manufactured medicines and health supplies more competitive in the regional market.

A number of local manufacturers look to the EAC as a good opportunity for expanding their market, particularly once all the countries have a common market and national policies and processes are harmonized.

2.3.4 Plant-level assessments

In the course of preparing this report, a number of local manufacturers were visited and interviewed on various subjects ranging from their legal status, size and ownership to their production lines. The government's industrial policy and incentives were also discussed, as were business opportunities and the challenges they are facing.

This section of the report presents summary profiles of the companies, including a SWOT analysis (Strengths, Weaknesses, Opportunities, and Threats) as perceived by the manufacturer, together with a brief summary of those areas where the company feels that it needs external assistance.

There are 11 local pharmaceutical manufacturers in Uganda and they can be categorized into large, medium and small size manufacturers as described below.

Large scale manufacturers

- There are currently four large manufacturers, employing more than 100 people each, and licensed by the NDA for production of generic medicines for the local market. Some of these firms are in the process of registering their products in other EAC countries
- All these large manufacturers are foreign owned or jointly owned by Ugandans and foreign investors

Medium scale manufacturers

- Uganda has six medium sized manufacturers employing between 31 and 99 people. According to the NDA classification based on installed production capacity, one of these firms has a similar production capacity to that of large scale production activities but is restructuring its management and, as a result, currently employs only 60 people compared with over 150 in 2006
- Two of these six medium size manufacturers are 100 per cent owned by Ugandans.

Small scale manufacturers

- Small size manufacturers in Uganda employ between six and 30 people. There is only one small manufacturer that is 100 per cent owned by Ugandans. Tables 4.1 to 4.4 provide a brief overview of large scale local manufacturers in alphabetical order.

COMPANY PROFILES

Table 4.1 ABACUS PARENTERALS DRUGS LIMITED (APDL)

Company legal status and ownership	Limited company. 100 per cent foreign owned (75 per cent Indian and 25 per cent Kenyan)
Contact details	Factory: Block 191, Plot 114, Gwawanya Kinga and Kapeka Mukono Head office: Kiboko House, Plots No. 28B, 32B, 34B, Coronation Avenue, UMA Show Grounds, Lugogo, P.O. Box 31376, Kampala, Uganda

Contact details	Telephone:	+256- 417-100900
	Fax:	+256- 417-100920
	Email:	apdl@kiboko.co.ug
	Website:	www.apdl.info
Company size	Number of employees:	300 (50 per cent are temporary workers)
	Capacity utilization	N/A[a]
	Turnover (million UGX)	Projected turnover (million UGX)[b]
	2006 2007 2008	2009 2010 2011
	N/A N/A N/A	
Product range	Large Volume Parenterals (LVP); Small Volume Parenterals (SVP); and eye drops	

SWOT ANALYSIS

Strengths

- Established regional marketing and distribution channels
- Unique essential products

Weaknesses

- New to the manufacturing sector
- High investment costs

Opportunities

- Government incentives if implemented
- A large potential market in the EAC given the nature of the manufactured products which are cheap if locally manufactured

Threats

- Cost of utilities like electricity
- Competition from cheap imports[c]
- Limited market given the installed capacity

Areas of interest where company requests support

1. Collaboration with universities on skills and technology transfer
2. Improved quality control capacity, collaboration with UBOS and NDA

[a]Just started marketing but has capacity to produce 10 million LVP units annually and there is a plan to increase this to 20 million.

[b]Too early to talk about turnover.

[c]Since APDL started production, importers of SVP and LVP have been reducing prices and the company is not sure how far importers are willing to go to stay in the market.

Table 4.2 KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED

Company legal status and ownership	Limited company, owned by the Aga Khan Development Network (AKDN)	
Contact details	Plot M444B, Stretcher Road, Ntinda P.O Box 7551, Kampala, Uganda	
	Telephone:	+256-414-285645/414-287827/256-752-285645
	Fax:	+256-414-220129
	Email:	info@kpi.co.ug
	Website:	www.kpi.co.ug
Company size	Number of employees:	300 (156 permanent and 32 with technical training)
	Capacity utilization	50 per cent of installed capacity
	Turnover (million UGX)	Projected turnover (million UGX)

	2006	2007	2008	2009	2010	2011
			13,000	16,000	18,000	N/A
Product range	Oral liquids, tablets, capsules and creams (80 registered products)					

SWOT ANALYSIS

Strengths

- A wide product portfolio
- Established market

Weaknesses

- Limited knowledge and skills
- Lack of WHO GMP certification

Opportunities

- EAC—there will be benefits from harmonized inspection and registration of medicines
- Government embossing of public medicines has reduced pilferage and, as a result, led to high demand for medicines from private sector distributors

Threats

- Global initiatives like GFATM and AMFm (procurement rules require that manufacturers of essential medicines are WHO prequalified)
- Immature patent offices in the East African region, especially Uganda—there is limited evaluation and decision making capacity which hinders local innovation
- Very large investment requirements

Areas of interest where company requests support

1. Skills, knowledge and technology transfer
2. Government import restrictions on specific medicines where there is local manufacturing capacity for them
3. Training—specifically in research and development for new formulations, with specific collaboration with local universities

Additional notes:

The company plans to build a new manufacturing plant in Arusha, Tanzania because management feels that government support and incentives for local manufacturers are more attractive there.

Table 4.3 QUALITY CHEMICAL INDUSTRIES LIMITED (QCIL)

Company legal status and ownership	Limited company with local and foreign ownership (Cipla of India, Quality Chemicals Ltd of Uganda, and GoU)					
Contact details	Plots 1-7, Luzira Industrial Park, Kampala P. O. Box 34871, Kampala, Uganda					
	Telephone:	+256-312-341100				
	Fax:	+256-414-221319				
	Email:	info@qcil.co.ug				
	Website:	www.qcil.co.ug				
Company size	Number of employees About 200 (80 per cent with technical training)					
	Capacity utilization			50 per cent of installed capacity		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	N/A	N/A	N/A			
Product range	Tablets: producing only ACTs and ARVs					

SWOT ANALYSIS

Strengths

- New and well planned plant
- Has WHO GMP certification
- Now working towards product prequalification[a]

Weaknesses

- Limited research capacity
- Limited collaboration with local universities and other institutions of learning

Opportunities

- To obtain WHO product prequalification
- EAC—harmonization of medicines registration in the region
- TRIPS flexibilities: may manufacture some medicines through compulsory licensing by the government

Threats

- Competition from cheap imports
- Increasing cost and maintenance of technology
- Poor national infrastructure
- High cost of borrowing in Uganda

Areas of interest where company requests support

1. Research and development—QCIL is planning to work closely with Ugandan universities in research and development
2. Implementation of existing government incentives for local manufacturers
3. Support to ensure the smooth functioning of the Uganda National Council for Science and Technology (UNCST)
4. Implementing the special 15 per cent price preference when evaluating bids from local pharmaceutical manufacturers

[a] As this report was being published, UNIDO learnt that QCIL has achieved prequalification status for one ARV as an additional production site of Cipla Ltd., India

Table 4.4 RENE INDUSTRIES LIMITED.

Company legal status and ownership	Limited company, locally owned by Ugandans of Indian origin					
Contact details	Plot 680, Kamuli, Kireka P. O. Box 6034, Kampala, Uganda					
	Telephone:	+256-414-236595/341416				
	Fax:	+256-414-236596				
	Email:	rene@siticable.co.ug; info@rene.co.ug				
	Website:	www.rene.co.ug				
Company size	Number of employees			250 (120 permanent, 17 technical)		
	Capacity utilization			30 per cent to 70 per cent depending on line		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	N/A	N/A	N/A	N/A	N/A	N/A
Product range	Registered products and 14 free sale certificates Non betalactam: Tablets, hard gelatine capsules, oral liquids Betalactam: Hard gelatine capsules, powders for oral suspension					

SWOT ANALYSIS

Strengths

- Established capacity in key essential medicines like Paracetamol
- Established market

Weaknesses

- Reliance on imported raw materials, especially APIs
- Lack of WHO GMP certification

Opportunities

- New markets in neighbouring countries
- Growing number of local universities
- TRIPs flexibilities

Threats

- Global initiatives like GFATM, AMFm that fund essential medicines yet require WHO prequalified products only
- Cheap imports

Areas of interest where company requests support

1. Research and development in ARV production—collaboration likely with Roche
2. Skills, knowledge and technology transfer
3. Lobbying for implementation of the special 15 per cent price preference when evaluating bids from local pharmaceutical manufacturers

Tables 4.5 to 4.9 provide brief overviews of medium scale local manufacturers in alphabetical order.

Table 4.5 KISAKYE INDUSTRIES LIMITED

Company legal status and ownership	Limited company, owned 100 per cent by Ugandans					
Contact details	Lugala–Masanafu Road, Kampala Office: Plot 13, William Street P.O. Box 30219, Kampala, Uganda Telephone: +256-414-251767/772-525793 Fax: N/A Email: kisakye@spacenet.co.ug Website: N/A					
Company size	Number of employees			40		
	Capacity utilization			100 per cent of installed capacity		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
		400	456.6	650	N/A	N/A
Product range	12 different oral liquid and topical liquid preparations					

SWOT ANALYSIS

Strengths

- Building own premises that are well planned and expanded
- Located at the heart of Kampala business district and very easily accessed

Weaknesses

- Limited resources for expansion
- Manual step-by-step processes which limit large scale operations
- Specialization in unique but non-essential products

Opportunities	***Threats***
• Availability and low cost of casual labour • Expanding local market • Increased production capacity when new premises are ready	• High cost of borrowing • Cheap imports • EAC- may result in limited market for local manufacturers with limited production capacity

Areas of interest where company requests support

1. Capital investment for new premises needed to increase capacity in order to meet current demand
2. Technical support for machinery installation and training
3. Collaboration between NDA and URA to ensure tax exemptions on machinery are implemented and the process shortened

Table 4.6 KWALITY AFRO ASIA LIMITED

Company legal status and ownership	Limited company 100 per cent owned by investors from India					
Contact details	165 Bombo Road, Kawempe P.O. Box 23133, Kampala, Uganda Telephone: +256-414-232500/782-133497 Fax: +256-414-232500 Email: kwalityafroasia@yahoo.com Website: N/A					
Company size	Number of employees			35 (inc. five technical)		
	Capacity utilization			70 per cent of installed capacity		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	N/A	N/A	600	1,000	1,000	2,000
Product range	Oral and external liquid preparations					

SWOT ANALYSIS

Strengths	***Weaknesses***
• Established skilled and experienced labour force • Improving processes and technology • Established reliable market, good distribution channels and strong marketing strategies	• Limited number of personnel • Limited financing • Premises (needs own premises which can be expanded)
Opportunities	***Threats***
• Unique oral liquid production line range of medicines • Expanding regional market • Support by NDA for local pharmaceutical manufacturers to develop further	• EAC—could be squeezed out of market by better financed regional manufacturers • Increasing number of cheap imports • Limited skills, e.g. pharmacists leaving the industry

Areas of interest where company requests support

1. Financing for expansion of production lines
2. Specific skills and knowledge transfer for the pharmaceutical industry
3. Collaboration with universities on research and development

Table 4.7 MAVID PHARMACEUTICALS LIMITED

Company legal status and ownership	Limited company, owned locally by two Ugandans					
Contact details	Plot 1099, Kyadondo-Kireka, Block 232, Kampala, P.O. Box 7069, Kampala, Uganda					
	Telephone:	+256-414-340003/414- 251898/772-566950				
	Fax:	N/A				
	Email:	buka@fricaonline.co.ug				
	Website:	N/A				
Company size	Number of employees			52 (six technical, 38 non technical and eight part-time)		
	Capacity utilization			50 per cent, projected to increase to 70 per cent in 2010.		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
				2,600	N/A	N/A
Product range	Oral and topical liquid preparations					

SWOT ANALYSIS

Strengths

- Established distribution channels
- Unique range of products
- Established customer base

Weaknesses

- Limited financial and skilled human resources
- Limited technology to increase output to meet available demand

Opportunities

- Possibility of 15 per cent preferential price margin in public procurements for local manufacturers
- Potential to export to neighbouring countries

Threats

- Competition from East African companies (especially Kenyan) following EAC integration

Areas of interest where company requests support

1. Access to low cost loans for substantial capital investment
2. Human resource development—skills and knowledge transfer
3. Technology transfer
4. Coordination of collaboration with local universities for human resource development and R&D

Table 4.8 MEDIPHARM (E.A) LIMITED

Company legal status and ownership	Limited company, jointly owned by Kenyans (51 per cent) and Ugandans (49 per cent)					
Contact details	Plot 65, Kakajjo Road, Bweyogerere P.O. Box 6218, Kampala, Uganda					
	Telephone:	+256-414-285451/392-785451				
	Fax:	+256-414-289134				
	Email:	sales@medipharm.co.ug				
	Website:	www.medipharm.co.ug				
Company size	Number of employees			50 (including five technical and 15 casual staff)		
	Capacity utilization			About 27 per cent of installed capacity		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	3,691	3,887	4,200	N/A	N/A	N/A
Product range	Oral Rehydration Salts (ORS), oral powders for reconstitution and oral liquid preparations					

SWOT ANALYSIS

Strengths

- Emphasis on quality
- Existing market segment for unique products, especially ORS

Weaknesses

- Under utilized capacity
- Lack of WHO GMP Certification

Opportunities

- Emerging markets, both local and regional

Threats

- Competition from cheap imports
- High cost of money needed for infrastructure development

Areas of interest where company requests support

1. Research and development—especially formulation development for ACT powders for oral use
2. In-house training for technical staff
3. Industrial technology, knowledge and skills transfer

Table 4.9 UGANDA PHARMACEUTICAL (1996) LTD

Company legal status and ownership	Limited company 100 per cent foreign owned (70 per cent Libyan and 30 per cent Indian)
Contact details	Plots 1 & 3, Oboja Road, Jinja P.O. Box 484, Jinja, Uganda
	Telephone: +256-431-21418
	Fax: +256-431-20491
	Email: upl@dawda.co.ug
	Website: http://houseofdawda.com/uganda_pharma.html

Company size	Number of employees			60[a] including five technical staff		
	Capacity utilization			70 per cent of installed capacity		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	N/A	N/A	N/A	7,200	8,400	9,600
Product range	Tablets, hard gelatine capsules, oral liquid preparations, dry powders					

SWOT ANALYSIS

Strengths	***Weaknesses***
• Established marketing and distribution channels • High quality products	• Because of ongoing management changes, future investment decisions cannot be made • Located away from the business centre. Whilst currently a weakness, this could turn into a strength in future
Opportunities	***Threats***
• Low cost labour • Accessible and expanding market • Tax exemptions on raw materials and other government incentives if implemented	• Competition from cheap imports • Import of raw materials is too costly because Uganda is landlocked • Need to import all industrial inputs

Areas of interest where company requests support

1. Use of import restrictions to allow initial development of the local pharmaceutical industry
2. High cost of capital
3. Technology, knowledge and skills transfer

[a]The number of employees has fallen from 150 in 2006 to the current 60.

Table 4.10 provides a brief overview of the only small scale local manufacturer.

Table 4.10 SEV PHARMACEUTICALS LIMITED

Company legal status and ownership	Limited company 100 per cent owned by Ugandans					
Contact details	Plot 100, Nalukolongo Masaka Road, Kampala P.O. Box. 26025, Kampala, Uganda					
	Telephone:	+256-414-272933				
	Fax:	N/A				
	Email:	sevpharmaceuticals@yahoo.com				
	Website:	N/A				
Company size	Number of employees			25 (including five technical)		
	Capacity utilization			N/A		
	Turnover (million UGX)			Projected turnover (million UGX)		
	2006	2007	2008	2009	2010	2011
	373	488	499	612	725	838
Product range	Oral and external liquids preparations					

SWOT ANALYSIS

Strengths	***Weaknesses***
• Professional ownership—owned by pharmacists • Existing unique formulations	• Limited capital for investment • Limited space for expansion given that current premises are rented
Opportunities	***Threats***
• Expanding local market	• EAC—competition from regional and foreign imports • Limited capital for expansion is threatening the company's future economic viability

Areas of interest where company requests support

1. Sourcing and import of raw materials and machinery
2. Human resource development—skills and knowledge transfer
3. Cost of capital for investment

These summary profiles of local manufacturers highlight a number of opportunities and threats that are common to almost all of them and, in particular, the following:

Opportunities

- 15 per cent preferential price margin for locally manufactured medicines and health supplies in public procurements
- Expanding local and regional (EAC) markets

Weaknesses and Threats

- Lack of WHO GMP certification and product prequalification
- The need for skills, knowledge and technology transfer

Through the Uganda Pharmaceutical Manufacturers' Association (UPMA), pharmaceutical manufacturers have made progress in lobbying government to allow locally manufactured pharmaceuticals a 15 per cent preferential price margin in public procurements. However, the scheme is not yet in place and the line ministries involved cannot develop guidelines for implementation of the scheme until the Public Procurement and Disposal of Public Assets Authority (PPDA) has finalized the procedures involved.

Increased investment in technology, skills and knowledge transfer will be needed if local pharmaceutical manufacturers are to obtain WHO GMP certification. Research and development has been particularly singled out as one area where progress is urgently needed. Manufacturers argue that, given the increasing volume of funding of essential medicines by donors and international agencies who require manufacturers to have WHO GMP certification in order to prequalify for procurement exercises, they are slowly being pushed out of the local essential medicines market. This, according to some manufacturers and the chairman of the UPMA, might be the single biggest threat to the survival of local pharmaceutical manufacture.

3. THE IMPACT OF THE POLICY, LEGAL AND REGULATORY ENVIRONMENT ON PHARMACEUTICAL SECTOR DEVELOPMENT

3.1 The policy framework

All policies in Uganda are strategically aligned to contribute to the achievement of the Poverty Eradication Action Plan (PEAP) objectives. The pharmaceutical sector is guided by the following ministerial policies:

- The national industrial policy of the Ministry of Tourism, Trade, and Industry (MTTI)
- The national investment policy of the Ministry of Finance, Planning and Economic Development (MoFPED) which is implemented by the Uganda Investment Authority (UIA)
- The national health, and the national drug, policies of the Ministry of Health (MoH)

3.1.1 Policy framework for industrialization

The path of industrialization in Uganda is defined within the framework of the National Industrial Policy (NIP) of 2008. This sets out the strategic direction for industrial development in Uganda for the following nine years. The policy sets clear indicators for what the government would like to achieve during, and by the end of, this period, as follows:

25 per cent—contribution of manufactured products to total GDP

30 per cent—contribution of manufactured exports to total exports

30 per cent—value added in industry (as a percentage of GDP)

4.2 score—on the Global Competitiveness Index of the World Economic Forum

The policy focuses on four main areas, the third of which directly relates to the development of the local pharmaceutical industry and puts emphasis on:

> *"Knowledge-based industries such as: ICT, call centres, and pharmaceuticals that exploit knowledge in science, technology and innovation"*
> *(MTTI 2008, p.7).*

There is recognition of the general constraints on the industrialization process in Uganda and key among them are:

- Electricity supplies as the most severe impediment to industrial development, followed by inadequate infrastructure and finance
- Low level of expenditure on research, and shortcomings in the institutional framework which should identify research priorities, greater commercialization of research, and the need to adopt advanced technologies
- Limited support for trade policy, trade support services and trade institutions
- Inadequate managerial skills in quality management and compliance with international standards[14]

The policy singles out HIV/AIDS and malaria as having a negative impact on Uganda's industrialization progress and therefore on the country's overall economic development.

To overcome these challenges, the National Industrial Policy mandates MTTI to create a business friendly environment in which private sector-led industries will develop, improve productivity and product quality, and achieve competitiveness at regional and global levels.

3.1.2 National Investment Policy

The country's investment policy is implemented by the Uganda Investment Authority (UIA) which is under MoFPED. The agency is a government body responsible for the promotion and facilitation of private sector investment in Uganda.

The investment policy mandates UIA to:

- Review and make policy recommendations to government on investment
- Provide first hand information on investment opportunities in uganda
- Issue investment licences and assist in securing other licences and secondary approvals for investors, such as acquisition of industrial land, work permits and special passes for investors and their expatriate staff
- Help investors implement their project ideas by providing help in locating relevant project support services
- Arrange contacts for potential investors and organize itineraries for visiting foreign missions in the country
- Assist investors in seeking joint venture partners and funding

In addition, the UIA is responsible for the implementation of Uganda's investment incentive regime which allows exemption from payment of duties and taxes on imports of specific products used in local investment. The regime is implemented under the fifth schedule of the EAC Customs Management Act of 2004.

The current 2009/2010 exemption regime covers three areas that relate to the pharmaceutical industry, namely computer software, industrial spare parts, and packaging

[14]Achieving GMP certification remains difficult for local pharmaceutical manufacturers due to the extensive investment requirements involved.

and raw materials for the manufacture of medicaments. In addition, there are capital investment allowances (initial allowances and deductible annual allowances) applicable for investors in the local industry, as summarized in table 5:

Table 5. Capital investment allowances

Initial allowances—deductible once only from company income		
Type of allowance	***Rate***	***Condition***
Initial allowance granted in Year One of production	50%	Granted on cost base of plant and machinery for industries located in Kampala, Entebbe, Namanve, Jinja and Njeru
	75%	Granted on cost base of plant and machinery for industries located elsewhere in Uganda
Start up costs	25%	Granted on actual cost over the first four years in four equal instalments
Training expenditure	100%	Granted on actual cost of training incurred during the tax year for the training or tertiary education of a citizen or permanent resident of Uganda employed in the business by the employer (not exceeding five years in total)
Initial allowance granted in Year One of use of an industrial building	20%	Granted on cost base of an industrial building used for approved manufacturing operations
Repairs and minor capital equipment	100%	Of actual cost incurred in a year on: Repairs of property occupied or used by the business Cost of minor capital equipment (a depreciating asset costing less than fifty currency points and functioning in its own right)
Deductible annual allowances—under declining balance method per annum		
Class	Rate	Condition
Class 1	40%	Computers and data handling equipment

Although these exemptions are in place, interviews with manufacturers indicate that the process of benefiting from them is very slow and costly. Consequently, these incentives are more theoretical than actual and are not readily accessible for the local pharmaceutical industry.

Local manufacturers comment that the most realistic and immediate incentive would be the implementation of the 15 per cent preferential margin on the price quoted in bids made by them in public sector procurements of medicines and health supplies. While this incentive is currently under review by the PPDA, it is important to note that it should be viewed as a short-term strategy which would allow local pharmaceutical industries to build up their capacity over a specified period.

3.1.3 National Health Policy

Up until 2009, the health sector was guided by the first National Health Policy (NHP I) of 1999. Today, there is a new policy, NHP II, which is informed by the National Development Programme (NDP) which runs from 2009/10 to 2013/14. The NDP sets

the overall development agenda for Uganda. The focus of NHP II is on health promotion, disease prevention, and early diagnosis and treatment of disease. Relevant to local production of medicines is the NHP's emphasis on the need for adequate quantities of affordable, good quality essential medicines and health supplies accessible to all who need them and its specific strategy to "Encourage local production of medicines and ensure compliance with Standards of Good Manufacturing Practices" (MoH 2009b, p. 19).

There are other NHP II policy strategies that may facilitate the local manufacture of medicines (see below). However, the challenge remains the actual implementation of these strategies by the MoH and other line ministries.

NHP II strategies that could indirectly facilitate local pharmaceutical production—MoH 2009

- Ensure adequate financing of essential medicines and health supplies in the national budget and gradually reduce donor dependency
- Strengthen distribution and delivery systems at government health facilities
- Strengthen the existing regulation and its enforcement in the pharmaceutical sector including setting prices for the private sector
- Ensure that the National Drug Authority conducts pharmacovigilance surveys in order to ensure the safety of medicines, including traditional medicines
- Promote, support and sustain interventions that ensure rational prescribing, dispensing and use of medicines and other supplies
- Promote regional and international collaboration on medicine regulation and bulk purchasing in line with East African Community and other international initiatives
- Integrate relevant aspects of private sector activities into the MoH pharmacy policy framework on issues such as accreditation, standards of practice and cooperation and collaboration with training institutions

Like the NHP I, NHP II puts emphasis on the delivery and improved utilization of the Uganda National Minimum Health Care Package (UNMHCP), which is structured into four clusters as follows:

- Health promotion, disease prevention and community health initiatives, including epidemic and disaster preparedness and response
- Maternal and child health—focusing on safe motherhood and child survival
- Prevention and control of communicable diseases—these include HIV/AIDS, malaria, tuberculosis, and diseases targeted for control, eradication and/or elimination (i.e. guinea worm, onchocerciasis, leprosy, lymphatic filariasis, and trachoma), rabies, plague, human african trypanosomiasis, schistosomiasis, and intestinal worms
- Prevention and control of non-communicable diseases—emphasizing healthy lifestyles for prevention of non-communicable diseases and control of poverty-producing conditions such as mental health, deafness and blindness, age, and disability

Local pharmaceutical industries in Uganda mainly produce generic medicines for communicable diseases although Kampala Pharmaceutical Industries Ltd. (KPI) recently introduced one product for diabetes. As a result, KPI has the potential to benefit from clusters 3 and 4 of the UNMHCP. Communicable diseases in Uganda are mainly attributed to poverty and so make it difficult for families and communities to get out of the poverty cycle. Furthermore, according to MoH, non communicable diseases are becoming common among the middle income and/or "well to do" sections of Uganda's population due to changes in lifestyle.

3.1.4 National Drug Policy (NDP)

The NDP guides the import, production, distribution, marketing, export, and use of pharmaceuticals in the public as well as the private sectors in Uganda. It aims to ensure the availability, accessibility, and affordability at all times of essential medicines of appropriate quality, safety and efficacy, and also promotes their rational use.

Published in 2002, the NDP provides a policy framework for local manufacturing of medicines. The policy's goal is "to consider, and support, if appropriate, development of efficient local production of essential drugs of good quality, safety and efficacy, relevant to national needs and resources" (MoH 2002, p. 11). This is in line with government efforts to ensure reliable provision of the National Minimum Healthcare Package.

In order to create an environment conducive to increased national capacity for the production of essential medicines and to ensure that local production meets current Good Manufacturing Practices (cGMP) requirements, the NDP outlines the following key strategies:

- Provision of incentives for local pharmaceutical manufacturers of essential medicines, such as tax incentives, tender preference, reduced import tariffs on inputs, reduced rates for electricity and water consumption
- Systematic inspection of premises and processes to ensure full adherence to licensing and cGMP requirements; creation of a monitoring system and mechanism for support supervision to ensure maintenance of required standards
- Improving local pharmaceutical technical capacity by encouraging and assisting in the training of sufficient numbers of staff in pharmaceutical production techniques, quality assurance, and cGMP

There has been progress in the implementation of the NDP strategies. For example, the pharmaceutical section of the MoH has provided scholarships for pharmacists involved in the local production of medicines. Yet despite this progress, significant challenges remain as indicated below:

- Limited MoH resources and the failure of the industry to retain trained personnel threaten MoH plans to continue providing scholarships for pharmaceutical industry technical staff
- The MoH does not control the incentive regime which has the potential to be a major force behind increased local pharmaceutical production. It can only recommend and offer technical briefings. This is because the incentives for local

investors are controlled and implemented by the Uganda Investment Authority (UIA). Interviews have revealed that local manufacturers have to lobby for incentives on their own, often with only limited success

At present, the MoH is in the process of formulating a new National Pharmaceutical Sector Strategic Plan (NPSSP II), which will run until 2013, and the UPMA has been a key stakeholder in this process. The NPSSP II builds on NPSSP I, which ran from 2003 to 2007, and aims at improving and sustaining local production of essential medicines in order to reduce dependency on imported medicines and health supplies. It is hoped that the new plan will improve cGMP at local pharmaceutical manufacturers and thus enhance their competitiveness on the domestic market, shorten procurement lead time, and create jobs in line with the PEAP and Uganda's industrialization policy.

Furthermore, upgraded local pharmaceutical industries would have the potential to provide backup supplies to ensure availability in case of failure or delays in international procurement.

The NPSSP II proposes a number of strategies to promote and sustain local production of medicines and health supplies. Their strategic objectives are:

- Facilitation of acquisition of appropriate manufacturing facilities/equipment in order to comply with cGMP requirements
- Enable acquisition of improved technology and encourage research and development by facilitating collaboration with foreign industries and academia
- Build human resource capacity for the local industry and strengthen the regulatory capacity of the National Drugs Agency (NDA)
- Facilitate reduced operational costs

The NPSSP identifies UPMA, schools of pharmacy, the Pharmacy Department of the Ministry of Health, MoFPED, and PSU as the main implementing partners. The level of MoH's support to the development of the local pharmaceutical industry will be measured by progress in implementation of these strategies.

Table 6 summarises the Plan's strategies at policy, institutional and plan level.

Table 6. Strategies for supporting local pharmaceutical production in the new National Pharmaceutical Sector Strategic Plan

Level	*Strategy*	*Activities*	*Implementing partner(s)*
Policy	Promote a sustainable market for locally produced medicines	• Develop and implement an MoH policy on price preference for locally produced medicines in public procurements	National Medical Stores (NMS) and MoH

Level	*Strategy*	*Activities*	*Implementing partner(s)*
Policy	Advocate level playing field through favourable tax regime for local pharmaceutical manufacturers	• Appoint multi-disciplinary task force to study the Ghana/Nigeria models and how they could be applied to Uganda • Study recommendations of the task force and develop policies for implementation with particular emphasis on taxation of imported finished pharmaceutical products and removal of all taxes on replacement/ spare parts and other pharmaceutical equipment.	MoFEPD/ MoH/UPMA
Institution	Collaboration between industry and academia	• Set up a pharmaceutical development research fund and identify areas of research that are of interest to industry and academia • Develop a comprehensive protocol for industrial training • Implement the protocol both before and during internship training of students	UPMA/Schools of Pharmacy
	Adequate training and support supervision	• Increase training of NDA inspectors in cGMP • Carry out regular inspections and support visits to local manufacturers • Carry out regular meetings with manufacturers to discuss emerging issues	NDA/UPMA
Firm Level	Facilitate linkages with pharmaceutical equipment manufacturers	• Develop a comprehensive paper on preferred investment approaches • Talk to stakeholders and reach consensus on strategic direction • Advocate stronger links between foreign and local manufacturers	UPMA/ Pharmacy Department of MOH

Source: Adapted from MOH 2009 –NPSSP II.

3.2 Legal framework

As a Least Developed Country (LDC), Uganda faces significant public health challenges. Nonetheless, given its LDC status, the country can take advantage of special exemptions under the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement, which provides for a third transitional period for LDCs. It can also benefit from the related TRIPS flexibilities for pharmaceutical patents and test data protection, at least until 2016, by virtue of the TRIPS Council's decision of 27 June 2002 (WTO document IP/C/W/25) under Article 66.1 of TRIPS. These flexibilities offer LDCs the possibility of waiving the general obligation under which any person wishing to exploit a third party's

invention should remunerate or compensate the "inventor" (patent-holder). The period may even be extended beyond 2016 and this would be of significant importance for all LDCs.

Yet, although Uganda signed the TRIPS agreement with WTO in 1995, it has not incorporated the flexibilities and safeguards into national law. A respective amendment was drafted in 2004 but has not yet been approved by the Ugandan Parliament.

For local pharmaceutical manufacturers, TRIPS and the related flexibilities are the least of their immediate concerns since, with the exception of ACTs and ARVs, all currently locally produced medicines are off patent generics. Manufacturers also say that the local patent office has, in any case, very limited capacity to offer them technical support should it be needed. Nonetheless, local pharmaceutical manufacturers remain hopeful that the TRIPS flexibilities will be extended beyond 2016.

Uganda's patent law, like almost all other laws, was adapted from British law after Independence. There have been limited reviews and patenting locally produced medicines is not seen as a top priority by local manufacturers as explained above. The protection of intellectual property rights in Uganda falls under the Ministry of Justice and Constitutional Affairs and is based on the following laws:

Patents:

- The Patents Statute No. 10, December 1991
- Schedule to the Patents Act: The Patents Rules No. 22, December 1993

Trade Marks:

- The Trade Marks Act, cap. 83 (Ord. 14 of 1952, L.Ns. 281 of 1952, 161 of 1962, 261 of 1962, Act 3 of 1965), January 1933
- The Trade Marks Rules, S.I. 83-2 (L.Ns. 275 of 1952, 262 of 1959, 261 of 1962, S.I. 57 of 1964, Act 15 of 1965) (first schedule substituted by S.I No. 142 of 1982)
- The Trade Marks (Amendment) Rules, S.I. 1982 No. 142 of 1982, as last amended by Trade Marks (Amendment) Rule, S.I. No. 11/89 of 1988
- Banjul Protocol, as last amended November 1999, effective November 2000

Industrial Designs:

- The United Kingdom Designs (Protection) Act, cap. 84 (Ord. 6, June 1937, L.N. 261 of 1962)
- Copyright:
- Copyright Act (cap. 81), July 1964

Uganda has been a member of the African Regional Intellectual Property Organization (ARIPO) since 1978 and is a member of the World Intellectual Property Organization (WIPO). It is a signatory of the following WIPO Treaties:

- WIPO Convention, since October 1973
- Paris Convention (Industrial Property), since June 1965
- PCT (Patent Cooperation Treaty) , since February 1995

- PLT (Patent Law Treaty), since June 2000
- Nairobi Treaty (Olympic Symbol), since October 1983

3.3 Regulatory environment

The regulation of pharmaceuticals in Uganda is governed by the Pharmacy and Drugs Act of 1970 and the 1993 Act of Parliament that set up the National Drug Authority (NDA).[15] This is an autonomous body under the MoH and its operations are guided by provisions in the NHP and NDP. The mandate of the NDA is to ensure the availability, at all times, of high quality, essential, efficacious, and cost-effective medicines (both human and veterinary) to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of medicines.

The NDA is responsible for:

- Regulation of import and export and sale of pharmaceuticals
- Promotion and control of local production of essential medicines
- Control of quality of medicines and health supplies
- Development and regulation of pharmacies in the country
- The national Essential Drugs List and its revision
- Estimation of medicine needs and ensuring that needs are met as economically as possible
- Promotion of rational use of medicines through appropriate professional training
- Establishing and revision of professional guidelines and dissemination of information to health professionals and the general public
- Encouraging research and development of herbal medicines

To effectively execute this role, the NDA has four technical departments responsible for medicines—whose functions are outlined below in the section covering the institutional environment.

Based on the findings of this chapter, it can be argued that, whereas there are legal structures and policies to promote local manufacturing of medicines and health supplies, there is a need for coordination between line ministries to ensure that local pharmaceutical manufacturers make proper use of existing policy provisions such as tax incentives.

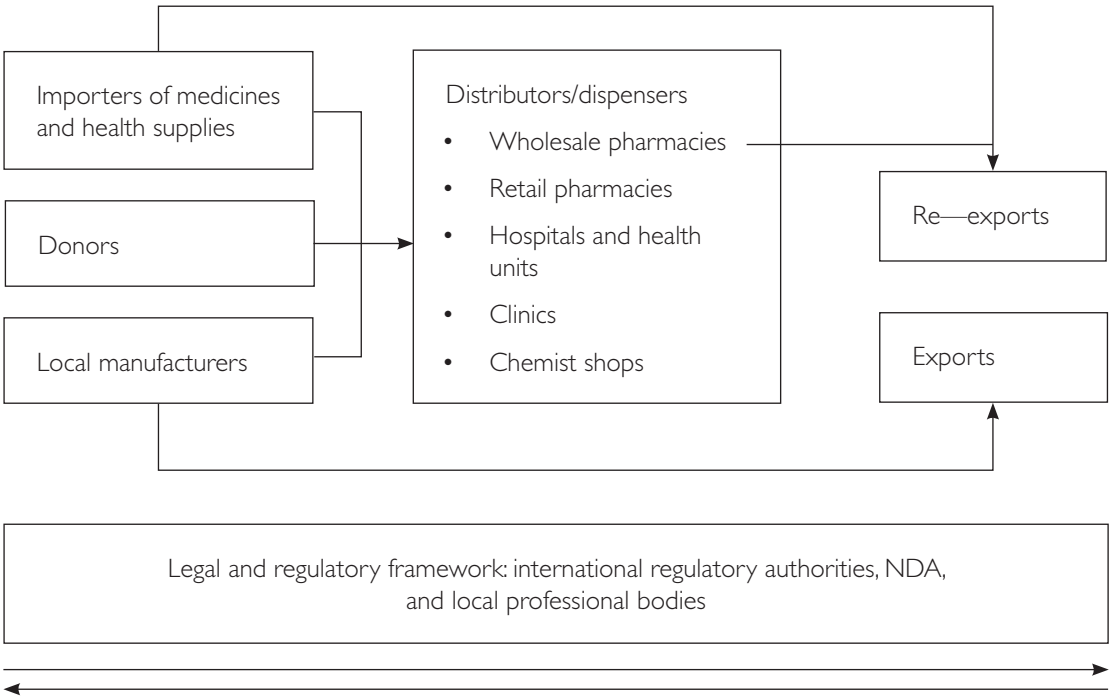
[15] NDA was established by the National Drug Policy and Authority Act of 1993.

4. INSTITUTIONAL ENVIRONMENT

There are a number of institutions involved in the manufacture, sale, and distribution of pharmaceuticals in Uganda (figure 6 below). This section presents an overview of the following key institutions:

- The National Drug Authority
- Pharmaceutical research bodies; and
- Business membership organizations

Figure 6. Stakeholders in the pharmaceutical sector in Uganda



4.1 The National Drug Authority (NDA)

The NDA was established by the National Drug Policy and Authority Act of 1993 and is an autonomous institution under the Ministry of Health. It is responsible for the regulation of local production of medicines and health supplies. The Authority is also responsible for registration of all pharmaceuticals used in the country and, as part of its routine activities, NDA conducts cGMP inspections both pre-production and during production (for local manufacturers) and is responsible for post market surveillance. Advisory inspections and cGMP trainings for local pharmaceutical manufacturers are also provided.

As will be pointed out in section 3.3, NDA executes this responsibility through inspection, assessment and registration, drug information, and quality control activities which are carried out by the four departments described below.

4.1.1 Inspection of medicines and health supplies

The Drug Inspectorate Services Department of NDA is responsible for the inspection of pharmaceutical manufacturers (local and foreign) and distributors (pharmacies, chemist shops, health units, and hospital dispensaries). The purpose of the inspections is to ensure that all those involved in the pharmaceutical value chain comply with statutory requirements that are aimed at maintaining the quality of medicines and health supplies throughout their shelf lives. Through inspections, the department guarantees that medicines and health supplies which officially enter or exit the Ugandan market are documented and are suitable for their intended use.

For local pharmaceutical manufacturers, the Inspectorate Department of NDA is responsible for cGMP audits/inspections. The audits, according to the Executive Secretary of NDA, serve two purposes; firstly, all production processes are checked to ensure compliance with cGMP and, secondly, they provide an opportunity to offer free cGMP advice to the local pharmaceutical industry.

4.1.2 Assessment and registration of medicines

The Drug Assessment and Registration Department of NDA is responsible for assessing, registering and maintaining a register of all medicines in Uganda. Medicines and health supplies are only registered and retained on the National Drug Register if the NDA is satisfied that they are suitable for their intended use. This is a control measure to ensure that only pharmaceuticals of proven quality, safety, and efficacy are registered and licensed for import and local production. Control is carried out through evaluation of documentary evidence, inspections and quality analysis to ensure that pharmaceutical products are suitable for their intended purpose.

4.1.3 Quality control/assurance, testing of medicines

Quality control/assurance and testing of medicines and health supplies is the responsibility of the National Drug Quality Control Laboratory (NDQCL), which is one of the four departments of the NDA. The NDQCL provides services for the analysis, assessment and quality assurance of pharmaceutical products. The aim is to ensure that all pharmaceutical products on the market, whether locally manufactured or imported, are of good quality and are therefore safe and suitable for their intended use.

The Laboratory was constructed and equipped as part of a health services rehabilitation project, funded by the African Development Fund and the Government of Uganda. As part of its quality control activities, the NDQCL conducts:

- Mandatory testing of all anti-malarials, ARVs, and tuberculosis medicines, whether imported or locally manufactured

- Mandatory visible particulate matter screening for all injectables and eye drops which are clear solutions
- Testing of other medicines based on a representative sample

Medicines from manufacturers that have not had any quality problems over a five year period no longer have to undergo mandatory testing. This is part of NDA's recent strategy to reduce the Laboratory's backlog and to ensure that medicines are readily available to patients. The quality of such medicines is, instead, monitored through post market surveillance activities.

According to NDA, the availability of analytical and quality control services has made a significant contribution to the enforcement of the national drug policy and statutory provisions and has helped to curb the dumping of substandard and counterfeit pharmaceuticals in Uganda. However, a number of challenges remain and key among them is technology improvement at NDQCL. As new pharmaceutical plants are built, there is a need for the NDQCL to continuously upgrade and acquire new equipment and analytical skills in order to adequately regulate the quality aspects of the pharmaceutical industry. The NDA acknowledges this need for better equipment and technical training in order to keep pace with private sector developments and aspires to move ahead of technological trends in the local pharmaceutical industry.

4.1.4 Drug information

The Drug Information Department of the NDA is responsible for disseminating unbiased information on medicines in Uganda. This is part of NDA's mandate, which requires that the Ugandan public has access to accurate, reliable, objective and non promotional information on medicines and health supplies. To meet this objective, the Department provides guidelines for and screens advertisements, vets medical/marketing representatives, conducts post marketing studies, surveillance and dissemination of the information obtained. Through pharmacovigilance activities, the Department is responsible for assessing, preventing, monitoring and reporting of adverse drug reactions. It is also responsible for improving public awareness concerning the proper use of medicines and health supplies.

4.1.5 Financing of the National Drugs Authority (NDA)

In earlier times, the NDA received substantial development assistance. Today, however, it has only limited sources of funding and does not receive any annual statutory allocation from the government. It has to generate its income from fees paid by importers and local manufacturers, among others. Fees are charged for inspection, registration, quality control, and information vetting activities. The Authority concedes that lack of resources hinders efforts aimed at staff skills development, technology transfer, and purchase of equipment. This situation, in turn, hinders improvement of NDA's regulatory capacity.

According to its Executive Secretary, the development of the pharmaceutical sector is not NDA's direct responsibility although, given the Authority's regulatory mandate, NDA is technically responsible for supervision of pharmaceutical research and development. NDA recognizes that, if the local pharmaceutical industry is to develop, more research

and development is required but there is currently very little activity in this area by local pharmaceutical enterprises. This is a major limitation and is one that needs to be addressed.

Despite these challenges, the NDA continues to support local pharmaceutical manufacturers through fast tracking of the registration process for locally manufactured pharmaceuticals and by extending cGMP support through training workshops.

4.2 Pharmacists' training institutions

Uganda has three universities with pharmacy training programmes at undergraduate level. Of the three, Makerere also conducts post graduate studies in collaboration with a foreign university. In total, the three have trained over 400 pharmacists, 348 of whom are currently practising in Uganda. Pharmacy technicians are trained by the School of Pharmacy Technicians, which is a member of the Paramedical Training Institute. The Pharmaceutical Society of Uganda (PSU) also plays an active role in training pharmacists.[16]

Pharmacy training in Uganda is entirely clinically oriented and, as a result, there has been little progress in the field of industrial pharmacy and industrial pharmaceutical research and development. Nonetheless, there are currently plans for local universities, in collaboration with the PSU and UPMA, to contribute to the local manufacturing of generic medicines through collaboration with local manufacturers in research and development and areas of quality control and stability studies. Table 7 gives details of pharmacists' training institutions in Uganda.

Table 7. Pharmacy training institutions in Uganda

Name of the institution	*Contact address*	*Courses offered*
Department of Pharmacy, School of Health Sciences, Kampala International University	Kampala International University (Western Campus) P.O. Box 71, Bushenyi, Uganda Tel: +256-41-267 634/+256-77-708 829 Fax: +256-41-501 707 Email: admin@kiu.ac.ug Web: www.kiu.ac.ug/westerncampus	Bachelor of Pharmacy (four year programme)
Department of Pharmacy, Mbarara University of Science and Technology	Mbarara University of Science and Technology, P.O. Box 1410, Mbarara, Uganda Tel: +256-48-520 394/+256-48-521 373 Fax: +256-48-520 782 Kampala Liaison Office Tel: +256-414-533 162 Web: www.must.ac.ug	Bachelor of Pharmacy (four year programme)

[16] In addition to facilitating part-time university lecturers, especially at Makerere University, the PSU plays an active role in pharmacists' internship training and in organizing attachments for students to the pharmacy industry. The PSU is also responsible for the pre-registration examination for pharmacists in Uganda.

Name of the institution	*Contact address*	*Courses offered*
College of Health Sciences, School of Pharmacy, Makerere University	P.O. Box 7072, Kampala, Uganda Tel: +256-414-530 020 Email: inquiries@med.mak.ac.ug Web: www.med.mak.ac.ug	1. Bachelor of Pharmacy (four year programme) 2. MSc. Clinical Pharmacy* (three year programme)

*This is a new programme organized in collaboration with the University of York in the United Kingdom.

4.3 Pharmaceutical research bodies

Pharmaceutical research and development in Uganda is limited. However, there are a number of local pharmaceutical manufacturers who are setting up research and development departments/sections in their plants with a focus on new generic formulations and the improvement of existing ones. Interviews with the NDA and the UPMA indicate that the biggest constraints experienced by local firms are limited technical capacity, suitable research laboratories, equipment, and funding for day to day research and development activities.

However, for health research in general, four Ugandan institutions are involved in different research activities:

1. Uganda National Health Research Organization (UNHRO): UNHRO's research activities are supported by the African Health Research Forum (AfHRF). Although the bill which regulates the functioning of UNHRO has now been passed by parliament, research activities are still limited due to funding constraints.

2. Uganda Virus Research Institute (UVRI): UVRI's activities include disease surveillance and prevention. It also contributes to national quality assessments for HIV/AIDS, Syphilis, and Hepatitis B but research activities are constrained because of limited funding.

3. National Chemotherapeutics Research Laboratory (NCRL): The NCRL works on policy, legislation and standardization of traditional medicine therapies and carries out research on herbal products for malaria, HIV/AIDS, and other diseases.

4. Makerere University, College of Health Sciences: Through the School of Public Health and other departments, the College of Health Sciences is increasingly involved in collaborative research projects, especially in the area of HIV/AIDS and malaria. However, little work is being done in pharmaceutical research.

Efforts are being made to promote collaboration between Uganda's universities and local manufacturers in order to expand local pharmaceutical research and development. However, limited resources (knowledge and skills, and funding—especially for equipment) mean that early research activities will focus on adapting formulation and production processes to suit Uganda's tropical conditions.

4.4 Business membership organizations

There are two important business membership organizations for the pharmaceutical sector, the Uganda Pharmaceutical Manufacturers Association (UPMA) and the Uganda Pharmaceutical Promoters Association (UPPA), which is mainly for importers of medicines and health supplies. Since a number of local pharmaceutical manufacturers are also importers, they are members of both associations.

4.4.1 Uganda Pharmaceutical Manufacturers Association (UPMA)

UPMA is a registered umbrella organization for local pharmaceutical manufacturers. All large scale local pharmaceutical manufacturers and a few medium scale manufacturers are active members of UPMA. Its main activity is to lobby for government support (e.g. incentives such as a levy on imports of finished medicines) to strengthen their competitiveness. UPMA is a member of the Uganda Manufacturers Association (UMA), which was revived in 1988 as an association representing all industrial and commercial sectors of Uganda's economy. UMA's membership comprises private and public, small, medium and large scale enterprises and its main objective is to promote, protect and coordinate the interests of industrialists in Uganda.

4.4.2 Uganda Pharmaceutical Promoters Association (UPPA)

UPPA brings together importers of medicines and health supplies in Uganda. The interests for which it lobbies are very often exactly the opposite of those of the manufacturers (for example, the Association strongly opposes a levy on imported medicines that can be manufactured locally).

4.4.3 Uganda Small Scale Industries Association (USSIA)

USSIA is an association that represents the interests of all registered small scale manufacturing firms in Uganda. Although our analysis of the pharmacy sector lists only one small scale pharma manufacturer in the sector, this categorization can vary according to the parameters used to measure a company's size. As a result, while the classification used in this study puts several firms in the medium scale category, they are still members of the USSIA. The Association is essentially a commercial interests grouping for manufacturers, irrespective of their industry. It offers management and technical training, organizes exhibitions, lobbies for favourable policies, and invites stakeholders to discussion fora.

4.4.4 Uganda National Chamber of Commerce and Industry (UNCCI)

UNCCI is the umbrella organization for private sector business in Uganda. It has over 6,000 members drawn from trade, agriculture, industry, services and tourism, banking, insurance, in-country transportation, clearing and forwarding, agricultural processing and arts and crafts. The Chamber maintains offices in almost all of Uganda's 94 districts.

4.4.5 Pharmaceutical Society of Uganda (PSU)

Membership of the Pharmaceutical Society of Uganda (PSU) is obligatory for all those practicing pharmacy. In addition, all pharmaceutical manufacturers must employ a registered pharmacist. PSU has a current membership of 348, mainly national, but also a few internationally registered pharmacists. Its activities include coordination of pharmacists' internships, training and pre-registration examination, workshops, exhibitions, and publication of the Pharmaceutical Bulletin. The Society is also responsible for enforcement of professional pharmacy standards, monitoring and evaluation of pharmacy training and pharmaceutical services.

5. ACCESS TO ESSENTIAL MEDICINES: CONSTRAINTS AND INTERVENTIONS TO OVERCOME THESE CONSTRAINTS

Uganda's National Health Policy (NHP) provides for adequate quantities of affordable and good quality essential medicines and health supplies to be accessible to all who need them. Nonetheless, this objective was not met during the ten year period of National Health Policy I and significant constraints in the health sector continue to limit its achievement in the immediate and near future. Key among these constraints are:

- The increasing cost of medicines in the private sector
- Inadequate financing—only 30 per cent of the Essential Medicines and Health Supplies (EMHS)—required for the NMHCP basic package are provided for in the health budget[17]
- Lack of adequate human resources, capital investment, and management limitations have resulted in the public sector being unable to fulfil its mandate of providing medicines to all those who need them
- Delays in procurement because of poor quantification and late orders from health facilities
- The pharmaceutical industry in the country is embryonic, with limited production technology

These problems reveal limitations at various levels in the health sector. This chapter categorizes these problems into demand and supply side constraints, discusses them, and explores possible interventions in the pharmaceutical sector that might improve access to essential medicines.

5.1 Present situation

Key to accessing essential medicines and health supplies are good procurement and supply chain management policies. Essential Medicines and Health Supplies (EMHS) are currently mainly ordered by health units through the Ministry of Health's established Essential Drugs Account (EDA) at the National Medical Stores (NMS) and the Joint Medical Store (JMS). This arrangement ensures access to EMHS at health units although this access does not reach the target level stipulated in the HSSP II 2005/2006 to 2009/2010. In addition, funding, procurement planning, and national harmonization of all donor procurements of EMHS remain uncoordinated. As a result, performance against set targets has been poor as indicated below:

[17] Global initiatives provide the bulk of resources needed for malaria, HIV/AIDS, tuberculosis, vaccines and reproductive health commodities. For example, in financial year 2006/2007, the contribution from these global initiatives amounted to US$ 2.39 per capita out of the total US$ 4.00 per capita that was spent.

- Per capita funding (excluding funding from global initiatives) for medicines remains below the set minimum of US$ 2.40 with the result that only 30 per cent of EMHS needs are provided for in the health budget
- Some 72 per cent of government health units have monthly stock-outs of indicator medicines with the result that patients continue to rely on the private sector where costs of medicines are three to five times more expensive than when they are obtained through public sector procurement
- Third party contributions (including new initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria) are not delivered according to an agreed national procurement plan
- Procurements by the National Medical Stores (NMS) still take a long time as, under the Public Procurement and Disposal of Public Assets Act, NMS does not have the maximum flexibility and responsiveness needed to meet public sector EMHS needs. The Essential Drugs List of Uganda (EDLU) and the Uganda Clinical Guidelines (UCG) were revised and updated during the 2008/2009 financial year but are not yet published and therefore are not available for use

One area in which the local pharma industry might help to overcome constraints is in speeding up the time taken in public procurements of medicines and in ensuring a reliable supply. Moreover, the additional revenue generated by this expanded business could be used to improve local production of pharmaceuticals.

5.1.1 Demand side constraints

With a population currently estimated at around 31 million and an annual average population growth rate of 3.2 per cent, Uganda will have an estimated population of more than 36 million by 2015. This represents a sizeable market segment for local manufacturers. Moreover, combining the total EAC population of just over 127 million with that of the Common Market for Eastern and Southern Africa (COMESA) results in more than 450 million potential pharmaceutical consumers in 20 countries. In addition, the growth of the Ugandan economy—although still low by international standards—means that more and more people are becoming capable of paying for their medicines and health supplies. There is, therefore, a steadily increasing local and regional demand for medicines and health supplies.

From interviews with local manufacturers, it is evident that two important factors continue to affect this demand for locally manufactured essential medicines and health supplies:

- The final medicine price paid by patients in the private sector, which is often three to five times higher than the manufacturers or importers selling price; and
- Procurement restrictions imposed by donor agencies

Although the NHP I and NHP II provide a framework for medicines pricing policy with the aim of ensuring affordability by the population, this strategy has not been put into practice for various reasons. These include the fact that Uganda operates a market driven economy and the idea of price setting is not welcomed by the private sector. During interviews, both the MoH and local pharmaceutical manufacturers acknowledged that the price setting process is complex and therefore difficult to implement as a final price

is also composed of costs that are not within the control of MoH, such as transportation and storage costs.

A high proportion of HIV/AIDS, malaria and TB medicines and health supplies are financed by donor organizations and global health initiatives. These organizations' procurement requirements, especially the quality requirements, essentially eliminate local manufacturers from the procurement process. Although the GoU is putting aside funding for local procurements, this amount is too small in relation to locally available manufacturing capacity. These government funds can only cover a small fraction of the population's needs.

According to the MoH annual Health Sector Performance Report (2008/2009), procurement planning and coordination of all donor agencies' procurements remained below expectations and made it impossible to reduce stock outs at health facilities. The report contends that initiatives like GFATM, the (US) President's Emergency Plan for Aids Relief (PEPFAR) and the anticipated Affordable Medicines Facility for malaria (AMFm) are creating an increasingly complex environment which limits the ability of the MoH Pharmacy Department to coordinate and manage the EMHS procurement process. This situation, according to MoH, demonstrates the need to focus on a National Health Policy strategy aimed at increasing funding, reducing reliance on donors and imported EMHS. MoH argues that such a strategy, if implemented, has the potential to increase demand for locally manufactured medicines and will help improve local pharmaceutical manufacturing capacity. In addition, MoH needs to take a respected leading role in coordinating, supporting, supervising and monitoring implementation of the National Drug Policy and national pharmaceutical sector development initiatives. However, as indicated in NHP II, this will require significant human resources at different levels in the health sector.

The government requires that all public procurements be carried out through the National Medical Stores. However, the special nature of pharmaceuticals and other health supplies requires that the mandate of NMS, as set out in the NMS statute, be reviewed and harmonized with existing public procurement legislation in order to shorten the procurement process at NMS and to meet the increasing demand for medicines and health supplies.

Given the above, local pharmaceutical manufacturers contend that growing demand for medicines and health supplies does not necessarily translate into direct business because of funding conditions, and policy and coordination constraints among others.

5.1.2 Supply side constraints

On the supply side, local pharmaceutical manufacturers enjoy a business and operating environment with a mix of characteristics that both support and limit the supply of locally manufactured EMHS. These characteristics are summarized below.

Supporting characteristics

- Tax exemption from all taxes on pharmaceutical raw materials and exemption of import duty tax on machinery
- Some sectors, such as telecommunications and water supply, are improving (despite still poor infrastructure) and are vital for pharmaceutical sector development

- The open market economy
- A growing local and regional market for EMHS

Limiting characteristics

- Unreliable and uncoordinated enforcement of policies and regulations in different line ministries and relevant departments
- Inadequate electricity supply and poor transport network
- Limited support from the authorities (NDA, MoH and MTTI), mainly because of lack of funding and expertise
- Lack of local pharmaceutical industrial knowledge and skills, especially in the field of research and development
- Relying 100 per cent on imported machinery, Active Pharmaceutical Ingredients (APIs) and a range of excipients and packaging materials

The need to import machinery, especially vital replacement parts and the necessary maintenance expertise, translates into high operational costs on top of the inherent delays created. In addition, there are exchange rate risks, the need to transport from Mombasa port to Kampala and slow clearing procedures for imports.

The limited number of appropriately qualified experts (pharmacists, operations managers, quality control specialists) not only affects local manufacturers but also the ministries and line institutions that have regulatory oversight of the manufacturing enterprises. It also hinders policy review and development processes. For example, it became clear in the course of interviews for this report that, as industries improve their production lines and set up quality control laboratories, regulatory authorities like the NDA and the Uganda Bureau of Standards need to match these technological and expertise developments if they are to provide effective support supervision and carry out regulatory activities. In this respect, limited resources (human and financial) continue to limit NDA's capacity to monitor all customs entry points and to establish a computerized system to track the flow of pharmaceuticals within the health sector and across borders.

Insufficient research and development in the pharmaceutical sector continues to limit local manufacturers' ability to invest in the manufacture of APIs and other imported excipients (although the limited market for APIs may also mean local production would be uneconomical). This situation also restricts local manufacturers to known formulations with little or no adaptations to the local environment.

5.2 Challenges and possible interventions

Given the constraints discussed in section 5.1 above, developing the local pharmaceutical industry in Uganda requires a two-pronged approach that takes advantage of the supporting characteristics while at the same time addressing the limiting ones. A number of challenges will have to be met at the policy, institutional and enterprise levels of the value chain, as summarized below:

- Improving access to and application of government incentives for the local pharmaceutical industry—the problem is mainly attributable to the lack of a

harmonized policy position between the Ministries of Health; Finance, Planning and Economic Development; and Tourism, Trade and Industry

- Access to local and regional markets—especially for donor funded programmes that require WHO cGMP certification and/or product prequalification
- Competition from low cost imported medicines—mainly from India and China, where industries are significantly developed and receive direct support from their governments in promoting their exports
- Regulation—as industries develop, the National Drug Authority and the National Drug Quality Control Laboratory, in particular, need to develop at the same pace, especially in new technologies. This is not, however, the case and is causing delays in registration of new medicines
- High operational costs—this is attributed to the high cost of money, electricity and other utilities
- Limited Research and Development—this is mainly due to limited funding and limited availability of skilled manpower
- Limited utilization of installed capacity—on average, manufacturers are using only 30 per cent to 55 per cent of their installed manufacturing capacity because of the small volume of demand

The challenges above can be addressed through carefully formulated interventions at their respective levels within the pharmaceutical value chain, as indicated in sections 5.2.1 to 5.2.4. However, given the nature of these challenges, there is a need for short, medium, and long-term strategies that specifically focus on activities that build sustainable production and quality control capacity in local manufacturers.

5.2.1 Recommended interventions at government policy and programme level

Policy development and implementation is one area that local manufacturers and key stakeholders agree can lead to significant improvement in the pharmaceutical industry. There is a consensus that policies and policy strategies should aim at improving the competitiveness of locally manufactured EMHS. The following key actions are suggested:

- Line ministries should harmonize their strategies to ensure that existing subsidies and incentives for local manufacturers are accessible and are utilized

- Preferential treatment of locally manufactured medicines in public procurements for a given period of time to encourage upgrading of production capacity; and lobbying for local manufacturers to participate in donor funded procurements if they meet the required quality standards

- Establish a coherent promotional policy for the pharmaceutical sector. Ideally, this should cut across the relevant ministries. Nigeria and Ghana have incorporated import restrictions into their policies; however, if Uganda decides to adopt this option, it should be used only as a temporary measure with a clear strategy for achieving market competitiveness in the medium term

- Promotion of pooled procurement of raw materials, machinery and technology. There is potential for cost reduction in this area and for government support, for example, through low interest loans and/or grants. This measure could have a substantial positive impact
- The reliability and cost of electricity remains an absolute priority. Having the industrial electricity incentive reactivated and putting mechanisms in place to ensure that its properly utilized would help reduce operating costs
- Beyond the MoH and NDA spheres of influence, there is little information available on local pharmaceutical manufacturing. As a result, the pharmaceutical sector continues to be grouped together with the chemical industry in key country statistics. Having dedicated indicators for the pharmaceutical sector developed and monitored will highlight its importance. It will also provide a justification for planning and allocation of government resources to the sector

5.2.2 Recommended interventions at institutional level

The National Drug Authority is the most important institution for local manufacturers. Given its critical regulatory role in the pharmaceutical sector, interventions should focus on capacity-building, specifically:

- Training for NDA staff and relevant staff from the local pharmaceutical manufacturers. Short-term attachments of local staff to international drug regulatory authorities is suggested
- Improvement of NDQCL infrastructure; the NDA also needs additional office space, and an easy to retrieve document storage system
- Computerization of the drug management information system, which could create an easy to use data base for policy/programme and medicine control activities, as well as provide relevant data for manufacturers

In addition to NDA, the three teaching universities could be supported. For example, working in collaboration with the Pharmaceutical Society of Uganda and the Uganda Pharmacy Manufacturers Association, the training of pharmacists could include university students' attachments to local pharmaceutical industries. This would have the potential to promote industrial pharmacy and also foster interest in industrial pharmaceutical research and development.

5.2.3 Recommended interventions at firm level

Pharmaceutical manufacturing is a business that needs to be both financially viable and sustainable. As such, interventions to promote viable local production of pharmaceuticals at manufacturer level should focus on:

- Improving production and quality management capacity and aiming to enable manufacturers to qualify for national, and especially international, tenders. This will require technical assistance aimed at improving cGMP and assistance in obtaining WHO cGMP certification and product prequalification

- Capacity-building, especially in technical disciplines (possibly in collaboration with regulatory experts). For example, technical assistance in quality control equipment handling and uses
- Improving operational performance (mainly through cost reduction). This can be achieved through international business partnerships which would facilitate technology, knowledge and skills transfer to local pharmaceutical industries
- To improve operational performance, initiatives that enable pooled procurement of raw materials could save some 60 per cent to 70 per cent of overall costs. In addition, technical assistance in operations management (short and long term experts) might be beneficial

It is important to note that, if it is to be successful, technical assistance should be at the request of local manufacturers and should address their identified needs and not the needs as perceived by the provider of technical assistance. However, local manufacturers have to develop viable business plans which should be a basis for the implementation of interventions at firm level.

5.2.4 Other areas of possible interventions

As other industries in Uganda develop, there is potential in the medium term for the pharmaceutical sector to source excipients such as starch, sugar, and oil-based industrial raw materials from local suppliers. To this end:

- The agricultural sector has the potential to improve and supply industrial grade starch and sugar. For example, there is work being done under the Presidential Initiative on the Banana Industry (PIBI) on the possible use of banana starch in the pharmaceutical industry
- Small scale artisanal enterprises have the potential to fabricate basic equipment (such as mixing pans) and spare parts for the pharmaceutical industries

Addressing the pharmaceutical sector challenges will require the inputs of different stakeholders at all three levels within the pharmaceutical sector, including manufacturers, the regulatory authority, and the government. Table 8 summarizes suggested interventions and identifies potential institutions/stakeholders for their implementation.

Table 8. Challenges, recommendations and possible implementation partners for the local pharmaceutical production sector in Uganda

Challenge	*Recommendation*	*Implementation institution/ partner*
Limited research and development	• Explore the possibility and set up research collaboration between the pharmacy schools and the manufacturers • Specialized training for industrial pharmacists, specifically for formulation development and improvement	• Makerere, Mbarara, and Kampala International Universities; local manufacturers • Scholarships at foreign universities is the only option given in-country training limitations

Challenge	*Recommendation*	*Implementation institution/ partner*
Utilization of installed local capacity	• Establish a coherent promotional policy for the pharmaceutical sector. Ideally, this should find consensus across the relevant ministries. The costs and benefits of policy measures such as import restrictions have to be carefully examined and debated. Experiences from Nigeria and Ghana can be studied but compatibility with WTO membership obligations needs to be ensured	• Local Pharmaceutical Manufacturers; Ministry of Health; National Drug Authority; Ministry of Tourism, Trade and Industry
Limited regulatory authority capacity	• Explore the possibility of equipping the NDQCL with the latest equipment and providing training on its use	• Local Manufacturers and National Drug Authority Note: There is a need for the NDA to match and be able to regulate quality developments in the manufacturing plants. The two parties need to work hand in hand if this is to happen.
Government policy development and harmonization	• Support the Ministry of Health in ensuring that other ministries' policies reflect the needs of the local pharmaceutical manufacturing industry	• Local Pharmaceutical Manufacturers; Ministry of Health; National Drug Authority; Ministry of Tourism, Trade and Industry (MTTI); and Ministry of Finance, Planning and Economic Development (MoFPED).
Accessibility and utilization of government incentives	• Support the lobbying activities of the Uganda Pharmaceutical Manufacturers Association Note: This could specifically include coordinating their meetings with different line ministries and institutions	• Local Pharmaceutical Manufacturers; Ministry of Health; Ministry of Tourism, Trade and Industry; Uganda Investment Authority

Additional recommendations

It is important to note that, while some of these challenges are within the control of the local manufacturers, others will require national policy review which will take some time. As such, interventions will need to be thought through and categorized into short, medium and long term. Efforts must also be made to ensure that all the stakeholders are involved.

Currently, the MTTI and MoH are in the process of formulating their strategic plans for the next five years. This is a great opportunity to ensure that these plans include activities that promote development of the local pharmaceutical industry. Local pharmaceutical manufacturers need to continue lobbying for strategies that address some

of the challenges they are facing, such as easier access to existing government incentives. UPMA has been a key and active stakeholder in the development of the Pharmaceutical Sector Strategic Plan (NPSSP II), and efforts should be made to ensure that the Union is involved in the development of the Industrial Sector Strategic Plan.

There needs to be a long term strategy to facilitate the process of technology and skills transfer. While collaboration with industries and training institutions in the developed world will address the medium term needs, there should be a process to ensure that the transferred technology and skills can be locally supported and therefore sustained.

6. CONCLUSIONS

Uganda's local pharmaceutical manufacturers have the potential to contribute to improving access to essential generic medicines and health supplies in their country. Today, local pharmaceutical manufacturers only utilize a fraction (on average some 30 per cent to 55 per cent) of their installed production capacity. This installed capacity, with additional investment in technology and human resources, can easily be utilized given the relatively large market in Uganda and a huge market in the EAC and COMESA region. Since some 90 per cent of medicines and health supplies in Uganda are imported, there is clearly scope for import substitution. This, however, will only be achieved over time as manufacturers gradually invest in manufacturing and quality control capability, new formulations and/or products. One such example is the recently developed capacity for production of intravenous fluids (by Abacus Parenterals Drugs Limited, APDL), and of ACTs and ARVs (by Quality Chemical Industries Limited).

However, as noted above, local manufacturers continue to operate in an environment that both supports and limits their potential to manufacture essential medicines. These factors are summarized in table 9.

Table 9. Supporting and limiting factors for local pharmaceutical manufacturers in Uganda

Supporting factors	*Limiting factors*
Open market economy	High investment requirements for WHO GMP certification and product prequalification
High demand due to expanding regional market size (EAC and COMESA, southern Sudan and DRC)	Lack of coherent and effective government support
Industrialization policy of government and support from NDA	Limited technical expertise (in both firms and regulatory institutions)
Existing distribution networks both in public and private sectors	Limited access to technology
Financial capacity[a]	Unreliable and costly electricity supply
Low local labour costs (for non-technical tasks)	Limited financial capacity for new development[a]

[a] Financial capacity is both a supporting and limiting factor according to the situation of the individual manufacturer

To overcome these constraints and increase local pharmaceutical manufacturers' contribution to the population's access to essential medicines, appropriate interventions are necessary at policy, institutional, and firm levels.

- *At policy level*: there is a need to harmonize the policies of different line ministries so as to arrive at a comprehensive policy framework that supports the local manufacture of essential medicines. The Ministry of Health, Ministry of Tourism, Trade and

Industry, and that of Finance, Planning and Economic Development must work together to ensure that local manufacturers benefit from the available incentives

- *At institutional level*: technical and financial support to NDA is needed to facilitate appropriate regulation, quality assurance, documentation and information, as well as the implementation of strategies that support and advance the performance of local manufacturers. Special attention should be placed on the human resource and quality control capabilities of NDA. It is suggested that the impact that an integrated EAC drug regulatory authority would have on NDA's regulatory capacity should be explored
- *At firm level*: manufacturers require support but, as discussed in chapter 5, the degree of support needed varies from manufacturer to manufacturer. This means that, in addition to support that cuts across the industry, such as electricity and tax incentives, additional support must be tailored to the needs of individual local manufacturers and should be based on viable business plans
- In the long term, developments in other sectors, such as agriculture and artisanal crafts, which can support the local pharmaceutical sector, are a positive trend and could eventually enable local pharmaceutical manufacturers to substitute imported raw materials, such as industrial sugar and starch, with local ones. This would not only develop and create jobs in other sectors but would also ensure a reliable source of raw materials for the local pharmaceutical industry

The greater challenge, however, remains the need for the coordination of all interventions at all levels.

Annex 1. PERSONS, INSTITUTIONS AND ENTERPRISES INTERVIEWED

1. Adakun le Marine Okiror, Pharmacist-In-Charge, Uganda Pharmaceutical (1996) Ltd.
2. Ajith V. Prasad, General Manager, Operations, Administration and Commercial, Uganda Pharmaceuticals (1996) Ltd.
3. Babu Ramesh, Managing Director, Abacus Parenterals Drugs Ltd.
4. Baguma W. George, Director/Chief Commercial Officer, Quality Chemical Industries Limited
5. Joshua Mutambi, Principal Industrial Officer, Ministry of Tourism, Trade and Industry
6. Kitimbo, Brenda, Company Pharmacist, Mavid Pharmaceuticals Ltd.
7. Kitumba Benjamin Benson, Managing Director, Kisakye Industries Ltd.
8. Mbaziira K. Nasser, Senior Inspector, GMP Coordination Desk, National Drug Authority
9. Muhairwe Apollo, Executive Secretary, National Drug Authority
10. Mukasa Venie, Production Pharmacist, SEV Pharmaceuticals Ltd.
11. Mukiibi Swaibu, Secretary, Pharmaceutical Society of Uganda
12. Mutumba Rajab, Pharmacist-in-Charge, Kwality Afro-Asia Ltd.
13. Muwonge Rogers, Human Resources Manager, Abacus Parenteral Drugs Limited
14. Mwesigwa, Denis, Senior Inspector of Drugs, National Drug Authority
15. Mwigo B. John, Company Pharmacist, Rene Industries Ltd.
16. Nabbale Asha, Company and Production Pharmacist, Kisakye Industries Ltd.
17. Nakamya Sr., Dr. Anthonia, Head, National Drug Quality Control Laboratory, National Drug Authority
18. Nassali Huldah, Drug Information Officer, National Drug Authority
19. Nazeem, Mohamed, General Manager and CEO, Kampala Pharmaceutical Industries (1996) Ltd; and Chairman, Uganda Pharmaceutical Manufacturers Association

20. Ogaa, Moses, Senior Drug Assessment Officer, National Drug Authority

21. Okware, Paul, Technical Director, Medipharm Industries, (E.A) Ltd.

22. Oria, Hussein, Acting Head of Pharmacy Department, Makerere University

23. Oteba, Martin, Assistant Commissioner, Ministry of Health

24. Owino, Dr. Erisa, Company Pharmacist, Abacus Parenteral Drugs Limited

25. Patel, Hemant, Quality Control Manager, Abacus Parenteral Drugs Limited

26. Prajapati, Vijay, Production Manager, Abacus Parenteral Drugs Limited

27. Sarkar Tapan Kumar, Company Pharmacist and Head of Regulatory Affairs and Drug Registration, Kampala Pharmaceutical Industries (1996) Ltd.

28. Shah, J. Prinkal, Senior Production Executive, Kwality Afro-Asia Ltd.

29. Shakti G. Monpara, Production Manager, Rene Industries

30. Ssemango Patrick, Managing Director, SEV Pharmaceuticals Ltd.

31. Sserunkuuma B. Richard, Quality Control Chemist, Kwality Afro-Asia Ltd.

32. Vasudeo V. Naik, Production/Research and Development Manager, Kampala Pharmaceutical Industries (1996) Ltd.

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