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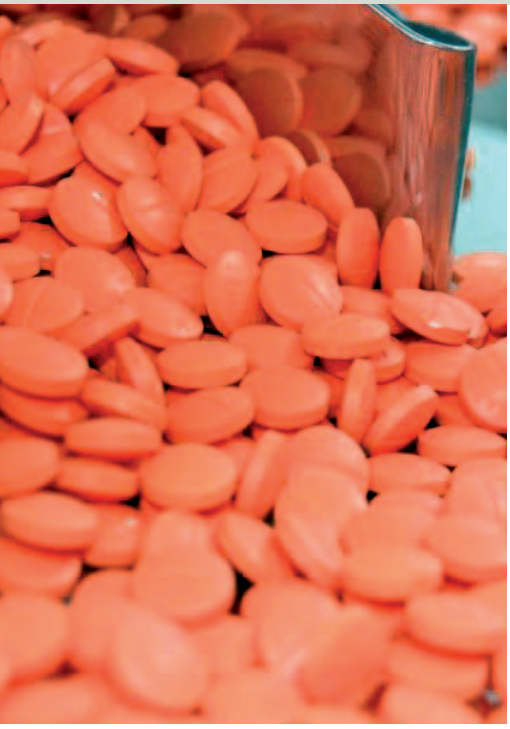

Pharmaceutical Sector Profile: Kenya

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

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INDUSTRIAL DEVELOPMENT ORGANIZATION

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PHARMACEUTICAL SECTOR PROFILE
Kenya

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

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna, 2010

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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 realize 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

ACCT	African Centre for Clinical Trials
ACSM	Advocacy, Communication and Social Mobilisation
ACT	Artemisinin-based Combination Therapy
ADR	Adverse Drug Reactions
AHU	Air Handling Unit
AL	Artemether Lumefantrine
API	Applied Pharmaceutical Ingredient
ART	Anti-Retroviral Treatment
ARV	Anti-Retroviral
AUC	African Union Commission
BE	Bio-equivalence
BMI	Business Monitor International
BMZ	Federal Ministry for Economic Co-operation and Development (Germany)
CAGR	Compound Annual Growth Rate
CCR	Centre for Clinical Research
CDC	Centers for Disease Control and Prevention (US)
CHAK	Christian Health Association of Kenya
CHMP	Committee for Medical Products for Human Use
COMESA	Common Market for East and Southern Africa
CRO	Clinical Research Organization
CTMDR	Centre for Traditional Medicines Drugs Research
DALY	Disability-Adjusted Life Year
DARU	Drug Analysis Research Unit
DLTLD	Division of Leprosy, TB and Lung Disease
DC	Developing Country
DFID	Department for International Development (UK)
DMS	Director of Medical Services
DOTS	Directly Observed Treatment—Short course
EAC	East African Community
EDL	Essential Drug List
F & S	Frost & Sullivan
FBO	Faith-based Organization
FDI	Foreign Direct Investment
FKPM	Federation of Kenya Pharmaceutical Manufacturers
GDP	Gross Domestic Product
GDP	Good Distribution Practice
GFATM	Global Fund for Aids, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
GoK	Government of Kenya
GSK	Glaxo Smith Kline
GTZ	Deutsche Gesellschaft fur Technische Zusammenarbeit
HERA	Health Research Action
HMS	Health Management Sciences (US)
HMIS	Health Ministry Information System
IPT	Intermittent Preventive Treatment
IRS	Indoor Residual Spraying

IT	Information Technology
ITC	International Trade Centre
ITN	Insecticide-Treated Nets
IV	Intravenous
JSI	John Snow Inc.
KAM	Kenya Association of Manufacturers
KAPI	Kenya Association of the Pharmaceutical Industry
KEC	Kenya Episcopal Church
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KEPSA	Kenya Private Sector Alliance
KHF	Kenya Health Federation
KIPI	Kenya Industrial Property Institute
KNASP	Kenya National Aids Strategic Plan
KNBS	Kenya National Bureau of Statistics
KNDP	Kenya National Drug Policy
KNH	Kenyatta National Hospital
KNPP	Kenya National Pharmaceutical Policy
KPDA	Kenya Private Developers Association
KRA	Kenya Revenue Authority
LCL	Less-than-Container-Load
LDC	Least Developed Country
MCP	Malaria Control Progamme
MEDS	Mission for Essential Drugs and Supplies
MDR	Multi-Drug Resistant
MoMS	Ministry of Medical Services
MoPHS	Ministry of Public Health and Sanitation
MRA	Medicines Regulatory Authority
MRA	Mutual Recognition Agreement
MSF	Médecins sans Frontières
MSH	Management Sciences for Health
MTSH	Minimum Technical Standards of Harmonisation
MVA	Manufacturing Value-Added
NACC	National Aids Control Council
NASCOP	National Aids and STD Control Programme
NCQL	National Quality Control Laboratories
NDRA	National Drug Regulatory Authority
NEPAD	New Partnership for Africa's Development
NGO	Non-Governmental Organization
NHIF	National Health Insurance Fund
NQCL	National Quality Control Laboratory
NSHI	National Social Health Insurance
OTC	Over-the-Counter
PCV	Pharmacovigilance
PEPFAR	President's Emergency Plan for AIDS Relief (US)
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PLHIV	Persons living with HIV
PMI	President's Malaria Initiative (US)
PoE	Port of Entry
PMS	Post Market Surveillance

PPB	Pharmacy and Poisons Board
PPC	Pharmacy Practice Centre
PPP	Public Private Partnership
PSI	Statisticians in the Pharmaceutical Industry Limited
PSK	Pharmaceutical Society of Kenya
QA	Quality Assurance
QC	Quality Control
RBM	Roll Back Malaria Partnership
REC	Regional Economic Community
RHF	Rural Health Facility
RHK	Rural Health Kit
SGS	Société Générale de Surveillance
SICM	Strategic Intervention through Case Management
SME	Small and Medium-Sized Enterprise
SOP	School of Pharmacy
SP	Sulfadoxine/Pyrimethamine
SPI	Statisticians in the Pharmaceutical Industry Limited
SS+	Sputum-Smear positive
TB	Tuberculosis
TRIPS	Trade and Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
UoN	University of Nairobi
WHO	World Health Organization
WTO	World Trade Organization

1. Disease incidence and product class

HIV/AIDS: The number of patients receiving—and consequently demand for—ART has increased substantially in recent years. The Kenya National AIDS Strategic Plan (KNASP) projects that, if the entire HIV population were to be treated, it would have cost US$ 237 million in 2009-2010 to cover Anti-Retroviral (ARV) therapy costs. HIV control in Kenya is mostly donor funded, with the Government of Kenya providing only about 5 per cent of total funding.

The US President's Emergency Plan for AIDS Relief (PEPFAR) is the largest donor for ARV purchases. In 2008-2009, it approved US$ 110.9 million for ARV procurement, about 70 per cent of which was to be expended on generics. In 2009-2010, US$ 219.1 million were for "treatment" but it is unclear how much of that was intended for ARV purchase. The Global Fund (GF) is also a big contributor; it approves funding in rounds, which are typically multi-year allocations, making it difficult to quantify GF funding on an annualised basis. GF's Round 7 funding, which commenced in November 2008, had disbursed US$ 11.8 million to Kenya's HIV Programme as of mid-April 2010 but how much of that was spent on medicines is not known.

Malaria: Total funding for malaria control in Kenya was about US$ 62 million in 2008 but, at only 0.5 per cent of this total, the Kenyan government's contribution was very low, with most of the funding coming from donors. The Global Fund was the biggest contributor, providing US$ 37.5 million, followed by the US Government's PMI (President's Malaria Initiative), which donated US $19.8 million. A breakdown of what was spent on medicines from these amounts was not available. However, the estimated budget in the year 2009-2010 for public procurement of anti-malarial medicines was US$ 19.3 million.

Tuberculosis: The Global Plan for WHO's Stop TB Programme estimated the requirement for Kenya's TB Programme at US$ 37 million in 2009. Of this amount, 6 per cent, or only US$ 2.2 million, was budgeted for the purchase of first-line drugs. The Government of Kenya was to provide 21 per cent of the required funding and the Global Fund was also contributing. However, there was still a funding gap of 40 per cent.

A review of outpatient data between 2004 and 2008 indicates that ten disease categories accounted for an average of 79.26 per cent of all disease incidences causing morbidity. By far the most common disease causing morbidity is malaria. After malaria, the second highest diseases causing morbidity are those of the respiratory system, mainly upper respiratory systems and allergies. Thus, it is understandable that antibiotics, analgesics, and antihistamines are popular medicine categories in the Kenyan market.

2. Procurement

The Government of Kenya procures medicines mainly through KEMSA (Kenya Medical Supplies Agency). It has been estimated that KEMSA's purchases constitute 30 per cent of all prescription drugs in the Kenyan market. The Agency also procures for some donor partners.

KEMSA's 2010/2011 Government budget (not counting donor contributions) for the procurement of essential medicines for public hospitals is US$ 19.8 million; together

with US$ 29.7 million for Rural Health Facilities (Dispensary Kits + Health Centre Kits + Loose Drugs RHF), this makes a total of US$ 49.5 million. Out of 343 items on the Essential Drug List (EDL), KEMSA procures only about 117 selected items, based on available funds. Many EDL medicines cannot be purchased because of budgetary constraints.

Mission for Essential Drugs and Supplies (MEDS) is another large-scale, bulk procurer of medicines. It is a not-for-profit organization which procures medical items for Faith-Based Organizations (FBO) and some donors. About 45 per cent of MEDS' annual turnover of 800 million to 1 billion KSh (about US$ 12 million) is spent on medicines.

Some donors procure directly. Purchases from Global Fund donations are undertaken by the Procurement and Supply Chain Management Consortium, which is made up of four partners, KEMSA, Crown Agents, Deutsche Gesellschaft fur Technische Zusammenarbeit (GTZ), and JSI – John Snow Inc.

3. Exports

Kenya's pharmaceutical exports grew by 96 per cent between 2004 and 2008, corresponding to a Compound Average Growth Rate (CAGR) of 18.3 per cent over this period. About half of Kenyan exports of pharmaceutical products are destined for the United Republic of Tanzania and Uganda and the expanding market in these countries may be attributed to:

- The general growth in demand in pharma markets in these destination countries
- The advantages enjoyed by Kenyan exporters in these neighbouring markets relative to overseas suppliers (for more details, see section 2.1.4)

Yet, despite the fact that Kenya's exports of medicines are expanding, a comparison with exports from South Africa over this same period shows that Kenya still has further export growth potential within COMESA. Comparative advantages for Kenyan pharma manufacturers within the subset of neighbouring COMESA countries include their proximity to import markets and the freer movement of goods they enjoy as of 1 July 2010 when the East African Community's protocol on goods, labour, services, and capital came into force.

4. Health insurance

At present, 1.6 million Kenyans (9.5 million, when dependants are included) are covered by the National Health Insurance Fund (NHIF). In 2005, legislation for a National Social Health Insurance (NSHI) was passed with the objective of covering 60 per cent of the population by 2015. With greater insurance coverage, the demand for medicines is naturally expected to rise although the impact is difficult to quantify at this stage.

On the supply side, market estimates are that the local pharma market was about US$ 240 million in 2008, with two important caveats. Namely, these estimates almost certainly do not include all donor-funded purchases of pandemic medicines. The US Government's PEPFAR, for instance, allocated over US$ 110 million for ARV procurement alone in

the financial year (FY) 2008 although this figure includes purchase cost, warehousing, distribution, etc. Secondly, local market estimates ignore the unwitting but substantial spending on counterfeits. Estimates for spending on counterfeits range from US$ 65 million to US$ 130 million per year although there are no systematic studies to support these figures. On the supply side, the critical challenge to help the local pharma industry is to control counterfeit and substandard drugs.

On the demand side, the local pharma industry would benefit from actions to:

- Improve availability and affordability of medicines
- Increase purchases of medicines from the Essential Drug List (EDL); and
- Pursue export markets more aggressively

Local pharmaceutical production

The sector in general

In 2008, the pharma sector contributed about 2 per cent of Manufacturing Value Added (MVA) in the Kenyan economy, or 0.2 per cent of Gross Domestic Product (GDP). It employed 3,389 persons. At current levels, if the industry utilized full capacity and instituted two shifts per day, this would boost wage employment in the sector by over 30 per cent.

The domestic pharma market

Kenya has a significant and growing trade imbalance in pharmaceuticals. There has been a steady increase of imports from 2004 to 2008, when—at US$ 277 million—they totalled more than four times the value of exports at US$ 59.4 million.

Although the market estimate of US$ 240 million in 2008 is an underestimate since actual spending includes donor-funded purchases of medicines and unintentional spending on counterfeits, this figure has been used to calculate market shares, because:

- Local pharma producers cannot, at present, participate in donor-funded procurement because of the technical standards laid down by donors
- Donor funding is uneven and uncertain
- There is uncertainty about actual spending on medicines from donor contributions
- Estimates of spending on counterfeits vary widely

Based on a total market of US$ 240 million in 2008, local industry has less than a 30 per cent market share. This is, however, an upper estimate of local producers' share in the domestic pharma market. If donor-funded purchases were taken into account, the market share of local manufacturers would be substantially lower and, correspondingly, the market share of imports would be higher, since donor procurement is sourced entirely outside Kenya.

Structural characteristics of the local pharma industry

There are 42 companies listed as local pharmaceutical manufacturers in Kenya. Amongst these, there is only one multinational, GlaxoSmithKline (GSK). Together, these companies constitute an important pharma manufacturing centre in the region.

Local pharma companies are characterized by:

- *Common product lines*

The indigenous firms produce generics. Most of the leading firms have similar product portfolios, in that they all produce the same categories of pharmaceutical products.

- *Low capacity utilization*

Most companies are running their production lines at low capacity of between 50 per cent and 66 per cent. Since companies are not operating at optimum capacity utilization levels, production costs per unit are relatively higher and this impacts negatively on their ability to be cost competitive.

- *Variation in GMP standards among local firms*

Some firms have already made the investment in plant and equipment to meet World Health Organization (WHO) basic good manufacturing practices (GMP) standards. Other pharma firms are deterred from making GMP upgrades through lack of finance and/or access to technical assistance. Inevitably, there are also some that have so far exhibited no interest or initiative in improving their technology levels. There are limitations on the regulatory side as well. The inspectors in the Pharmacy and Poison Board's (PPB's) GMP Inspectorate are not experienced in industry practices and are, in any case, too overworked to make follow up inspections in all the local firms effectively.

- *Shortage of qualified personnel*

The number of trained pharmacists is increasing with time but is still insufficient relative to the population in need (one pharmacist for every 8,710 persons, or approximately 0.1 per 1,000 persons). Pharmacists trained locally in Kenya lack a basic industrial orientation.

- *Need for greater production efficiencies*

A major factor in the dominance of imported generics in the domestic pharma market is the higher relative prices of locally-produced medicines. Obviously, efforts need to be made to lower production costs in local companies. There is inadequate data on the economics of pharma manufacturing in Kenya and the cost structure of manufacturing operations. In view of this, more in-depth analysis needs to be done to identify ways of making production more efficient.

- *Requirement of bioequivalence (BE)*

It is difficult for local manufacturers to carry out bioavailability/bioequivalence studies due to financial constraints, lack of know-how, and non-availability of national guidelines on this subject. The studies performed abroad may not be applicable to the Kenyan population and patients. Moreover, the costs involved in doing these studies are prohibitive.

The competitive environment faced by domestic pharma producers

Local pharmaceutical companies in Kenya face competition on two fronts:

- They compete with each other
- Collectively, they face stiff competition from imports

A number of factors have contributed to the flood of imported pharmaceuticals, many of which are substandard, into Kenya, including:

- Foreign drugs are easy to register with the PPB
- Kenya was one of the first countries in the region to reduce its pharmaceutical import tariffs to zero
- The PPB has little capacity to monitor the GMP status of foreign pharma factories producing drugs for import into Kenya
- Quality testing of incoming imported drugs is uneven and irregular
- Penalties on importers for importing substandard drugs are low

At the same time, local pharma producers are disadvantaged on a number of fronts:

- Since they lack WHO pre-qualification, they are excluded from donor-funded procurement
- Since many are small firms, they do not have the capacity to participate in large volume tenders
- They are facing severe price competition from imports
- They are financially strained by delayed reimbursements from the government of duties and VAT already paid

Need for finance

To upgrade the Kenyan pharma industry as a whole to the next level, the sector will have to absorb transfers of new technology and training. If the sector is to become a significant player in the region, firms will also have to make significant investment in plant and equipment, and personnel. The best option for local industry to gain access to this investment is to conclude strategic partnerships or joint ventures with pharma players in more developed countries—in other words, Foreign Direct Investment (FDI). Preference for local firms, non-tariff barriers to imports, special incentive packages for foreign investors in the sector, and other policy options all need to be examined if the Kenyan pharma industry is to become an attractive FDI destination

The business environment for pharmaceutical sector performance and development

Policy framework

The Kenya National Pharmaceutical Policy, Second Edition 2009 (KNPP) is being revised and a Sessional Paper is to be submitted to Parliament. The current policy

encompasses the key elements needed to revitalize the pharmaceutical subsector in Kenya. The Master Plan for Kenyan Industrial Development, completed in 2008, is intended as a road map by which the Government can catalyse the implementation of strategic actions to accelerate industrial development. Pharmaceuticals is not one of the target subsectors selected. In fact, there is very little mention of pharmaceuticals in the Master Plan.

Legal framework

Pharmacy and Poisons Act, Cap 244

The main legislation for the control of pharmacy in Kenya is the Pharmacy and Poisons Act, Cap 244. Its main purpose is to regulate the profession of pharmacy and control the manufacturing, trade, and distribution of pharmaceutical products.

Industrial Property Act, 2001

The Act provides for the promotion of inventive and innovative activities to facilitate the acquisition of technology by granting and regulating patents, utility models, technical innovations and industrial designs. It is popularly known as the "Patent Act". Kenya acceded to the Trade-related Intellectual Property Services (TRIPS) agreement by enacting this legislation in 2001.

Anti-Counterfeit Act, December 2008

This Act was legislated to prohibit trade in counterfeit goods and pharmaceuticals are not exempted. The definition of counterfeiting has generated controversy because it is broad and over-encompassing.

Kenya Public Procurement and Disposal Act, 2005

This legislation provides for the establishment of procedures for public procurement. The Public Procurement and Disposal regulation in this legislation states that "the procuring entity may grant a margin of preference of up to 15 per cent in the evaluation of bids to candidates offering goods manufactured, mined, grown, and extracted in Kenya". The Act also provides for pre-qualification of suppliers. Local pharma manufacturers complain of a lack of implementation of these provisions for preferential treatment, and pre-qualification of suppliers.

Regulatory environment

Pharmacy and Poisons Board

The Pharmacy and Poisons Board (PPB) is the pharmaceutical regulatory authority in Kenya established by law under the Pharmacy and Poisons Act, Cap 244. The Board regulates the practice of pharmacy and the manufacture and trade in drugs and poisons. Interviews have been conducted with each of the major departments within the PPB, i.e. Drug Registration, Pharmacovigilance, the Pharmaceutical (Good Drugs Practice—GDP) Inspectorate, the GMP (Good Management Practices) Inspectorate, Trade Affairs, and IT (Information Technology).

The PPB is in need of substantial reform. Its resources and systems are simply not up to the regulatory burden. The PPB staff is overwhelmed by the very large numbers of

companies and products which it is expected to regulate, such as unregistered outlets, unregistered medicines, substandard medicines and counterfeits, and manufacturing premises. The system to monitor authorised or unauthorized imports, exports, or locally produced medicines on the market is inadequate. Although the PPB collects a lot of useful information, its capturing and retrieval systems are not consistent with modern times. Unfortunately, this very useful information is collected on hand-written forms, which are then filed in a haphazard fashion. The data cannot be accessed or used electronically and is, effectively, lost to anyone who could make good use of it. The policy and decision-making organs do not have reliable data on a routine basis. In the event of a crisis in public health and safety, necessitating withdrawal or recall of a medicine, information on the product name, quantity, price, source, and distribution channels is required, yet this information is simply not accessible in a timely manner.

The result of very weak and ineffective regulation has been a flow of substandard medicines in the domestic market both in the form of imports, which dominate the Kenyan market, as well as the products of some local manufacturers. In general, there are very strong views in the Kenyan pharma industry that, unless there are deliberate and urgent reforms at the Pharmacy and Poisons Board (PPB), there cannot be any meaningful programme to strengthen local production. These views are commonly shared between local industry, distributors, importers, associations, and professionals and policy makers.

National Quality Control Laboratory (NQCL)

The National Quality Control Laboratory (NQCL) was established as the technical arm of PPB to provide for the examination and testing of drugs and to ensure quality control. The functional relationship between NQCL and PPB is implicit but not clearly defined.

From the regulatory standpoint, the most important development that would improve local production is to reform the PPB and to implement better coordination between PPB and NQCL. Specifically:

- Post-market surveillance needs to be significantly enhanced to control substandard drugs on the market and to level the playing field between imports and locally-manufactured products
- Information flow and coordination, internally between PPB departments, and between PPB and NQCL, should be improved
- Equivalent GMP standards should be enforced for all Kenyan pharma firms and foreign suppliers
- A system of checks and balances has to be introduced in PPB operations

The institutional environment

Business membership and sector governance organizations

There are several organizations active in the pharma sector. The main ones are:

- Federation of Kenya Pharmaceutical Manufacturers (FKPM)
- Kenya Association of Pharmaceutical Industry (KAPI)

- Kenya Association of Manufacturers (KAM)
- Kenya Private Sector Alliance (KEPSA)
- Kenya Health Federation (KHF)
- PPP-Health Kenya
- Pharmaceutical Society of Kenya (PSK)

It is the strongly held view of several organizations, especially KHF, that FKPM's mandate should be reviewed with the aim of strengthening the Federation. The establishment of a permanent secretariat in a reformed FKPM would be an important factor.

Drug procurement and distribution

As the primary public procurement agency for medicines, KEMSA plays a significant role in the pharmacy sector. The pattern of procurement at KEMSA has recently been modified to alleviate certain problems that had risen in the procurement process in recent years. A joint survey funded by the US Agency for International Development (USAID), the Millennium Challenge consortium, and Management Sciences for Health (MSH) was carried out in 2007-2008 to compare KEMSA's procurement prices with those of MEDS, Kenyatta National Hospital (KNH), and local manufacturers and distributors. The conclusion of the study was that, for the most part, KEMSA's prices are more competitive than those of similar products purchased by health facilities from all the other entities surveyed.

The legislative provision which allows a "margin of preference of 15 per cent" in public procurement for goods manufactured in Kenya is not currently being respected by KEMSA with the reason given being the lack of guidelines for implementation from the Finance Ministry. Since local pharma plants do not meet WHO pre-qualification standards, local manufacturers are locked out of most donor-funded procurement in KEMSA's open international tenders. However, if stock-outs and emergencies occur, local companies have, on occasion, supplied urgently needed Anti-retrovirals (ARVs) for which local companies could not normally bid. KEMSA provides no incentives to procure the pandemic drugs from local pharma producers to ensure sustainable sources of supply. Consequently, local suppliers have little opportunity to expand their market other than in the case of emergency supplies.

The drug distribution system in Kenya can be classified into public (government), non-governmental organizations (NGOs), and private channels. The private sector is served by distributors (distributing both imports and locally-manufactured goods) and the local manufacturers directly. There are many distributors and wholesalers registered by the Pharmacy and Poisons Board and some wholesalers also retail. A large number of unregistered outlets also exists and this number is currently estimated at between 3,000 and 4,000.

The traditional pricing structure norm for medicines is intended to allow a 10 per cent mark-up for the drug manufacturer over produced cost, a 15 per cent margin for the distributor/wholesaler over the manufacturer's or importer's price, and a 33 per cent margin for the retailer above the wholesale price. However, due to competitive pressures, these norms are breaking down and discounting is common.

With regard to the institutional environment in which the domestic pharma industry operates, actions from which it would benefit are:

- Implementation by KEMSA of the preference in public procurement for local manufacturers, as provided for by law
- Strengthening FKPM to make it the real "voice" of the industry

Potential steps to enhance local pharmaceutical production capabilities

The domestic pharmaceutical industry in Kenya shows considerable strengths and has significant opportunities for growth and development, as revealed in a SWOT analysis in this report. In addition, there are major public health and economic benefits to be derived from local production of essential medicines and a thriving domestic pharma sector.

From the public health perspective, the perceived benefits of local production include:

- Improved access to essential medicines, through a regular, reliable supply of these medicines to the public
- Shorter supply chains and continuous availability of medicines in the public and private sector, plus better responsiveness during disasters or emergencies
- Cost-effective regulatory oversight and better quality accountability
- Local innovation in new treatment regimes and dosage forms

The economic benefits include:

- More local jobs and skills development for nationals
- Savings of foreign exchange through import reduction
- Facilitation of technology transfer
- Stimulation of pharmaceutical exports
- Local innovation in new treatment regimes and dosage forms

There is a paramount need for a coordinated approach to strengthening the local pharma sector. Progress through piecemeal actions which focus on one or more aspects of the market or production is likely to be difficult. What is required is a holistic strategy for the sector.

Based on a review of possible improvements derived from the UNIDO assessment from various perspectives, a set of potential actions at the regulatory level, at the sector/enterprise level, and at the policy level are proposed:

Regulatory level

At the Pharmacy and Poisons Board (PPB):

- Strengthen post market surveillance in order to control substandard and counterfeit drugs in the Kenyan market

- Design and install an IT system to capture and allow easy retrieval of relevant data by appropriate personnel (including field inspectors)
- Establish a GMP Standard for the Kenyan pharma industry in consultation with relevant stakeholders/experts

At the National Quality Control Laboratory (NQCL):

- Build capacity in NQCL to enable it to adequately support PPB in testing drugs at Ports of Entry (PoE) and on request by PPB Departments
- Benchmark response times on test results and institute performance criteria for NQCL functions
- Create a mechanism for monitoring and review of NQCL performance against set criteria

At PPB/NQCL:

- Develop joint procedures/linkages for efficient testing of suspect drugs to ensure fast withdrawal of non-compliant products from the market
- Set up a forum for top management of both institutions to regularly coordinate joint activities and iron out problems

Sector/enterprise level

- Build capacity in the pharma trade association, the Federation of Kenya Pharmaceutical Manufacturers (FKPM)
- Train pharma companies' personnel in industrial pharmacy practices
- Improve efficiency in plant operations to reduce production costs
- Develop a domestic marketing scheme for locally-manufactured pharmaceutical products that meet minimum product quality standards and GMP criteria
- Establish linkages for technology and know-how transfer at local, regional and international level

Policy level

- Implement regulation providing for 15 per cent preference for local manufactures in public procurement of medicines
- Establish a package of incentives (in terms of taxes, duties) to spur development of the Kenyan pharma industry
- Review measures to improve the possibilities for local firms to raise financing for upgrades, and/or encourage foreign investment in the sector
- Fast track harmonization of regulation within the East African Community (EAC) and the Community of East and Southern Africa (COMESA), especially the recommendations on strengthening the PPB
- Modify the legal framework so that PPB becomes autonomous

1. INTRODUCTION

1.1 Background and objective

The United Nations Industrial Development Organization (UNIDO) has embarked on a project to strengthen local manufacturing capacities in the production of a range of essential generic drugs in selected developing and Least Developed Countries (LDCs), with funding from Germany's Federal Ministry for Economic Cooperation and Development (BMZ). Kenya, which has a strong base from which to develop its pharmaceutical industry, decided to collaborate with UNIDO in an effort to further develop this sector.

The project aims at the expansion and upgrading of small and medium size enterprises (SMEs) for the local manufacture of essential generic drugs (with a particular emphasis on those combating the three major pandemics: HIV/AIDS, malaria and tuberculosis) with the aim of improving access for the poor to these drugs at affordable prices.

The first stage of the project involved carrying out a broad review of the pharmaceutical sector in Kenya. This report summarizes the findings of this initial review. In addition to a comprehensive survey of publicly-available information, such as government statistics and earlier related studies, the UNIDO team gathered information through interviews with a wide range of players, who are directly or indirectly involved in the domestic pharmaceutical (pharma) sector. Those interviewed included relevant ministries, regulating institutions, trade groups, medicine procurement agencies, individual pharma companies, representative bodies in the distribution chain, and non-governmental organizations (NGOs) active in the sector. Where necessary, particularly with regard to information on the local pharmaceutical producers themselves, targeted questionnaires were used to gather data. These questionnaires covered topics such as personnel, plant capacity, market performance, compliance level with certain registration requirements, and production costs.

This report begins with an examination of the demand for and supply of medicines in Kenya, with a focus on drug requirements for the pandemics. Next, the local pharma sector is described, with profiles of the leading firms and information on the challenges they face to increase their production. The policy, legal/regulatory, and institutional environment in which the pharma sector is operating is outlined and, finally, some recommendations for action to strengthen local pharmaceutical production capabilities are put forward, comprising a combination of advisory, promotional, institutional capacity-building, and sector/enterprise-level interventions.

1.2 Overview of Kenya's economic structure and the role of the manufacturing sector

The population of Kenya was estimated at 38.3 million in 2008 and has been expanding by around 2.9 per cent annually in recent years.[1] According to the Kenya Economic

[1] *Economic Survey 2009*, Kenya National Bureau of Standards.

Survey 2009, gross domestic product (GDP) at market prices totalled US$ 27,997 million, giving a GDP (current) per capita figure of US$ 731.93. Table 1 below provides an overview of the main social and economic indicators.

Table 1. Some basic indicators

Demographic social and economic indicators												
			2000	***2001***	***2002***	***2003***	***2004***	***2005***	***2006***	***2007***	***2008***	
Total population (millions)			30.4	31.3	32.2	33.2	34.2	35.1	36.2	37.1	38.3	Population Reference Bureau
Rate of natural increase			2.1	2	2		2..3	2..2	2..5	2..8		Population Reference Bureau
Births per 1,000 population			35	34	34		38	38	40	40		Population Reference Bureau
Deaths per 1,000 population			14	14	14		15	15	15	12		Population Reference Bureau
Total fertility rate			4.7	4.4	4.4	4.9	5	4.9	4.9	4.9		Population Reference Bureau
Population per sq kilometre			135	133	139	147	145	151	155	156		Population Reference Bureau
GNI per capita (USD)			350	376..3	400	447.7	481.6	558.3	646.9	778.1		Economic survey
GDP growth rate			-0.2	0.8	1.2	2.9	5.1	5.8	6.4	7		Economic survey
Govt expenditures on health (per cent of GDP (USD/ PP))				3.1	4.9	6.4	7.2	7.6	7.8	8		Economic survey

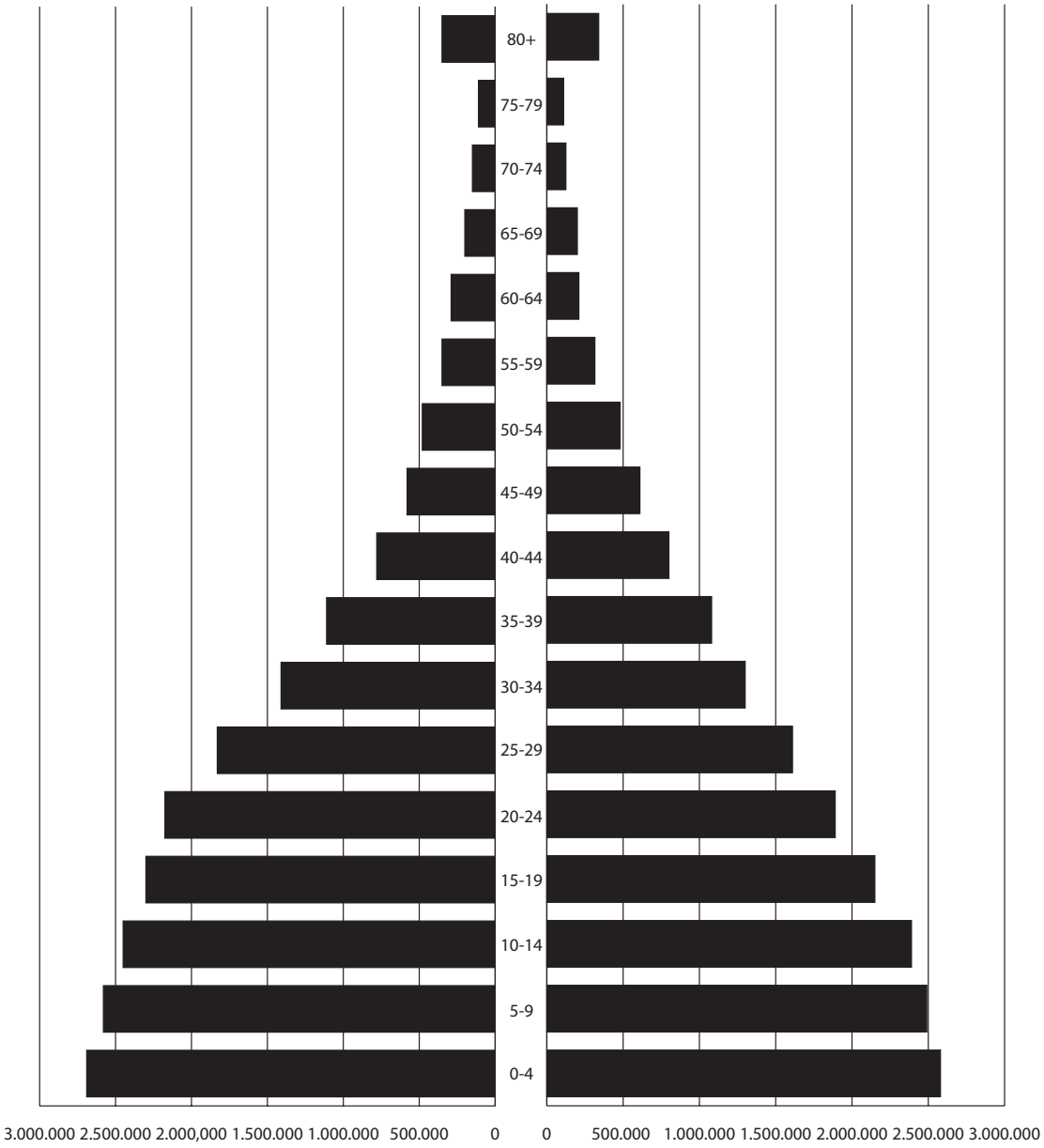
Source: HMIS – Kenya Annual Report 2009.

The strong economic growth that had started in 2003 slowed from 7.1 per cent in 2007 to 1.7 per cent in 2008 as a result of both exogenous and endogenous factors, including the global financial crisis and the 2008 post election crisis in Kenya. There was a corresponding contraction in growth in some of the main economic sectors with manufacturing, for example, growing by only 3.8 per cent in 2008 compared with 6.5 per cent in 2007. Nonetheless, the sector did continue to expand in 2008 despite depressed domestic and external demand, supply disruptions as a result of post election violence, and heightened competition from cheap imports and counterfeit products. manufacturing value added (MVA) from food, beverages, and tobacco actually contracted but manufacture of non-food items grew by 6.3 per cent, resulting overall in net positive growth in the sector. In the five years from 2004 to 2008, the manufacturing sector maintained a steady contribution of around 34 per cent to 35 per cent of total GDP.

1.3 Background of disease in Kenya

The Kenyan population is predominantly young, as seen in figure 1. However, the number of aged is increasing, and more people ageing will naturally increase healthcare needs. This is important because the disease burden is bound to shift over time towards lifestyle diseases like hypertension, diabetes, etc., which require long term treatment.

Figure 1. Population distribution: Kenya population pyramid 2008

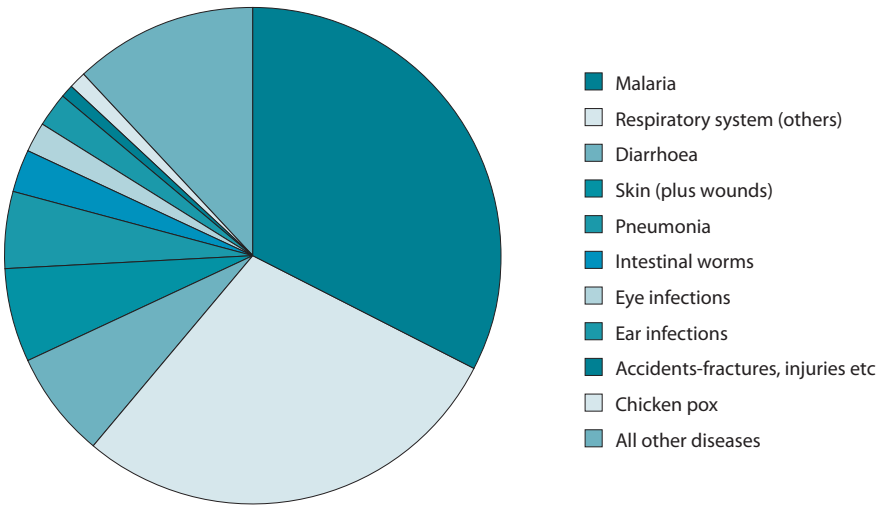


Source: Annual Health Sector Report, July 2009

Data in tables 2 and 3 below show the morbidity pattern of individual outpatient cases at national level and indicate that the prevalent disease burdens in both the under- and over-five age groups are from malaria, respiratory infections, diarrhoeal diseases, and skin diseases. (HIV/AIDS is already a leading cause of death in Kenya[2] but is not included in this data—see note under table 2). In under-fives, pneumonia and intestinal worms are also among the major causes of morbidity and, in over-fives, accidents and eye infections are significantly greater disease burdens than in under-fives. Rounding out the 10 major causes of morbidity in outpatients are rheumatism and joint pains, urinary tract infections, skin diseases, and accidents (including fractures and burns).

Table 2. National major causes of outpatient morbidity in under fives—2008

Diseases	*NO. CASES*	*% CONT*	*IR/1000POP*
Malaria	1,176,826	33	185
Respiratory system (others)	1,032,266	29	163
Diarrhoea	250,164	7	39
Skin (plus wounds)	220,399	6	35
Pneumonia	185,266	5	29
Intestinal worms	122,312	3	19
Eye infections	65,093	2	10
Ear infections	55,471	2	9
Accidents – fractures, injuries etc	30,326	1	5
Chicken pox	28,313	1	4
All other diseases	427,331	12	67
Total new cases	**3,593,767**	**101**	**566**
Population	**6,347,748**		



Source: Health Ministry Information System (HMIS) Annual Report 2009 (final draft).

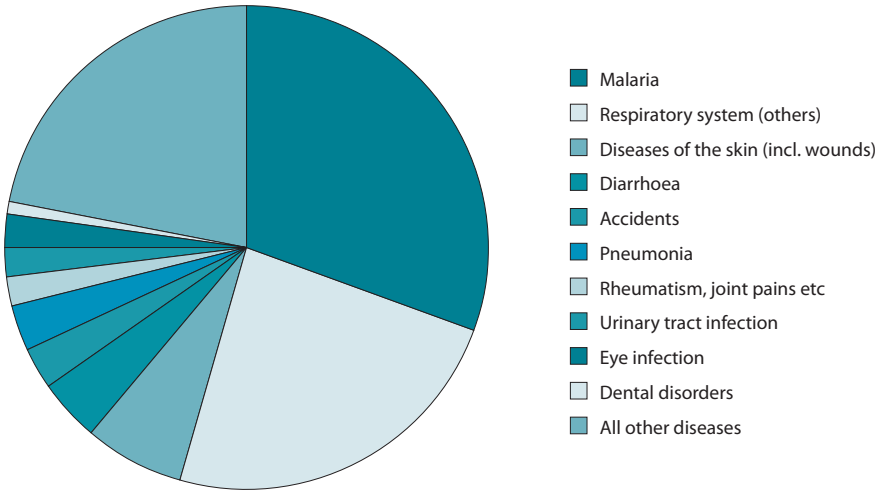
Note: HIV cases are not captured in the outpatient data in tables 2 and 3. Suspected HIV cases are referred to a special clinic because HIV requires diagnosis by specially-trained staff. However, opportunistic infections in HIV patients are included in the outpatient data.

[2]WHO, Death and Disability-adjusted life year (DALY) estimates by cause, 2002.

Table 3. National major causes of outpatient morbidity in over fives—2008

Diseases	*NO. CASES*	*% CONT*	*IR/1000POP*
Malaria	3,028,310	31	105
Respiratory system (others)	2,395,618	24	83
Diseases of the skin	658,891	7	23
Diarrhoea	359,637	4	12
Accidents	260,781	3	9
Pneumonia	253,869	3	9
Rheumatism, joint pains etc	236,136	2	8
Urinary tract infection	191,320	2	7
Eye infections	173,114	2	6
Dental disorders	117,879	1	4
All other diseases	2,183,602	22	76
Total new cases	**9,859,157**	**101***	**342**
Population	**28,917,517**		

*Discrepancy is caused by rounding up of decimal places.



Source: Health Ministry Information System (HMIS) Annual Report 2009 (final draft).

1.4 Malaria

Malaria has a significant impact on African economies and Kenya is no exception. According to the World Health Organization (WHO), malaria costs Africa US$ 12,000 million a year. It has been estimated that Kenya loses 170 million working days annually to the disease and, in view of the impact of this on the economy, the fight against malaria is a high policy priority for both governments and development partners. In April 2004, as part of the African Summit on Roll Back Malaria, African Heads of State made commitments "to an intensive effort to halve the malaria mortality for Africa's people by 2010". In 2005, the World Health Assembly resolved to "ensure a reduction in the burden of malaria of at least 50 per cent by 2010 and by 75 per cent by 2015". Kenya has adopted intervention measures to contain the problem, including insecticide-treated nets

(ITN), indoor residual spraying (IRS), intermittent preventive treatment (IPT) in pregnant mothers, and case management. In 2006, the country adopted Artemisinin-based Combination Therapy (ACT) as a first-line treatment, using Artemether Lumefantrine (AL). In a 2006/2007 study, it was found that a wide range of anti-malarials were available in Kenya but only 27.5 per cent of these formulations were recommended in the treatment guidelines.

The impact of malaria has remained fairly constant in Kenya in the last 12 years. The total population at risk, based on 2009 population projections, is approximately 27.6 million or 70 per cent of the population.[3] This includes an estimated 4.6 million children under five and 1.3 million pregnant women. Clinically diagnosed malaria is responsible for 30 per cent of outpatient consultations, 19 per cent of hospital admissions and 3 per cent to 5 per cent of inpatient deaths. Malaria and respiratory diseases account for more than 57 per cent of outpatient morbidity in both the under- and over-five age groups.

Although anti-malarial medicine is dispensed free of charge to patients in public health facilities, the facilities are unable to respond to total demand since the government's budget allocation for the purchase of these anti-malarials for public facilities is insufficient. In private pharmacies, the cost of the anti-malarial AL, for example, is high, at US$ 6 to US$ 8 per treatment course. Consequently, for malaria patients faced with stock-outs at public health facilities, self treatment with medicines bought from private pharmacies involves considerable out-of-pocket expenditure. The availability of low-cost, quality generic anti-malaria medicines in the private sector is, thus, essential for the management of malaria in Kenya. Access and continuous availability of anti-malarials would reduce the high mortality rate from the disease.

1.5 Tuberculosis

Kenya ranks 13th on the list of 22 high-burden tuberculosis (TB) countries in the world and has the fifth highest incidence in Africa. According to WHO's Global TB Report 2009, Kenya had a TB incidence of 353 per 100,000 population, corresponding to more than 132,000 new TB cases[4]—an increase from 110, 251 reported adult incidences in 2008. The incidence rate of new sputum smear-positive (SS+) cases was 142 per 100,000 population. Kenya's national Division of Leprosy, TB and Lung Disease (DLTLD) began to implement the WHO-recommended Directly Observed Treatment—Short course (DOTS), the internationally recommended strategy for TB control, in 1993 and reported 100 per cent DOTS coverage by 1996.[5] Treatment success was reported as 85 per cent in 2006.

According to the 2009 Health Ministry Information System (HMIS) report, over 100,000 new TB cases were reported in 2008. At about 45 per cent, the TB/HIV co-infection rate was quite marked among these newly diagnosed TB cases. Some 9 per cent of the new cases were for re-treatment, arising from either relapse of TB, treatment failure, or return after default. Of these re-treatment cases, 54 per cent were co-infected.[6] The re-

[3] Report on Anti Malaria Requirements for 2009/2010.

[4] Tuberculosis Profile USAID/Kenya Report 2009.

[5] USAID/Kenya TB Profile.

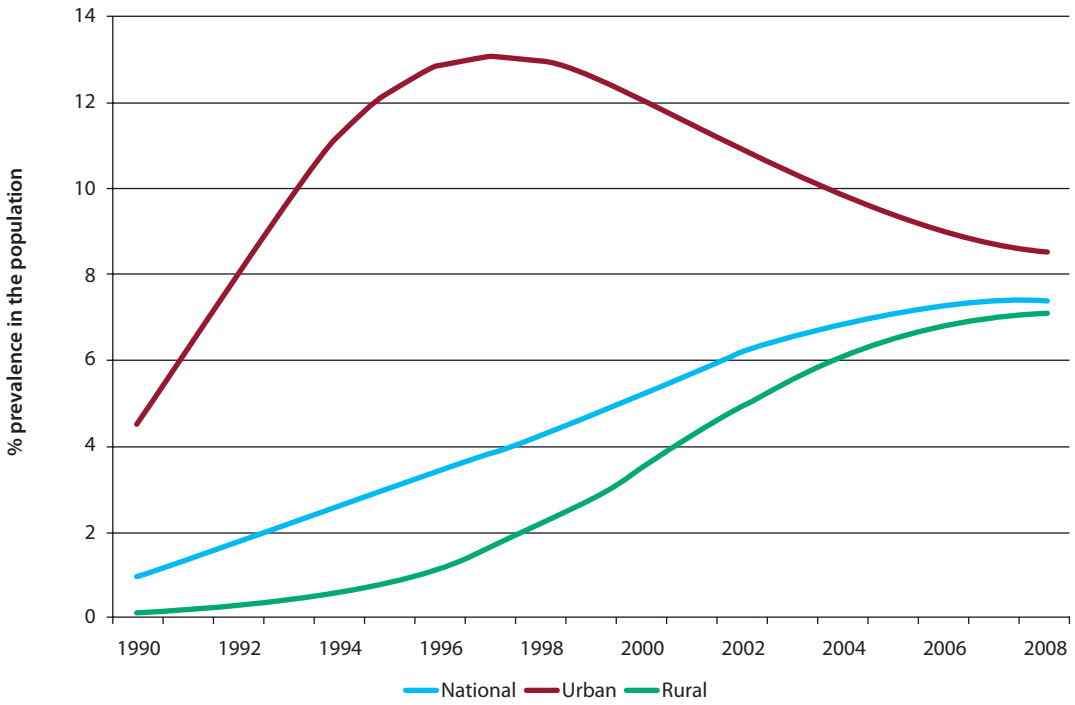
[6] HMIS Annual Report 2008.

treatment cases are particularly significant because of the risk inherent in developing Multi-Drug Resistant (MDR) TB. The MDR-TB strain amongst new TB was 1.9 per cent and this is a matter of great concern.

1.6 HIV/AIDS

As seen in Figure 2, HIV/AIDS prevalence in Kenya has been stabilizing since 2004. However, whilst there is a significant decline in urban areas, HIV among the rural population is on the increase. In sum, the prevalence of HIV nationally has stabilized, mainly as a result of awareness building, public knowledge on preventive measures, and Anti-Retroviral Treatment (ART).

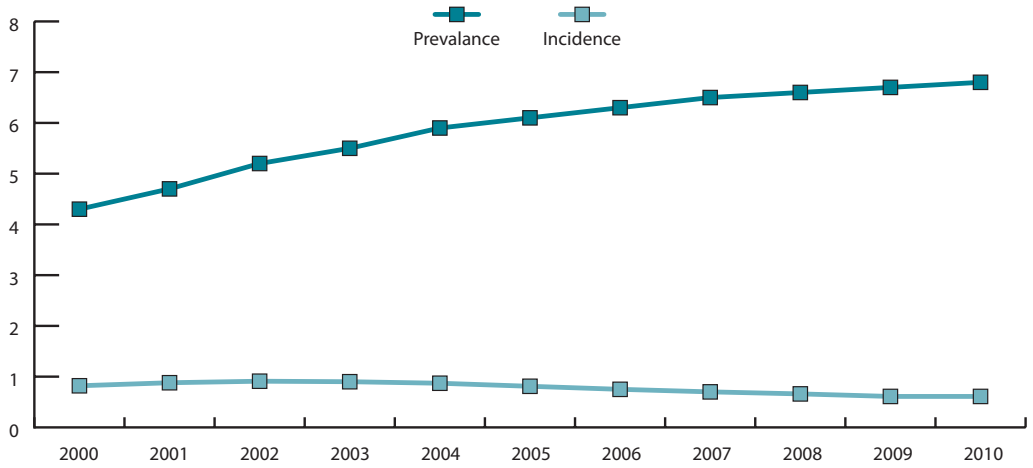
Figure 2. Prevalence trends by region



Source: The Kenya 2007 HIV and AIDS Estimates And interim projected HIV prevalence and incidence trends for 2008 to 2015: Report Prepared by National AIDS Control Council (NACC) and the National AIDS and STD Control Programme (NASCOP) July 2009.

Figure 3 shows that the rate of new incidences of HIV/AIDS is about 130,000 per year although the overall population with HIV/AIDS is still estimated to be about 1.56 million in 2010.

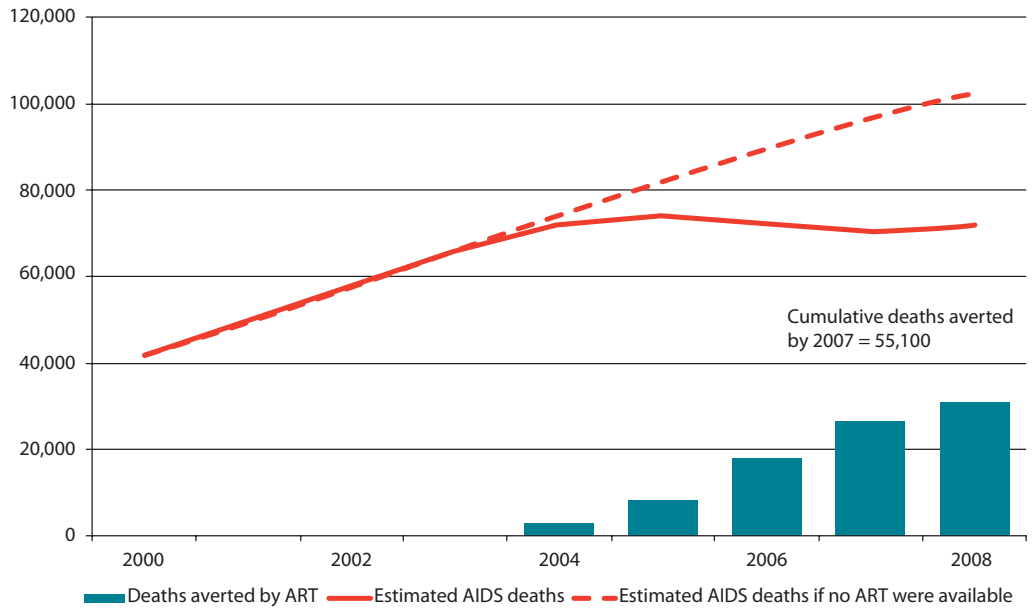
Figure 3. HIV trends: prevalence and incidence



Source: National AIDS Control Council (NACC) and the National AIDS and STD Control Programme (NASCOP) July, 2009.

The number of Kenyans accessing Anti-Retrovirals (ARVs) rose from as few as 11,000 in 2003 to 138,000 in 2007 and 250,000 by March 2009. Figure 4 shows that an estimated 30,000 deaths were avoided in 2008 by treatment with ARVs. The survival rate for both children and adults on ART treatment is over 85 per cent in the first year.51

Figure 4. Number of AIDS deaths avoided by ART



Source: The Kenya 2007 HIV and AIDS Estimates And interim projected HIV prevalence and incidence trends for 2008 to 2015: Report Prepared by National AIDS Control Council (NACC) and the National AIDS and STD Control Programme (NASCOP) July, 2009.

1.7 Viability of pharmaceutical production in Developing Countries (DCs) and Least Developed Countries (LDCs)

As discussed in section 1.6, it is against the backdrop of disease burdens for countries like Kenya that the African Union Commission (AUC) resolved to develop a Pharmaceutical Manufacturing Plan for Africa within the framework of the New Partnership for Africa's Development (NEPAD), under the theme "to pursue, with the support of our partners, the local production of generic medicines on the continent, and to make full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on TRIPS and Public Health (Gaborone Declaration, Doc. CAMH/Decl.1(II) 3 (10-14 October 2005).[7]

Yet doubts are often expressed as to the viability of pharmaceutical production in developing countries, mainly with regard to:

- Small national markets, making it difficult for local manufacturers to achieve economies of scale in production
- Little value addition in local production
- Reliance on government support or protection

The market size argument against local pharma manufacturing is losing a degree of potency with the increasing trend towards integration of markets within Regional Economic Communities (RECs). Within the East African Community (EAC) and the Common Market for East and Southern Africa (COMESA), for example, the harmonization of approaches and protocols for pharma are developing rapidly. Although some of the countries in the region are small, they are able to place a relatively high priority on health, as reflected in their health expenditures on a per capita or per cent of GDP basis. Rwanda, as an example, spends 10.4 per cent of its GDP on health, as shown in table 4.

Table 4 Comparative health expenditure in EAC countries—2008

	Burundi	*Kenya*	*Rwanda*	*Tanzania*	*Uganda*
Population (millions)	8	38	9	39	29
GDP per capita (US$)	320	732	730	980	880
Total expenditure on Health per capita (US$)	15	105	210	45	143
Total expenditure on Health as per cent of GDP	3.0	4.6	10.4	5.5	7.2

Source: UNIDO survey.

Table 5 shows the results of the sub-Saharan study[8] on Pharmaceutical Production in Developing Countries in 2006, which revealed a US$ 3,800 million (2006) market, of which local manufacturing supplied 28 per cent, imported generics 28 per cent, and

[7] Africa Union Pharmaceutical Plan for Africa.

[8] In 2006, the IFC and the Gates Foundation joined forces in funding a large study of private healthcare in sub-Saharan Africa, including pharmaceuticals and their distribution. IFC's team visited almost all manufacturers in key markets, such as South Africa, Nigeria, Ghana, Kenya and Tanzania.

imported original brands 44 per cent. Of the 49 LDCs in the world, most are in sub-Saharan Africa and they represent a large market which is currently dominated by imports of pharmaceuticals.

Table 5. Pharma Market in sub-Saharan Africa—2006

Local manufacturing	28 per cent	$ 1,064 million
Imported generics	28 per cent	$ 1,064 million
Imported original brands	44 per cent	$ 1,672 million
Total Market Value		US $ 3,800 million

Source: UNIDO survey (IFC Report Pharmaceuticals Production in developing countries 2009.

Local manufacturers account for only a small share of donor-funded drug procurement in sub-Saharan Africa, estimated to amount to between $750 million and $1,000 million.[9] The main reason for this is the requirement for WHO pre-qualification in donor sourcing, which no local manufacturers have yet achieved. However, given the size of the market, there is clearly considerable potential for local pharma manufacturers in both LDCs and DCs to move beyond the constraints of small national markets, probably by first penetrating broader regional markets. Local manufacturers could then supply the region competing on an equal basis with imports. Moreover, with access to financing and technical assistance, they could also upgrade their plant and equipment, and compete more strongly for donor-funded purchases.

Once the barrier of limited markets is removed, local pharma sectors could achieve a certain critical mass and be faced with sufficient demand to make it viable for them to explore backward integration and value addition through production of their own Active Pharmaceutical Ingredients (APIs), which are currently imported. Moreover, there are considerable public health and economic benefits to be derived from local production of essential medicines and a thriving domestic pharma sector.

From the public health perspective, the perceived benefits of local production include:

- Improved access to essential medicines through a regular, reliable supply of these items to the public
- There is a risk associated with over-reliance on donor-funded drugs which are sourced elsewhere. Donor support prevails when the political climate and governance issues are deemed favourable by development partners. The situation may change suddenly and donor funds could be withheld. Insofar as treatment of diseases such as HIV/AIDS and TB are concerned, interruption in the patients' regular supply of medicines could result in the development of resistance to particular strains, which then makes the infection more expensive to treat and may lead to early death
- Shorter supply chains and continuous availability of medicines in the public and private sectors, plus improved response during disasters or emergencies. Local sourcing of generic drugs can reduce the long and costly lead times often associated with purchasing

[9] A survey in the IFC 2009 report "The Business of Health in Africa: Partnering with the Private Sector to Improve People's Lives".

pharmaceuticals. An international tender can take more than nine months before supplies arrive in the country concerned. In contrast, local manufacturers typically play major roles in rapidly providing supplies of urgently needed drugs

- Cost-effective regulatory oversight and better quality accountability. It is always easier for regulators in the (L)DCs to monitor and enforce quality in local manufacturing than in imported medicines from distant countries
- Local innovation in new treatment regimes and dosage forms
- Improvement in local production and greater self-sufficiency in drug supply

The economic benefits include:

- Job creation and skills development at national level
- Foreign exchange savings through import reduction
- Facilitation of technology transfer
- Greater potential for pharmaceutical exports
- Local innovation of new treatment regimes and dosage forms

2. THE PHARMACEUTICAL MARKET IN KENYA

2.1 Demand for medicines

2.1.1 Demand derived from disease incidence

An estimate of demand for medicines in Kenya based on disease incidence would ideally examine the incidence of disease in the local population and derive the requirement for essential medicines from the figures and patterns identified. Unfortunately, such complete data on disease incidence in the general population is unavailable. The data shown in table 6 below illustrate the incidence of diseases causing morbidity among outpatients only[10] and it necessarily presents an incomplete picture. HIV/AIDS, for example, does not appear in the data because suspected HIV cases are not diagnosed easily in outpatient clinics. Similarly, the incidence of chronic diseases, such as hypertension and diabetes, is not captured since further investigations beyond the outpatient clinics may be necessary in the case of these diseases. Notwithstanding data limitations, however, table 6 does indicate that a significant part of demand for essential medicines in Kenya is a function of 10 disease categories, representing an average of 79.26 per cent of all disease incidences causing morbidity in outpatients between 2004 and 2008. In 2008, malaria and respiratory diseases accounted for more than 57 per cent of outpatient morbidity.

[10] The sharp increase in morbidity in the five years from 2004 to 2008 in table 6 is attributed to improved reporting of these figures.

Table 6. Incidence of diseases causing morbidity in Kenya, 2004-2008

	2004		2005		2006		2007		2008*	
DISEASE	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Malaria	5,338,008	34.5	9,147,412	27.6	8,926,058	28.6	9,610,691	30.8	9,312,357	32.8
Disease of the Respiratory System	3,489,589	22.5	7,972,443	24.0	7,001,349	22.4	7,626,100	24.5	6,840,004	24.1
Disease of the Skin (incl. Ulcers)	996,227	6.4	1,960,723	5.9	1,796,796	5.8	1,912,419	6.1	1,989,432	7.0
Diarrhoeal Diseases	700,013	4.5	1,378,620	4.2	1,373,073	4.4	1,453,529	4.7	1,397,659	4.9
Intestinal Worms	622,685	4.0	1,559,272	4.7	1,266,439	4.1	1,349,306	4.3	331,627	1.2
Pneumonia	439,511	2.8	765,157	2.3	875,459	2.8	1.060,789	3.0	989,095	3.5
Accidents (incl. fractures, burns, etc.)	411,121	2.7	796,724	2.4	696,906	2.2	737,110	2.4	568,457	2.0
Rheumatism, Joint pains etc.	280,047	1.8	569,411	1.7	538,550	1.7	578,408	1.9	488,908	1.7
Urinary Tract Infections	258,497	1.7	489,980	1.5	483,904	1.6	551,820	1.8	652,224	2.3
Eye Infections	254,996	1.6	488,584	1.5	479,405	1.5	507,145	1.6	492,225	1.7
All other Diseases	2,699,714	17.5	8,055,440	24.3	7,789,262	24.9	5,781,561	18.5	5,337,642	18.8
Total	**15,490,408**	**100**	**33,183,766**	**100**	**31,227,201**	**100**	**31,168,878**	**100**	**28,399,630**	**100**

Source: Health Management Information System, Ministry of Public Health & Sanitation.

* Provisional.

Malaria is by far the most common disease causing morbidity. The Report on Anti-Malaria Medicine Requirements for July 2009-June 2010 projects an increase in malaria episodes from 14,774,264 in 2009 to 16,354,123 in 2010, as shown in table 7 below. It is estimated that about 70 per cent of the Kenyan population is at risk of getting malaria.[11] Among local pharma producers, currently only two companies, Cosmos and Universal, had registered Artemether-Lumefantrine (AL) by the end of 2009.

Table 7. Projected Malaria Episodes in 2009 and 2010

Year	*2009*	*2010*
Projected annual population based on 1999 census (KNBS 2008)	39.4 million	40.4 million
Episodes per 1000 extrapolated by 8 per cent	375	405
Projected malaria cases (2009)	14.8 million	16.4 million

Source: Report on Anti- Malaria Medicine Requirements for July 2009-June 2010, Ministry of Public Health and Sanitation.

Table 6 also shows that respiratory diseases are the second highest cause of outpatient morbidity. The diseases of the respiratory system are various but are mainly upper respiratory infections and allergies. The management of such diseases depends on the cause and antibiotics play a key role in their treatment, which may include a combination of medicines such as antibiotics and antihistamines or anti-pyretics and analgesics as well. Antibiotics may also be used in combination to treat skin diseases, pneumonia, urinary tract infections, and also eye infections.

2.1.2 Demand projections by class of product

In general, the Ministry of Medical Services (MoMS) and the Ministry of Public Health and Sanitation (MoPHS) (formerly one single Ministry of Health) run programmes for diseases with a heavy impact on public health, including the promotion of good health lifestyles, prevention, and treatment or curative measures.

Malaria

The Division of Malaria Control under MoPHS is responsible for the control and management of malaria. The objective of Strategic Intervention through Case Management (SICM) is to provide good quality, safe and effective treatment for malaria patients. This is achieved by providing access to adequate supplies of quality anti-malarials. The recommended anti-malarials—ACTs—are available free of charge in public institutions but can also be bought without prescription from private pharmacies. The recommended ACT for first-line treatment of uncomplicated malaria is Artemether-Lumefantrine (AL). For severe malaria, quinine (tablets and injections), and Artemether and Artesunate injections are recommended. Under the Malaria Policy, Artesunate suppositories and

[11] Even more Kenyans would be at risk of contracting malaria were it not for preventive measures such as sleeping under insecticide-treated nets, house spraying, etc.

Artemether (intramuscular) injections have been approved for pre-referral treatment, whilst Sulfadoxine/Pyrimethamine (SP) is approved for intermittent preventive treatment (IPT) of malaria in pregnancy. There are no local manufacturers of ACT suppositories or injections.

As shown in table 8, total funding for malaria control in Kenya was about US$ 62 million in 2008 but the national government's contribution was very low, at only 0.5 per cent, compared with the Global Fund's contribution of about 61 per cent of the total amount. The government's contribution is also low when compared with the resources required for sustained implementation of malaria control, as envisioned in the Africa Summit on Roll Back Malaria 2000. Malaria funding, therefore, comes mainly from development partners. In addition to disease control activities in the field, the Division of Malaria Control has also received significant technical and financial support for its operating budget from the World Health Organization (WHO), Management Sciences for Health (MSH), the United Nations Children's Fund (UNICEF), the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Programme, the UK's Department for International Developmenbt (DFID), Statisticians in the Pharmaceutical Industry Limited (PSI), the (US) President's Malaria Initiative (PMI), the Roll Back Malaria Partnership (RBM) and other partners.

Table 8. Malaria programme funding in US dollars

	2001	*2002*	*2003*	*2004*	*2005*	*2006*	*2007*	*2008*
Other Bilateral								
PMI								19,838,000
European Union								
WHO								3,996,970
World Bank								
GFATM			3,976,069		53,698,910	39,858,515		37,543,753
G. of Kenya	27,631	774,984	84,882	1,233, 506	379,494	308,680	30,513	302,566

Source: World Malaria Report 2009.

Note: There were interruptions in funding from the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) in 2004 and 2007. In 2004, disbursement from the Fund's Round 2 allocation was suspended because of performance issues. Due to accounting and procedural complications, disbursement from Phase 2 of the Global Fund's Round 4 financing was also halted in 2007.

It should be noted that the figures in table 8 show total approved funding for the entire range of disease control activities, including prevention, case management, advocacy and communications, monitoring and evaluation, and capacity-building. Actual spending on medicines is only a small part of the overall funding allocation. As an example, from the total of US$ 40 million approved by the US President's Malaria Initiative (PMI) for malaria control in Kenya during Fiscal Year 2010, only US$ 7.54 million is expected to be spent on acquisition of 5.8 million AL treatments and other more severe malaria drugs.[12]

[12] PMI – Malaria Operational Plan 2010.

The estimated budget in the year 2009-2010 for public procurement of anti-malarial medicines is KSh 1,436,688,247 (US$ 19.3 million), which amounts to US$ 1.17 (KSh 87.85) per treatment. Table 9 lists the approved anti-malarials for public procurement. Quinine and Suphadoxine/Pyrimethamine are the non-ACT products.

Table 9. Anti-malarial drug requirements 2009-2010

Summary of requirements of anti-malarial drugs for fy 2009/2010				
Product	***Unit***	***Requirement (a)***	***Unit price in KSh (b)***	***Total US$***
Artemether Lumefantrine Tablets 6's	Pack of 6's	8,618,499	21.75	2,499,364.71
Artemether Lumefantrine Tablets 12's	Pack of 12's	3,773,968	42.75	2,151,161.76
Artemether Lumefantrine Tablets 18's	Pack of 18's	1,540,591	66.00	1,355,720.08
Artemether Lumefantrine Tablets 24's	Pack of 24'S	7,999,817	82.50	8,799,798.71
Quinine 300mg tablets	Tin of 1000's	11,802	3670.00	577,511.20
Quinine injection 600mg/2ml	2ml amps	4,670,193	14.00	871,769.36
Artesunate rectal caps 50 mg	caps	239,912	39.13	125,170.09
Artesunate rectal caps 200mg	caps	57,154	58.63	44,679.19
Artesunate injection	60mg amps	1,544,285	93.75	1,930,356.25
Artemether 40mg/ml injection	Ampoules	354,215	51.00	240,866.20
Artemether 80mg/ml injection	Ampoules	570,863	73.50	559,445.75
Sulphadoxine/Pyrimethamine	tablets	5,713	24.0	137,112.00
TOTAL				$ 19,292,955.29

Source: Report of the Drug Supply Management Sub-Committee of the Division of Malaria Control, July 2009, MoPHS.

Tuberculosis

The funding requirements for 2009 for TB control in Kenya, as assessed by the Global Plan for WHO's Stop TB Partnership, totalled US$ 37 million. Of this, only some 60 per cent or US$ 22.2 million was raised, with the government contributing about one-third of this money. Moreover, the amount allocated for purchase of first-line drugs was only US$ 2.2 million. The most under-funded component of the Plan was for Advocacy, Communication and Social Mobilisation (ACSM) and a planned disease prevalence survey during 2009-2010.

HIV/AIDS

There has been a massive scale-up of treatment and care for HIV/AIDS in the last few years. In the country's effort to achieve nationwide access to Anti-Retroviral (ARV)

treatment, Kenyans' access to ARVs for treatment of HIV/AIDS improved from as low as 11,000 persons in 2003, to 138,000 in 2007 and 250,000 by March 2009.[13] There is still, however, a large number of patients without access to treatment and at risk of dying since the unsatisfied need for first line therapy is estimated to be about 221,902 and 210,339 in 2009 and 2010 respectively, as shown in table 10 below. Seventy per cent of Persons Living with HIV (PLHIV) are in rural areas whilst the relevant services are concentrated in urban/peri-urban areas. Despite 80 per cent of TB patients being offered HIV testing, and 80 per cent of TB facilities providing HIV testing to patients, only between 27 per cent and 31 per cent of TB patients who are also HIV positive are on ART.

Table 10 also shows that the number of patients receiving ART has increased substantially—by a multiple of 14 between 2004 and 2010 in the above 15 years of age category, and by a multiple of four in the below 14 years category. The demand for ART is therefore increasing rapidly.

Table 10. HIV/AIDS indicators

Indicators	***above 15 years of age***						
	2004	2005	2006	2007	2008	2009	2010
HIV Population	1,134,266	1,222,238	1,303,658	1,377,472	1,442,723	1,500,928	1,558,449
New Incidences	153,664	146,967	141,272	135,081	130,066	128,159	127,905
Receiving ART	24,960	54,093	120,389	168,234	230,059	253,336	349,614
ART needed	250,250	285,629	324,569	367,985	414,695	463,599	511,813
Unsatisfied ART Demand	238,020	246,103	237,328	223,673	215,549	221,902	210,338
Adult prevalence	5.9	6.1	6.3	6.5	6.6	6.7	6.8
	0—14 years						
HIV pop	74,292	83,696	95,560	110,117	125,997	142,137	157,813
New Incidences	30,647	31,845	32,848	33,496	32,489	31,380	29,698
Need Cotri-moxazole	189,373	207,895	225,537	224,287	264,649	284,408	301,826
Need ART	38,489	40,509	42,157	45,422	48,816	52,712	55,544
Receiving ART	—	—	8,333	16,667	25,000	30,000	35,000

Source: National AIDS Control Council (NACC) and the National AIDS and STD Control Programme (NASCOP), July 2009.

[13] *Maisha Newsletter* Jan –April 2009.

In terms of expenditure, HIV/AIDS and malaria pose the greatest disease burden on the healthcare system, with HIV/AIDS alone consuming 17 per cent of general health spending. According to the Kenya National AIDS Strategic Plan (KNASP), the financial requirement for HIV/AIDS control has been rising steadily, with a total projected requirement for the four years from 2009 to 2013 of KSh 266.7 billion (US$ 3,556 million), as shown in table 11. Treatment and care takes the largest portion (57.9 per cent) of the total cost estimate, with ART accounting for 38.3 per cent.

Table 11. Cost estimates in the Kenya National AIDS Strategic Plan (KNASP)

	Cost estimates in KNASP (US$ millions)			
	2009/2010	2010/2011	2011/2012	2012/13
Total financing requirement	671	833	998	1,054
ARV therapy costs	237	319	390	415

Source: Kenya National AIDS Strategic Plan 2009/10 to 2012/13; November 2009.

Table 12 below shows that US organizations are expected to contribute over 81 per cent of the annual budget for HIV/AIDS control in Kenya. The government provides 5.4 per cent, about the same level of contribution as the Global Fund. Its application for funding in the last round (Round 9) of the Global Fund was rejected on the grounds of certain irregularities in accounting procedures and there are fears that no funding may be made available in Round 10 either. If this is so, and no alternative funding is mobilized, the distribution of ARVs and the access of HIV/AIDS patients to the treatment programme may be disrupted.

As in the case of malaria funding referred to earlier, it should be noted that:

- The figures in table 12 are expected contributions and not actual disbursements
- As an example, disbursements from Phase 1 of the Global Fund's Round 7 allocation of US$ 30+ million began in November 2008 but, as of mid-April 2010, only US$ 11.8 million had been disbursed
- Available data does not clearly indicate the proportion of funds shown in table 12 that are actually spent on purchasing medicines since there are substantial outlays on a range of activities encompassing prevention, patient care, and treatment
- For example, of the US President's Emergency Plan for AIDS Relief (PEPFAR)'s contribution of US$ 510 million in FY 2008, US$ 230.9 million was for treatment and US$ 110.9 million was destined for ARV medicines. Similarly, PEPFAR approved US $ 541.5 million for Kenya's HIV Control programme in FY 2009, with US$ 219.1 million for treatment. Current numbers on what proportion of the treatment budget for FY 2009 was spent on ARV purchases are not available

Table 12. Expected contributions by the Government of Kenya and development partners for HIV/AIDS control

Source	*2009/2010*	*% contribution*
US (PEPFAR, USAID,CDC*)	510.00	81.04
UN System	9.00	1.43
GFATM	32.50	5.16
DFID (UN-JP)	5.00	0.79
Clinton Foundation	11.70	1.86
KfW	4.50	0.72
JICA	2.60	0.41
Govt. of Kenya	34.00	5.4
TOWA (World Bank Credit)	20.00	3.18
	629.3	99.99

Source: Kenya National Aids Strategic Plan 2009/10 – 2012/13.
*CDC = Centers for Disease Control and Prevention.

While donors provide the bulk of funding for HIV/AIDS, households still contribute 26.3 per cent of the total,[14] mainly to take care of opportunistic infections and other medical needs.

2.1.3 Effective demand via procurement

Kenya Medical Supplies Agency (KEMSA))

The Government of Kenya (GoK) procures medicines through its national procurement agency, the Kenya Medical Supplies Agency (KEMSA). The Agency receives funding from the GoK and development partners for procurement of medical supplies for Rural Health Facilities (4,000 dispensaries and 511 health centres, which are operated by both the GoK and Faith-Based Organizations (FBOs)). It has been estimated that KEMSA's purchases constitute 30 per cent of all prescription drugs in the domestic market.

As indicated in table 13, the Rural Health Facilities (RHFs) take up about 60 per cent of the government-funded portion of KEMSA's procurement budget (i.e. not counting donor contributions) for 2010/2011. KEMSA's 2010/2011 government budget for the procurement of essential medicines for public hospitals is US$ 19.8 million and US$ 29.7 million (Dispensary Kits + Health Centre Kits + Loose Drugs) for Rural Health Facilities. This means that a total of US$ 49.5 million will be available over the period for selected items.

[14] The Kenya Health System—Analysis of the situation and enduring challenges, Richard G Wamai (JMAJ 52(2)), 2009.

Table 13. Government of Kenya's Budget for Drugs 2010/2011

Cost	*KSh*	*US$*
Dispensary Kits	1.3 bn	18.0 mn
Health Centre Kits	300 mn	4.3 mn
Loose Drugs RHF	555 mn	7.4 mn
Loose Drugs (Public Hospitals)	1.5 bn	19.8 mn
Grand Total	3.7 bn	49.5 mn

Source: UNIDO survey.
Note: Expenditure on Rural Health Facilities = Dispensary Kits + Health Centre Kits + Loose Drugs.

Essential Medicines are defined by WHO as "those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford". Out of 343 items on the Kenya Essential Drug List (EDL), KEMSA procures only about 117 selected items, based on available funds. Some medicines on the EDL which are not procured include medicines for what are commonly known as neglected diseases; for example, paracetamol syrup (antipyretic for children), diethylcarbamazine (falaricide), azithromycin (antibiotic), ivermectin (for onchoceriasis), cyclophosphamide (cancer drug), and pentamidine (leishmaniasis). These are often left out during selection of medicines considered to be of vital importance because of budgetary constraints.

KEMSA is not the only large-scale, bulk procurer of medicines in the Kenyan market. For example, PEPFAR procures and distributes ARVs and opportunistic infections medicines via another entity, the Mission for Essential Drugs and Supplies or MEDS (reviewed later in this section). The Clinton HIV Initiative apparently carries out direct international procurement for second-line paediatric medicines, which are then distributed by both KEMSA and MEDS. Purchases from Global Fund donations are undertaken by the Procurement and Supply Chain Management Consortium, which comprises four partners (KEMSA, Crown Agents, GTZ, and JSI—John Snow Inc.). Although KEMSA is a member of this consortium, the KEMSA Task Force Report of 2008 stated that "the Consortium operates as a parallel supply system with no interaction … between the Consortium and KEMSA". It is unclear whether this situation has since changed substantially.

The Mission for Essential Drugs and Supplies (MEDS)

MEDS is a Christian, not-for-profit organization based in Nairobi. It is a registered trust of the Kenya Episcopal Church (KEC) and the Christian Health Association of Kenya (CHAK). It was set up in 1986 as an ecumenical partnership of the two church secretariats to improve access to quality health care in a cost effective manner. MEDS procures medical items for Faith-Based Organizations (FBOs) and some donors. It serves nearly 1,000 health care providers, including 723 church health facilities (CHAK and KEC), 150 non-governmental organizations (NGOs)—mainly relief agencies serving in areas ravaged by war and/or famine in Kenya, the Horn of Africa, and the Great Lakes region

—donor-funded public health care projects, government health facilities, and community-based health care initiatives.

About 45 per cent of MEDS' turnover of KSh 800 million to KSh 1,000 million (about US$12 million) is spent on the purchase of medicines which are resold on the basis of cost recovery with a small margin to cover for general administration expenses and salaries.

2.1.4 Export demand

Kenya's exports of pharmaceuticals expanded by 96 per cent between 2004 and 2008, rising from US$ 30.3 million to US$ 59.4 million, in spite of the economic slowdown in 2008. This represents a Compound Annual Growth Rate (CAGR) of 18.3 per cent over the period.

Table 14. Medicinal and pharmaceutical products: principal exports 2004-2008

		2004	2005	2006	2007	2008
Exports	KSh million	2,274	2,648	2,997	4,436	4,457
	USD million	30.3	35.3	40.0	59.2	59.4
% increase			16.5	13.2	48.0	0.5

Source: Kenya Economic Survey 2009; Kenya National Bureau of Statistics.
Note: Figures include all pharmaceutical products, not just medicines, and also include re-exports.

About half of Kenya's exports of pharmaceutical products are to the United Republic of Tanzania and Uganda. Demand been expanding in these two countries but they buy in relatively small volumes. In view of this, Kenyan producers enjoy a comparative advantage since freight rates for less-than-container loads (LCLs) from China and India are proportionately higher than rates for full loads and it is China and Indian suppliers which represent the main competition in generic medicines.

Kenyan exporters also tend to offer more attractive supplier credit terms than Indian or Chinese companies. Exporters in the latter two countries usually work with up-front Letters of Credit which require regional importers to tie up their own capital or incur bank financing charges. In contrast, some Kenyan companies allow enough time for payment to be made after onward sale of the imported medicines. It is, however, doubtful whether these advantages will persist as pharma markets in the neighbouring countries grow and order volumes rise. When this happens, importers in those countries will have sufficient financial weight to buy full-container loads of medicines directly from China or India.

Nonetheless, there will still be potential for Kenya to establish itself as a major source of pharmaceutical products in the region. For example, neighbouring (southern) Sudan is emerging as another important market and there may be considerable scope in future for sales to Somalia. An estimate of the export potential can be drawn from a comparison of the export performances in pharma products of South Africa and Kenya within COMESA, as shown in table 15 below.

Table 15. African suppliers of 30 main pharmaceutical products to COMESA

African countries supplying pharmaceutical products to the Common Market and COMESA*					
Exporters	***Export value 2004 US$***	***Export value 2005 US$***	***Export value 2006 US$***	***Export value 2007 US$***	***Export value 2008 US$***
South Africa	46,723	43,380	39,849	58,383	77,451
Kenya	13,745	23,245	26,909	39,218	43,677
Egypt					25,720
Tunisia	6,653	3,894	5,220	6,755	5,365
Uganda	1,023	806	928	1,399	3,289
Mauritius	2,408	1,911	2,317	2,842	3,007
Ethiopia	16	48	131	131	1,170
Zambia	127	588	304	984	1,014
Namibia	12	10	13	27	487
Nigeria			0	92	355
Rwanda	36	140	85	288	210
Senegal	1	477	1,072	141	131
Burundi	100	70	103	204	71
Malawi	66	35	30	48	42
Mozambique	57	0	0	1	1
Seychelles	0	0	0		0

*Product : 30 Pharmaceutical products.
Source: Market Analysis and Research, International Trade Centre (ITC)

2.1.5 New demand from health insurance

Currently, some 1.6 million Kenyans (9.5 million, when dependants are included) are covered by the National Health Insurance Fund (NHIF), which covers only in-patient care, while the costs of diagnosis, treatment, and medicines are expected to be borne directly by the individuals concerned. An additional 400,000 Kenyans have private medical insurance, meaning that 70 per cent of Kenyans do not have any health insurance.

In 2005, legislation for a National Social Health Insurance was passed. This envisioned universal compulsory health coverage for all Kenyans, with free coverage for the most vulnerable sections of the population. The objective is to cover 60 per cent of the population by 2015, while offering increasing inpatient and outpatient services. Meanwhile, new, more affordable, private health insurance packages are also being launched, some through public-private partnerships involving donor assistance. As insurance coverage expands, the demand for medicines is naturally expected to rise although the impact is difficult to quantify at this stage.

2.2 Supply of medicines

An estimate of the Kenyan pharma market by Business Monitor International (BMI) shows[15] that expenditure on prescription medicines in 2008 was KSh 10.9 billion (US$ 158 million) and that this constituted 68.7 per cent of the total market. The market share of prescription drugs could rise in future if strict controls are introduced on the sale of drugs since many people currently buy such medicines without a prescription. Using the BMI definition, prescription medicines include generics, branded generics, and original brands. Self-medication is prevalent in Kenya and the Over the Counter (OTC) market is therefore very important. However, while sales volumes are large, OTC medicines are usually low-priced and competition is high. The OTC market component was estimated at KSh 4.96 billion (US$ 72 million) and, combining prescription medicines and OTC products, BMI estimates the total domestic market to have reached US$ 230 million in 2008.

For purposes of comparison, another market study by Frost & Sullivan (F & S) in December 2008 valued the Kenyan market for pharmaceuticals at $208.6 million in 2007 and expected it to reach $558.5 million by 2014, growing at a CAGR of 15.1 per cent. The generic pharmaceuticals market is expected to grow more rapidly than the market for branded pharmaceuticals, a trend that is expected to be driven largely by increased government purchases of generics and the price-sensitive nature of the overall market. The Frost & Sullivan report said that locally manufactured pharmaceutical products commanded 28 per cent of the overall pharmaceutical market in 2007.[16] F & S also forecast per capita expenditure on medicines at US$ 5.9 in 2009, increasing to US$14.1 by 2014. Of the total market in 2008, F & S estimated that generics would have accounted for 58.7 per cent of the total, while original branded pharmaceuticals would have accounted for the balance of 41.3 per cent.

The donor-funded market component

Although there appears to be consistency in the estimates of the local pharma market in the studies cited (BMI forecast for 2008: US$ 230 million; F&S projection for 2008: US$ 236 million), it is apparent that not all, if any, of the donor-funded supply of medicines is included in such estimates. As seen in section 2.1.2, there is significant funding of medicines, especially for the pandemic diseases, by donors. For example, PEPFAR became the principal funding source for ARVs in Kenya (practically overnight) in FY 2008, with a budget of over US$ 110 million for ARV procurement. Neither BMI nor F & S indicate explicitly in their reports whether donor-funded purchases of medicines for the Kenyan market are included in their estimates or forecasts. Given the relative magnitude of donor-funded purchases and the overall market estimates, however, it is unlikely that this very important component was taken into account.

Counterfeit products on the market

There is a very serious problem with regard to the supply of both counterfeit and substandard medicines to the Kenyan market. In fact, the distinction between these two

[15] Kenya Pharmaceuticals & Healthcare Report Q1 2010, BMI.

[16] Strategic Analysis of Healthcare Industry in Kenya, Frost & Sullivan, December 2008.

terms, and even legitimate generics, is not clearly understood. The main statutes governing retail outlets do not define these terms and, at times, generics are wrongly perceived as counterfeits, eroding confidence in the use of quality generics. Unknowingly, the two terms are often used inter-changeablyand this should not be the case.

One expert report indicates that[17] the problem of counterfeits is more common in countries where:

- The registration of medicines is ineffective or weak
- There is a large private (formal and informal) health sector that is insufficiently regulated
- Enforcement of laws on pharmacies is weak
- There are shortages, or an erratic supply, of medicines
- There is ineffective cooperation among different stakeholders
- Corruption is high
- The population is poor and has little knowledge about health issues

Most of the factors listed above would apply to Kenya. The problem of counterfeits could be solved by effective vigilance, greater political commitment, candid investigation and law enforcement. There is a need for strong pharmacy regulation to review the definitions of terms and to include them in the law as well as to cultivate political goodwill to formulate and enact the appropriate laws and to train appropriate personnel in the regulating body on good governance, ethics and moral standards.

In the present circumstances, counterfeits are another complication when estimating the size of the domestic pharma market. In 2005, a survey by the Pharmacy and Poisons Board (PPB) and the National Quality Control Laboratories (NCQL) showed that 30 per cent of medicines sold in Kenya were counterfeit. The Kenya Association of the Pharmaceutical Industry (KAPI) estimates spending on counterfeits to be as high as US$ 130 million per year. BMI estimates yearly spending on counterfeits at about US$ 65 million and clearly states that this phenomenon has been excluded from their market estimates.

2.3 Options that could benefit the local pharmaceutical industry

2.3.1 Demand side considerations

- *Improve availability of medicines*

  Stock-outs of essential medicines persist despite an improved distribution system introduced by KEMSA. They arise mainly from the long lead times involved in international tendering and lack of adequate funding. Local manufacturers could play a larger role in mitigating the impact of stock-outs by at least catering to acute shortages or emergency needs.

[17] Multi-country study on Effective Drug Regulation, Ms Sauwakon Ratanawijitrasin and Mr Eshetu Wondemagegnehu; Report of PRE 11th ICDRA Satellite Workshop on Counterfeit Drugs, 13 and 14 February 2004, Madrid, Spain.

- *Expand purchases of medicines from the Essential Drug List (EDL)*

  Although the list contains 343 items, only about a third are procured by government because of budgetary constraints. If the government were in a position to procure more items, this would obviously increase market possibilities for local producers.

- *Improve affordability of medicines*

  Most of the population live below the poverty line and their access to health services is inadequate. In this context, the costs of medicine at private-sector pharmacy outlets are higher than those paid by a public institution. This often results in self-medication without a prescription, as a way of saving the cost of professional consultation. Medicine purchase is driven by price considerations, with a little guidance from the sales outlet. Local manufacturers should seek efficiencies in production and distribution resulting in lower, more attractive prices to the consumer and thereby gain market share.

- *Pursue export markets more aggressively*

  Local manufacturers should look beyond Uganda and the United Republic of Tanzania to other countries within the EAC and the wider COMESA market.

2.3.2 Supply side considerations

- *Control counterfeit and substandard drugs*

  If this was achieved, quality local suppliers would have an expanded market space in which to operate and gain market share.

- *Clamp down on unregistered outlets*

  This action would have broad implications for dispensation of proper medicines to the public, preventing development of resistance to drugs due to improper dosage and follow-through, as well as control of poor-quality drugs. Again, the latter would benefit local manufacturers of quality medicines.

3. LOCAL PHARMACEUTICAL PRODUCTION

3.1 Overall sector importance

The manufacturing sector in Kenya is estimated to have contributed some US$ 3,000 million, or around 10.5 per cent of total GDP of around US$ 28,000 million in 2008, according to the Kenya Economic Survey.

No specific data are available on the contribution of the pharmaceutical sector to GDP but a rough estimate can be made from information gathered from local manufacturers in a survey conducted by UNIDO. Twelve leading manufacturers (not including GlaxoSmithKline) reported their turnover from domestic production[18] in the local market to be about US$ 83 million in 2008. These 12 leading companies probably represent about 80 per cent of the share of local producers in the Kenyan market, implying total turnover for local production of approximately US$ 103 million in 2008.

Most companies also reported that they import some 80 per cent to 95 per cent of the raw materials used (principally Applied Pharmaceutical Ingredients (APIs), and packaging). Proprietary data on production costs made available to UNIDO by some local companies reveal that a reasonable estimate of local value addition in the industry would be around 50 per cent to 60 per cent. Using the higher estimate, value addition from the pharma sector would generate around US$ 62 million and amount to about 2 per cent of manufacturing value added (MVA) and around 0.2 per cent of GDP.

Overall wage employment in Kenya declined by 0.4 per cent in 2008 to some 1,943,000, of whom the private sector employed 1,305,500 and the public sector 638,000 people. It is estimated that another 7.9 million people were employed in the informal sector. The manufacturing sector employed 264,100 people (private sector 237,000 and public sector 27,100) people and employment in the pharmaceutical manufacturing sector was 3,389 persons in 2007.[19] Consequently, waged employees in the pharma sector would represent about 0.17 per cent of total wage employment in the country and 1.28 per cent in the manufacturing sector alone. If demand for locally produced pharmaceuticals were to increase, the contribution to direct wage employment could be improved by strengthening the sector to utilise full capacity and by introducing two shifts per day. This strategy would have the potential to boost wage employment in the pharma sector by over 30 per cent.

[18] Some manufacturers are also importers of medicines, and part of their turnover derives from sale of imported drugs.

[19] Statistical Abstracts 2008, Kenya National Bureau of Statistics.

Table 16. Wage employment in Kenya in 2008

	Wage employment in 2008	
	No. of waged employees	***% Pharma Industry***
Pharma sector (2007)	3,389	100
Total wage employment	1,943,101	0.17
Total wage – private sector	1,305,500	0.26
Total wage – manufacturing	264,101	1.28
of which private sector	237,000	1.43

Source: Kenya Economic Survey 2008.

3.2 The domestic pharma market

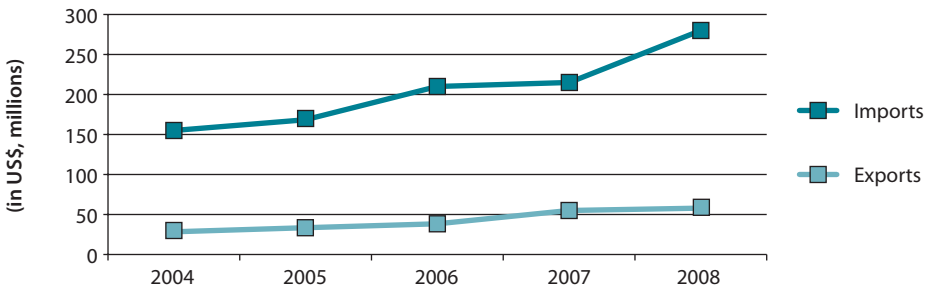
In recent years, Kenya's imports of pharmaceuticals (finished medicines as well as APIs) have been growing steadily and, by 2008, imports, which totalled US$ 277 million were more than four times the value of 2008 exports, which totalled US$ 59.4 million and may also include re-exports (see table 17). Thus, there is a significant and growing trade deficit in pharmaceuticals, as shown in figure 5.

Table 17. Kenya's trade in medicinal and pharmaceutical products

Year	***2004***	***2005***	***2006***	***2007***	***2008***
Exports KSh ('000)	2,274.00	2,648.00	2,997.00	4,436.00	4,457.00
US$	30,320.00	35,306.67	39,960.00	59,146.67	59,426.67
Imports ('000)	11,607.00	12,436.00	15,443.00	15,948.00	20,776.00
US$	154,760.00	165,813.33	205,906.67	212,640.00	277,013.33

Source: Economic Survey 2009; Kenya National Bureau of Statistics.
Note: Export figures include re-exports.

Figure 5. Kenya's trade balance in pharmaceuticals



Source: Kenya Economic Survey.

India is the dominant supplier of imported pharmaceutical products (raw materials and finished products taken together) accounting for almost 40 per cent of Kenya's imports. The other main suppliers are Switzerland, which provides around 10 per cent, followed by Belgium, South Africa, the United Kingdom, Denmark, Netherlands, France and the United States, none of which exceeded more than a 5 per cent share of Kenya's imports.

At present, Kenya's best export markets for pharma products are its immediate neighbours. Almost 50 per cent of these exports in 2008 went to the neighbouring East African Community (EAC) countries of the United Republic of Tanzania and Uganda, and Sudan accounted for some 14 per cent. Other African importers of Kenyan pharmaceuticals were Congo, Ethiopia, Malawi, Mozambique, Nigeria, Rwanda and Somalia.

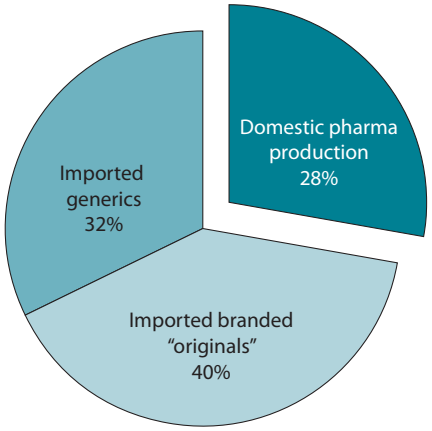
As noted in section 2.2, market studies estimated the domestic market for medicines in Kenya at around US$ 240 million in 2008 and this is the figure used in this report. It was also pointed out that this figure underestimates the actual yearly spending on medicines since it, necessarily, does not take into account donor spending (particularly on medicines for pandemic diseases) and the unwitting spending on counterfeits.

There is some justification for using this figure since:

- Local pharma producers cannot, at present, participate in donor-funded procurement with the result that a very important market segment remains inaccessible to them
- Donors require that the plant/facilities of suppliers participating in their procurement should be WHO-prequalified. Currently, no Kenyan pharma producer is listed as such
- Donor funding is unreliable and uncertain
- Estimates of the spending on counterfeits vary widely

The biggest donor for medicine purchases in Kenya at present is the US Government's PEPFAR, which is funding ARV procurement. Although PEPFAR was launched in 2003, it only came on the scene in Kenya in 2008. Its mandate has been extended by the US Congress until 2014 but it was originally conceived as a special short-term initiative and its future beyond 2014 is uncertain. Similarly, Global Fund finance for the pandemic diseases in Kenya has been uneven. Kenya did not receive any funding in Rounds 8 and 9 and has a record of disbursements being suspended in the past as a result of implementation problems on the ground. The US Government's PMI (President's Malaria Initiative) has also become a major donor to the Malaria Control Programme in Kenya but it, too, has only a five year mandate from 2005-2010, unless extended further. Taking US$ 240 million as the market size in 2008, it is clear that the domestic market for medicines (finished products) is dominated by imports (figure 6). The UNIDO survey referred to in section 3.1 indicated that the local pharma industry had a total turnover of about US$ 103 million in 2008, of which only about an estimated US$ 36 million were exports. The balance, approximately US$ 67 million, represents the share of local pharma producers in the domestic market and is less than 30 per cent of the total market. The largest share of demand is met by imports of branded originals and generics and the import value of generics alone was greater than the total value of locally-produced medicines consumed in the Kenyan market.

Figure 6. Domestic Market Shares—2008



Source: UNIDO estimates.

Note: a total market size of US$ 240 million was used to calculate shares; counterfeits and donor-funded purchase of medicines not considered.

The market share of local industry shown in figure 6 represents an upper bound. If donor-funded purchases were to be taken into account, the share of local pharma producers would be substantially lower and the market share of imports would be correspondingly higher since all donor procurement is sourced outside Kenya.

Based on interviews with market players, two salient observations can be made about the relative performance of local manufacturers in the domestic market. Firstly, imported generics have a larger market share than locally-produced medicines despite a market perception that some locally-made medicines are of better quality. In the hierarchy of market perception of quality, the branded "originals" are perceived to be of the highest quality. Interviews with players in the distribution chain (distributors, wholesalers, and retailers) indicate that they (and by their testimony, the consuming public) rate medicines produced by some local pharma manufacturers to be of higher quality than the generics imported from China/India. Some recognize the differences between product offerings by different local producers and importers and accept that some locally-produced medicines are also of poor quality and some imported "branded generics" are indeed of high quality. However, even these market participants maintain that the products of the leading Kenyan pharma firms are of equal, or better, quality than the quality imports.

The consumer often seems to prefer the imported generic because of price considerations and not quality. This implies that if the flow of substandard, imported medicines could be removed from the market through enforcement of regulations, this would open up market space for local pharma firms to grow and recoup market share.

Secondly, there seems to be a disconnect between the weakness of local pharma producers in their home market and their growing exports to other countries in the region. Whilst some of these firms are succeeding in expanding their exports, domestic sales of their products remain stagnant or are even declining, and this at a time when the Kenyan market is growing.

In fact, a number of leading pharma companies derive a significant part of their annual turnover from export sales (Regal – 55 per cent, Elys – 50 per cent, Dawa – 35 per cent,

Universal – 34 per cent). Reasons for their relative success in these markets were referred to in section 2.1.4. Nonetheless, it is doubtful whether these advantages will persist as pharma markets in the neighbouring countries grow and order volumes rise. This increased volume of demand will make it far more commercially viable for importers in those countries to buy full-container loads of medicines directly from China or India.

3.3 Structural characteristics

There are 42 companies listed as local pharmaceutical manufacturers in Kenya. Fifteen others are listed as institutional/facility based, and four companies are listed as dormant (closed). There is only one multinational, GlaxoSmithKline (GSK) among the 42 active producers. Most pharma firms are located around Nairobi and, as a group, these companies constitute an important pharma manufacturing centre in the region.

GSK is, of course, 100 per cent foreign-owned. Most other pharma firms in Kenya are 100 per cent locally-owned as family business enterprises, although foreign investment is becoming more common. Among the leading producers, Universal has 70 per cent equity participation from the FinnFund, Regal is 35 per cent foreign-owned, and Beta Healthcare is now part of the Tanzania-based Shelly's Pharmaceuticals. The percentage of local ownership has not so far been an issue in defining a "local" firm. The understanding is that a local firm is a company registered and domiciled in Kenya. KEMSA, for example, considers all locally-domiciled firms as local companies in its tendering process, as provided for in the regulations on procurement (section 39(8)(b) on goods manufactured in Kenya).[20]

Common product lines

GSK manufactures only Over-the-Counter (OTC) products. With the aim of improving local access to essential medicines, and ARVs in particular, Cosmos Ltd. and Universal Corporation Ltd. were granted voluntary licences under provisions in the World Trade Organization's (WTO's) Trade and Related Aspects of Intellectual Property Rights (TRIPS) to manufacture Lamivudine and Zidovudine by GSK and Nevirapine by Boehringer Ingelheim, the respective patent holders. The local companies had acquired the know-how on their own but, so far, other than gaining self esteem and confidence, the two companies have not won tenders or received any preferential terms in public procurement, except for orders to fill gaps when government stores face stock-outs.

Local firms also produce generics. Product lists are similar and there is little difference in the range of products and formulations from one company to another. Most of the leading firms have similar product portfolios in that they all produce the same pharmaceutical categories of products, such as antibiotics, analgesics, or bronchial spasm relaxants. In fact, there is a plethora of "me-too" products and formulations with slight variations. This, of course, makes it difficult to differentiate one company's offering from the next and also drives down margins because all tend to compete in the same market segments.

[20] Participation in procurement: Section 39(8). In applying the (local) preferences and reservations under this section (b), a prescribed margin of preference may be given in the evaluation of bids to candidates offering goods manufactured, mined, extracted and grown in Kenya. Sub-section (4): the preferences and reservations shall apply to (a) candidates such as disadvantaged groups, micro, small and medium enterprises.

Low capacity utilization

Commonality in product lines results in fragmentation of the market across the products so that each company ends up with low sales volume. That, in turn, results in the companies running their production lines at low capacity utilization, which is inefficient and raises production costs per unit. In fact, capacity utilization varies between only 53 per cent and 67 per cent. This situation is reviewed in table 18, which shows the average capacity utilization in the production of particular formulations for the 12 pharma companies which responded to a survey conducted by UNIDO.

Table 18. Capacity utilization (based on present shift operations)

Formulation	***% capacity utilization****
Tablets	67
Capsules	55
Dry syrups/powders	56
Liquid syrups	62
Creams/ointments	53

* Indicative figures from 12 Kenyan pharma companies.
Source: UNIDO Survey.

Variation in GMP standards among local firms

Another production issue is the significant variation in the Good Manufacturing Practices (GMP) standards with which local firms wish to comply and in manufacturing practices in general. Some firms have already made the investment needed in plant and equipment to meet WHO Basic GMP standards. In December 2004, a Public Private Partnership (PPP) project for improving Drug Quality Standards was launched in East Africa as part of an initiative by Germany's Ministry of Foreign Affairs and the Ministry of Economic Cooperation and Development (BMZ). The participating companies, six from Kenya and one from the United Republic of Tanzania, were helped to upgrade their facilities with the aim of reaching the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) level within two to three years. A joint GMP audit based on international/EU standards was conducted in December 2007 by EU-accredited GMP Inspectors. Three companies from Kenya, Cosmos, Regal and Universal, were successful and Shelly's from Tanzania qualified in November 2008.

Cosmos had originally applied for WHO prequalification but was not successful in a 2008 inspection. However, re-application was affected by the change in ART regime when the World Health Organization substituted Zidovudine with Stavudine. This change meant starting the entire procedure from formulation, registration and data from zero once more. Now, in view of the satisfactory subsequent audit, COSMOS is considering re-applying. Universal has also applied for WHO prequalification and was scheduled for an inspection in mid-2010.

There is interest from some other companies in the industry in upgrading both premises and practices to higher technological levels. Beta Healthcare, for example, is renovating a building that is expected to be compliant with WHO Basic GMP and Lab & Allied has similar plans to construct a new facility.

Other pharma firms who would like to implement GMP upgrades are constrained by lack of finance and access to technical assistance. Inevitably, there are also firms which have shown little or no interest or initiative in improving their technology levels. Only a few manufacturing premises are custom-built on company-owned premises and most are located on rented premises. This is a major limitation in adapting premises to quality assurance and GMP requirements, particularly for new start-up manufacturers whose initial investment is almost always in rented premises. Often, the facility has little additional space for upgraded installations and, in many cases, the premises are sandwiched between two buildings with little scope for upgrades.

There are limitations on the regulatory side as well. The inspectors in the Pharmacy and Poisons Board's (PPB's) GMP Inspectorate are not experienced in industry practices and are, in any case, too stretched to make follow up inspections in all the local firms effectively. There are no detailed guidelines on the suitability of premises for working with particular formulations. Consequently, much of the GMP inspectors' time is taken up in effectively monitoring corrective actions to rectify initial shortcomings. For example, some local companies are operating with one or part-time pharmacists, with untreated water from the municipal supply, or inadequate separation of air handling.

Despite these shortcomings, there is heightened awareness and sensitivity to GMP compliance and the PPB is not the only body requiring GMP inspections. Its enforcement of "Kenyan GMP" standards is not recognised by other countries and procurement agencies and, consequently, pharma companies are subjected to several other inspections by regulatory authorities in the destination countries for exports, as well as by leading international NGOs and buying agencies, such as MEDS. This hinders industry, with loss of production time and sometimes conflicting recommendations on compliance measures.

There is no existing classification of local pharma companies by GMP status so an attempt has been made below, based on local knowledge and information about the sector, to classify these firms into four broad groups (listed in table 19).

Table 19. Local pharma categories

Category	Description
Least Developed GMP infrastructure – New start up	Mainly new start-up facilities with less than two years experience. Most are in rented premises. Manufacturing mainly syrups, and re-packing without formulation. They may have limited air handling units, water purification units. QC lab is rarely fully installed. Lack manufacturing exposure and access to finance. Guidance and enforcement required.
Least Developed GMP infrastructure – Dormant	More than two years experience. Most are in rented premises and have only limited infrastructure like Air Handling Unit, water purification, QC lab. The rate of improvement is slow. Has manufacturing exposure. Stringent enforcement required.

Category	Description
Developing GMP infrastructure	Many own their premises. Several years manufacturing experience with good potential to do better but dormant GMP improvement. Stringent enforcement required.
Developed GMP infrastructure	Own premises. Export to regional and international markets. Have been benchmarked to international GMP status; some are in the process of WHO pre-qualification. Enforcement and incentives required.

Source: PharmaQ.

Based on this categorization, the following actions are needed:

Least Developed GMP infrastructure—New start up: this category of manufacturer will usually require exposure to best practices locally or abroad, and training at managerial and operational levels. Access to finance is difficult and the firm may need assistance to prepare technical business plans. A development time frame may be necessary, with periodic audits. In future, guidelines for suitability of premises should be a pre-requisite for start-up. A central QC lab may be necessary until the firm's own lab is fully installed. Release of products would be based on batch QC reports.

Least Developed GMP infrastructure—Dormant: these producers will require notice to improve. The length of the firms' existence should have already made them aware of the basic requirements. Release of products would be based on secondary batch QC reports.

Developing GMP infrastructure: these companies have the know-how and potential to do better. They would re-invest if regulatory enforcement is stringent. Release of products would be based on own batch QC reports

Developed GMP Infrastructure: these enterprises are already well on the way to acquiring new GMP status but they may require incentives and recognition. Release of products would be based on own batch QC reports.

If GMP standards are to be improved, technical assistance is required to assist both local pharma companies and the regulatory authority in acquiring the necessary knowledge and skills. Local pharma will benefit on three broad fronts by:

- Attaining minimum GMP standards by improving the facility and personnel
- Attaining international recognition of GMP status (WHO prequalification, and/or PIC/S)
- Identifying common facilities for GMP improvement (e.g. joint training, waste management, etc.)

A major impediment to upgrading of GMP status is lack of finance. Most local pharma companies are private and family-owned, and many lack the financial strength to implement plant upgrades, even if the willingness exists to make improvements. Several start-ups have faced difficulties in accessing bank loans adequate to the level required. Reasons may include the high capital investment required, the lack of a robust business plan, etc. Another constraint is know-how. Most of the directors of the local pharma companies

started out as distributors and they have little exposure or experience in advanced pharma manufacturing. They have to rely on foreign consultants and equipment producers for advice and counsel on plant upgrades.

The challenge of upgrading is a multi-faceted one. If any strategy to enhance or upgrade the local pharma industry is to be successful, it will need to address these and other challenges, such as the dearth of qualified human resources (see below).

Shortage of qualified personnel

The current situation with regard to availability of pharmacists is shown in table 20 below.

Table 20. Pharmaceutical personnel and training institutions—2009

Number of registered pharmacists	2,063
Pharmaceutical Personnel Population Ratio	1: 8,710
Number of pharmacists in basic training	280
Number of pharmacists in public service	538
Number of approved pharm. training institutions	Universities – 1 Diploma Colleges—18
Average annual output of pharmacists	70

Source: KNPP—Naivasha version 2009.

The number of trained pharmacists is increasing with time but is still insufficient relative to the population in need (one pharmacist for every 8,710 persons, or approximately 0.1 per 1,000 persons) table 21 illustrates the relative position of Kenya and other countries in the world with regard to the availability of pharmacists.

Table 21. Number of pharmaceutical personnel (per 10,000 population)

Country	
Kenya	1
Nigeria	1
South Africa	3
Egypt	12
USA	9
Japan	19

Source: Global Health Indicators, World Health Statistics 2010, WHO.

Kenyan pharma companies are challenged in meeting increasing technical requirements for pharmacists by a severe shortage of qualified technical personnel. Moreover, pharmacists trained in Kenya lack an industrial orientation. There are basic training institutions for pharmacists and pharmaceutical technologists at university and diploma levels respectively but these institutions do not have a demonstration centre to expose students to real situations in the industry. Instead, final year students are sent out to industry for a three to four week exposure and, after graduation, they are attached for a three month pre-registration exposure. This time period is not adequate for full training of pharma personnel.

As a result of this situation, the skills and know-how on production processes, engineering and management are really acquired rather by association and guidance on the job from colleagues with earlier exposure. There is neither local training nor information on best practices available to the majority of staff although GMP training is provided at plant level by experienced staff and occasionally by registered consulting firms.

Every manufacturer is required by law to contribute a training levy of KSh 50.00 (US$ 0.67) per employee per month. With an estimated workforce of about 4,000 in the pharma manufacturing sector, this computes to approximately KSh 2.4 million (US$ 32,000) annually. Yet the money is just accumulating since the pharma sector has not developed a common strategy to use the fund for the benefit of the whole sector. Similarly, the trade body for the sector, the Federation of Kenya Pharmaceutical Manufacturers (FKPM) also has no training programme to mitigate the lack of skills and training.

Need for greater production efficiencies

There is inadequate data on the economics of pharma manufacturing in Kenya and the cost structure of manufacturing operations. Industry interviews indicate that the major cost components are imported APIs, imported and locally-sourced packaging materials, electricity, labour, and various taxes. Of these, the APIs account for roughly 40 per cent to 50 per cent, and packaging materials account for 25 per cent to 30 per cent of product cost. More in-depth analysis needs to be done to identify other production efficiencies.

A major factor in the dominance of the domestic pharma market by imported generics is the higher relative prices of locally-produced medicines. This means that efforts are needed to lower local production costs. In addition to competing with the “fixed” costs of imported APIs and packaging materials, manufacturers point to electricity as a significant production cost. Electricity costs are higher in Kenya than, for example, in India and China (about US 25 cents per kwH, as opposed to US 4 cents to 11 cents per kwH in China, and about US 7 cents per kwH in Gujarat, India). However, as a proportion of total production costs, electricity accounts for less than 15 per cent. Nonetheless, the industry needs to improve energy efficiency in its plants and to examine ways to enhance plant efficiencies in general. One possibility would be to incorporate cleaner production methods.

Requirement of bioequivalence (BE)

Local manufacturers find it difficult to carry out bioavailability/bioequivalence studies because of financial constraints, lack of know-how, and non-availability of national guidelines on this subject. Studies carried out abroad are not necessarily applicable to

the Kenyan population and patients.[21] Moreover, the costs involved in doing these studies are prohibitive, in addition to delays and lack of qualified laboratories.

Some reasons for difficulties in completing BE studies include:

- High cost of bioequivalence studies—ranging widely from U$ 30,000 to about US$ 110,000 per product
- Samples have to be sent to a Clinical Research Organization (CRO) outside the country
- Long lag times of at least six months to carry out BE studies
- Identifying a suitable CRO, usually abroad
- Regulatory hurdles in sending samples of medicines to the country where the studies are to be carried out
- Evidence that genetic differences may lead to variable drug and chemical metabolism and elimination

In accordance with WHO guidelines, new drug registration guidelines from the PPB are intended to be more rigorous with regard to proof of bioequivalence. BE evaluators are being trained at the PPB in preparation for implementing the guidelines. However, the local pharma sector has pointed out that, if the new guidelines are implemented immediately, this will lock out some of their products, giving an undue advantage to foreign manufacturers unless a local BE centre is established at the same time. PPB and other regional regulatory authorities plan to enforce the BE requirement in drug registration in the near future. In response to the emerging regulations, the School of Pharmacy, KEMRI, and a few pharmacists from the manufacturing industry have initiated talks on the establishment of a Kenya BE study centre. A concept paper has been developed to support discussions on a voluntary basis with partners and GTZ has launched an initiative to establish a regional BE study centre in Addis Ababa, with collaborative centres in Kenya, Uganda and the United Republic of Tanzania. However, the initiative has not so far identified adequate funding possibilities.

3.4 Backward and forward linkages

The Kenyan pharma industry is handicapped by a lack of supporting industries. Local producers import between 80 per cent and 95 per cent of all raw materials, principally Applied Pharmaceutical Ingredients (APIs). Of the few industrial requirements[22] sourced locally, basic ingredients include maize starch, refined sugar, glucose syrup, rectified spirit and ethanol, and sodium chloride. Most of the packaging used by industry is also imported although a small percentage is sourced locally. Opportunities to establish backward linkages are limited until such time as the local pharma industry is sufficiently large to achieve economies of scale. Some potential for local production of packaging items currently imported may then arise.

[21] Report on Access to Essential Medicines, June 2005 (Health Research Action and PWC).

[22] Kenya Pharmaceutical Industry 2005 (EPZ).

One example of forward linkage is illustrated by the case of Botanical Extracts EPZ Ltd. This company is involved in the extraction of non-API grade Artemisinin from the Artemisia annua plant and is the leading producer in Africa. It exports artemisinin for further processing to Europe and Asia (Novartis; Sanofi-Aventis; Mangalam (India); Calyx (India); Cipla (India)). Purified and pharmaceutical grade artemisinin, used to manufacture anti-malarials, is then imported into Kenya as a basic ingredient along with finished anti-malarials in dosage form. This Kenyan company is currently expanding its facilities and implementing a quality enhancement programme scheduled for completion in late 2010. At that time, the company is expected to carry out further processing of artemisinin and will then be amongst world leaders in artemisinin capacity.

3.5 Competitive environment

Local pharmaceutical companies in Kenya face competition on two fronts. Firstly, from their peers, and, secondly—and collectively—from imports, often from suppliers of raw materials who also manufacture finished products. In fact, it could be argued that the more significant confrontation is the competition between local industry and imports because, as pointed out in section 3.1, imports are rising sharply and grew by more than 30 per cent between 2007 and 2008. As shown in section 3.2, imports account for the bulk of the domestic pharma market, supplying about 72 per cent of demand. Several distributors interviewed preferred locally produced products to imported generics and the market perception appears to be that imported generics are of lower quality than locally-made drugs. They are, however, cheaper than domestic products.

A number of factors have contributed to the flood of imported pharmaceuticals into Kenya, many of them substandard.[23] These include:

- Foreign drugs are easy to register with the Pharmacy and Poisons Board
- Registration costs for imported drugs are low and GMP and bioequivalence enforcement is lax
- Kenya was one of the first countries in the region to reduce its pharmaceutical import tariffs to zero; other countries in the EAC followed in 2007
- The PPB has little capacity to monitor the GMP status of foreign pharma factories producing drugs for import into Kenya. Its inspectors are supposed to visit foreign plants before drug registration but cases have been reported of inspectors being shown one plant during the registration process and drugs then being produced under contract at a different facility
- Quality testing of incoming imported drugs is patchy and irregular. The PPB introduced new guidelines requiring batch testing of imported drugs at the Ports of Entry (PoE) from March 2010 but it is unclear if personnel and equipment are in place to implement this
- Penalties on importers for importing substandard drugs are weak and the strengthening Kenyan shilling is making imports even cheaper

[23] *PLoS ONE Journal*, May 2008. A study in six African countries (Kenya included) where malaria is endemic found that over one-third of anti-malarials sold in the private sector were substandard.

- Many international pharma companies have offices for their regional marketing agencies based in Nairobi and their products are imported into Kenya first, for subsequent distribution to other countries in the region

At the same time, local pharma producers are disadvantaged on a number of fronts:

- Since they lack WHO pre-qualification, they are excluded from procurement by international NGOs and purchases funded by entities such as the Global Fund
- Since many producers are small, they do not have the capacity to participate in larger-volume tenders
- They are facing severe price competition from imports
- They are financially strained by delayed reimbursements from the government of duties and VAT already paid

In these circumstances, some local pharma producers are emphasizing the gap in GMP levels between those firms who have upgraded their plant and equipment and the rest of the industry. The handful of firms who have invested in upgrades feel disadvantaged because they are offering better quality products on the same market as others who are operating with lower quality standards. They, therefore, feel that they are not competing with other local firms on a "level playing field".

While this may be a valid point, the focus on leveling the playing field between local producers seems too inwardly-focused at a time when imports are taking over the domestic market. Similar attention should be paid to leveling the field between imports and locally-produced goods. There is little incentive for the majority of local pharma firms to be concerned with quality issues when low-quality imports are circulating freely in the market in large volumes. In fact, some manufacturing firms are of the opinion that there are better returns from imports and some are known to import medicines to complete large orders.

3.6 Need for financing

If Kenya's pharma industry is to move successfully along the value chain, the sector will have to absorb transfers of new technology and training, and make significant upgrades of plant and equipment, and personnel. Yet new technology and upgrades will require extensive investment if the sector is to become a market leader in the region. Most pharma firms in Kenya are family-owned and the current owners will find it difficult to raise the necessary finance. Similarly, the government or donor community is unlikely to be the source of the investment capital required and the best option would be strategic partnerships or joint ventures with pharma players in more developed countries.

A prerequisite for this inward foreign direct investment (FDI) is first to recognize that this is necessary and then to examine ways and means of turning the need into reality. Substantial flows of FDI into the pharma sector will require extensive changes in the policy environment as well as the business environment. Preference for local firms, non-tariff barriers to imports, special incentive packages for foreign investors in the sector, and other policy options all need to be examined.

3.7 SWOT analysis of the Kenyan pharma industry

The following assessment is an initial SWOT analysis of domestic pharmaceutical firms and the environment in which they are operating. It is recognized that further work needs to be done to shed light on a number of items alluded to, if the issues involved are to be fully understood. This is a prerequisite to formulating any meaningful strategy for the strengthening of the pharma sector.

Strengths

- Kenya has the most well-established pharmaceutical manufacturing industry in the region. Compared with its neighbours, it has the greatest number of pharma firms and local manufacturing of the main formulations (tablets/capsules, parenterals, ointments/creams, liquids/syrups/suspensions) is already taking place. Most essential medicines, including anti-malarials and medicines for HIV/AIDS and TB are locally manufactured. At least two firms have voluntary licensing to manufacture ARVs
- There is a growing domestic market with a projected CAGR of 11.5 per cent between 2008 and 2013
- A trained and skilled workforce in pharma manufacture and know-how to scale up production capacity are available
- Product profiles of the local pharma companies match the regional market disease patterns
- Basic international standards have been achieved by some companies

Weaknesses

- Imports dominate the local market
- Ineffective regulation has resulted in a flood of substandard and counterfeit drugs on the market
- High levels of competition from cheaper or subsidized products
- Lack of specialization in industrial pharmacy and plant management
- Inadequate facilities for specialized training in industrial pharmacy and management at university level
- Reliance on imported inputs for manufacturing
- High production costs in relation to competitors
- Regulators lack experience in pharmaceutical production
- GMP levels within the sector are uneven
- Unclear and poorly enforced quality standards (product, plant specific and inspections)
- Lack of a clear policy to promote access to or expansion of external markets
- Lack of common strategic vision for the pharmaceutical manufacturing industry
- Administrative hurdles and bureaucracy and lack of awareness of the need for rapid market development

Opportunities

- Local preference of 15 per cent for public procurement should be implemented
- Large and growing regional market in EAC, COMESA and sub-Saharan Africa
- Trend towards harmonization of standards and drug registration requirements within the EAC which will facilitate exports
- Potential to serve the regional market in most essential medicines
- Increased domestic demand from planned introduction of social health insurance
- Option of new product lines to suit emerging disease patterns and needs for the region, such as new demand for drugs for lifestyle diseases, such as diabetes, hypertension, etc.; diversification to produce other formulations within the sector is possible
- Backward linkages and integration to bulk production of starting materials, such as Active Pharmaceutical Ingredients (API) or non API and primary packaging materials
- Consolidation of functions within the industry and sectoral solutions to common problems such as environmental issues on disposal, quality standards, etc
- Strengthening cooperation within the sector to influence government policy
- Possibility of re-capitalization through joint ventures and partnerships
- Increased, aggressive efforts to attract foreign direct investment to the industry

Threats

- Increased dominance of imports from Asia, particularly India and China, which supply both finished and basic ingredients
- Continued poor regulation of the pharmaceutical market
- Growing influx of counterfeit and substandard medicines
- Deterioration of infrastructure and even higher utility costs
- Unilateral enforcement of non-tariff barriers by regulatory controls and regulations in export markets
- Domestic political risk and possible donor displacement
- Bilateral support to other countries in the region to set up pharma manufacturing
- Adverse currency exchange rate and deteriorating terms of trade
- Global financial crisis—leading to financial constraints, inflation and high costs

3.8 Options that could benefit the local pharmaceutical industry

Based on the above assessment of conditions in the local pharmaceutical industry in Kenya, the following section reviews the challenges faced by the industry and options for mitigation or potential remedial measures.

1. Stop the flow of substandard imports

A major problem for pharma companies is market penetration of cheap, imported generics. In response to this situation, the industry could demand stringent measures from the Pharmacy and Poisons Board (PPB) to stop the flow of substandard imports. Whilst the Board is already making some moves in this direction, much more could be done. For example, although the Board does not have the resources or authority to continuously monitor the state of plants manufacturing substandard medicines overseas, it could emulate the policies of international NGOs, such as Médecins sans Frontières (MSF) and the Committee for Medical Products for Human Use (CHMP), which rely on their own international network or the network of allied agencies to confirm the GMP status of producers. Another option would be for the PPB to require the latest GMP certification from a recognized and respected regulatory authority in the exporter's home country

The PPB could raise the fees for registration of foreign drugs to better reflect the costs incurred in monitoring quality and compliance of foreign drugs as opposed to local medicines.

Other possible actions include:

- The PPB could also require production/pre-shipment inspections at source from internationally recognised agencies such as Société Générale de Surveillance (SGS) or Bureau Veritas or, preferably, a WHO-certified QC laboratory as a condition for issuance of an import permit
- The PPB could make it a requirement for a National Quality Control Laboratory (NQCL) to test imports before issuance of import permits for all or some of the products
- Once the imported drugs reach Kenya, the PPB could institute random QC testing on batches before allowing entry into the distribution chain. Provision to do this at the Port of Entry is already envisioned in the new PPB guidelines.

2. Cut costs of importing basic ingredients and promote local production

Local pharma manufacturers import most of their basic materials with the result that they, themselves, are importers. They could undertake a comprehensive evaluation of the tax and duty structure affecting their business relative to import of finished medicines, and:

- Seek rationalization and equalization where there are existing inequities
- Lobby for advantages and incentives to support local production
- Local industry could make moves to differentiate their own products from imported generics

3. Upgrade GMP practices in the sector as a whole

The GMP status of the sector as a whole needs to be upgraded. There is considerable disparity in the quality of facilities, equipment and personnel among local firms which have been awarded the GMP standard. This is happening because:

- The GMP standard that all Kenyan pharma firms must meet has not been defined with adequate clarity
- Although all Kenyan firms get the same GMP certificate from the regulatory body, there is a wide variation in plant standards
- The bar is currently set too low. Some firms that are GMP-certified by the regulatory body may not merit this status and this could bring into disrepute the actual "quality" of the medicines they produce

Faced with this situation, it is desirable that a minimum standard (above what is accepted today) should be defined and enforced. This will be a complex task since upgrading GMP standards entails large expenditures. Investment financing is a problem and the large capital costs involved in upgrading will weigh against firms achieving competitiveness. Moreover, the regulatory body cannot simply impose stringent GMP standards at short notice since this would force many local firms into closing down their activities.

It is clear, nonetheless, that some action needs to be taken with regard to ensuring an improved, uniform GMP standard in Kenya. Initiatives that could be undertaken include:

- Assessment of the current GMP status of all interested local companies to establish facility needs. If a basic international GMP standard is taken as the objective to be met in future by all Kenyan firms, then it is important to assess accurately how close or how far these local firms are today from meeting such a standard
- The use of the findings to generate plant standards that meet basic hygiene and GMP requirements and a realistic timeline to achieve them
- Improved access to technical assistance for companies wishing to embark on GMP upgrades and aspiring to international GMP status.

Some firms are willing to consider, or even eager, to improve the GMP status of their operations but lack the financing and access to technical assistance to do so. By requesting technical assistance and funding for improved skills and technology transfer, they would simultaneously makes themselves more attractive candidates for FDI, joint ventures and partnerships

4. Strengthen cooperation within the sector and with other market players

For better market positioning and to increase local pharma production, local companies could improve cooperation among themselves and with other market players. They should aim at achieving improvements in marketing to enhance the image of local pharma; in training; in establishing a resource centre; and waste management.

Some companies have examined contract manufacturing options within the local industry but differences in quality practices present an obstacle to such arrangements at present. A general upgrade of quality standards would facilitate this type of working arrangement within the sector. Smaller companies could also come together and pool their capacities in order to meet the volume requirements for larger tenders. These arrangements would help participating parties use their production capacities better and enhance their competitiveness by becoming more cost efficient.

Local producers could also stimulate demand for their products by fostering closer relations with distributors and procurement agencies and by seeking ways to attract the latter such as offering discounts and improved services such as simplified ordering and tracking procedures and just-in-time deliveries; and/or by helping to solve distributors' problems with stock-outs. They could also be prepared to offer solutions to ad hoc problems, such as the need for urgent supplies of medicines during emergencies.

5. *Expand the role of the Federation of Kenya Pharmaceutical Manufacturers and the services offered to its members*

The pharma industry could invest in joint marketing of products under the slogan "Buy Kenyan". The Federation of Kenya Pharmaceutical Manufacturers (FKPM) could promote local products in terms of quality, economic growth and self reliance, and of preventing "exporting of jobs" through the importing of essential medicines. It could also establish criteria for quality achievements and coordinate a common marketing strategy for firms that meet and surpass minimum GMP requirements. A consumer awareness campaign on quality products and the achievement of WHO pre-qualifications or international status would also provide an opportunity to build public confidence in local medicines.

The establishment and operationalization of a functional secretariat at the FKPM would help in the gathering and capture of necessary data, as well as in driving forward programmes such as quality improvement.

6. *Upgrade curricula at university level*

The shortage of trained personnel (particularly industrial pharmacists) needs to be addressed. The School of Pharmacy at the University of Nairobi has a two year masters degree course in pharmaceutical analysis. The pharma industry could support this programme financially or sponsor their staff for training in the programme. It could also lobby for assistance in generating training programmes for training of its own personnel in maintenance of quality premises and quality production techniques.

7. *Introduce energy efficiency measures and cleaner production techniques*

There is ample scope for local industry to become more price competitive by producing more efficiently. In particular, local pharma companies could introduce energy efficiency programmes which would lower energy costs and production costs overall through adoption of cleaner production technologies.

The cost structure of local pharma production is, in fact, not well understood and an in-depth study—going beyond simple notions of scale economies—is necessary in order to fully understand the economics of pharma production.

4. THE BUSINESS ENVIRONMENT FOR PHARMACEUTICAL SECTOR PERFORMANCE AND DEVELOPMENT

4.1 Policy framework

Kenya National Pharmaceutical Policy

Although the first Kenya National Drug Policy (KNDP), introduced in 1994, addressed important issues affecting pharmaceutical services, including local production, policy, regulation, distribution, procurement, and training, the section on local production was unfortunately never implemented. The Kenya National Pharmaceutical Policy (KNPP),[24] second edition of 2009, is currently being reviewed and will form the basis of a sessional paper to be submitted to Parliament. The policy encompasses the key elements needed for revitalizing the pharmaceutical subsector in Kenya.

The KNPP acknowledges the challenges of trade liberalization and creating a manufacturing environment to ensure sustainability and competitiveness. A strong regulatory regime will ensure consumer confidence with regard to safety, effectiveness, and quality of products in production and on the market. This is a very important factor for both the domestic and export markets.

The main objectives are:

- To ensure equitable access to affordable medicines through the public, private, and other sectors
- To ensure continuous availability of safe and effective essential medicines, especially in the public sector
- To promote appropriate medicine use through good prescribing and dispensing practices and correct use by consumers
- To ensure appropriate regulation and control of human and veterinary medicines
- To ensure that the quality of medicines for human and veterinary use in Kenya meets internationally acceptable standards
- To ensure that chemicals for agricultural and industrial use, foods, and cosmetics are appropriately regulated and controlled to prevent or minimize potential harm to humans and animals
- To encourage self-sufficiency in local manufacture of essential medicines for the domestic market and to promote growth in pharmaceutical exports

[24] Kenya National Pharmaceutical Policy 2009 (final draft).

- To ensure integration of useful traditional, complementary/alternative, and herbal medicines into the national healthcare system
- To strengthen and institutionalise pharmaceutical care as a key component of the health-care system
- To enhance training capacity and regulate the training of pharmaceutical personnel at all levels
- To increase and strengthen institutional, technical, and human resource capacity for the effective provision of pharmaceutical services

The KNPP calls for effective legislation and regulation of the subsector, including personnel, premises, practices, and products. The policy aim with regard to local production is to ensure self-sufficiency in the production of essential medicines and growth in exports. The government aims to ensure an enabling environment for local pharmaceutical production, which is to be achieved through:

- Strengthening the capacity for GMP compliance and encouraging international certification for local manufacturers by a duly recognized agency or stringent regulatory authority; and providing incentives for local production of essential medicines to improve their affordability and availability
- Effective utilization of WTO/TRIPS flexibilities to promote local manufacture of essential medicines and other products and technologies of public health importance

The policy is clear on a quality assurance system based on quality, safety, and effectiveness of medicines in accordance with legal requirements and professional standards. On matters of waste management, it aims at environmentally-safe disposal of pharmaceutical waste.

Whilst the objectives are laudable, the mechanisms by which they are to be achieved have yet to be devised.

Vision 2030

Vision 2030 is a long-term development blueprint for Kenya. It outlines an ambitious programme for the country to become globally competitive and prosperous by the year 2030.[25] Three main pillars are identified, namely, the economic, social, and political pillars.

The economic pillar aims to move "the economy up the value chain" and identifies six key sectors to deliver the average 10 per cent economic growth envisioned. Manufacturing is one of these sectors and it is expected to register an annual growth of 10 per cent in the period 2008-2012. The vision is of a robust, diversified and competitive manufacturing sector, strengthened local production and a greater share for Kenyan products in the regional market.

One way of achieving this is emphasized as "adding value to intermediate imports and capturing the 'last step' of value addition". Vision 2030 also recognizes that currently only 5 per cent of Kenyan manufactures are in skill-intensive activities. Consequently, an important part of moving up the value chain would be to increase the level and share

[25] Kenya Vision 2030.

of such activities. This means that the strengthening of local production of essential medicines is very much in line with these Vision 2030 objectives.

Industrialization Policy

The Master Plan for Kenyan Industrial Development, completed in 2008, is intended as a road map by which the government catalyses the implementation of strategic actions to accelerate industrial development. It starts with a consideration of the national industrial development policy framework, as laid out in Vision 2030 and the Private Sector Development Strategy. It then examines issues in industrial development which are applicable to the manufacturing sector as a whole and recommends future directions and a development framework for the sector. It goes on to suggest some priority projects and identifies three priority subsectors for targeted development. Development strategies for these subsectors are then outlined.

Pharmaceuticals is not one of the target subsectors selected. In fact, there is very little mention of pharmaceuticals in the Master Plan. A section entitled "Evaluation of Growth Potentials" (section 9.3.4 of the Master Plan) states that "Although Kenya has a high concentration of the pharmaceutical subsector, its activities are simple: weighing raw materials, mixing, packaging, testing, and delivering. Universities have to educate more people in pharmaceuticals in order to send enough labour to the pharmaceutical subsector. This would give incentives to the private sector to go into more high value added activities".[26]

This seems to imply that human resources are the main impediment to development of the Kenyan pharma sector. Yet the subsector is more developed than implied. It carries out the actual manufacture[27] of pharmaceutical products which are registered by the Pharmacy and Poisons Board (PPB). Locally made pharmaceutical products are locally designed, formulated, and processed into finished products of tablets, capsules, syrups, ointments and creams, or both small and large volume sterile parenterals. The final steps in pharmaceutical production are actually more complex than the casual observer might appreciate. Quality assurance requirements dictate tight tolerances of composition and purity of ingredients which must be maintained. Whilst the universities do train pharmacists, these graduates lack an industrial pharmacy orientation, with the result that they are more qualified to work in retail pharmacy than in a pharmaceutical factory.

The industry does have some technical staff but there are only a small number of foreign-trained pharmacists. Specialization and skills development in industrial pharmacy are lacking and this gap should be a priority item on the reform agenda for skills and know-how training.

4.2 Legal framework

Pharmaceuticals should be highly regulated. Poor enforcement of regulations has resulted in a proliferation of poor quality and counterfeit products on the market and has eroded

[26] Kenya Industrialization Policy.

[27] WHO Definition of Manufacture: All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

growth of the formal market. This is the view expressed in a paper "How to control Pharmaceutical Traders/Brokers"[28] published in 2009 in the PharmaQuality Catalogue. Strong local regulatory authorities also tend to strengthen an exporter's position since foreign buyers usually have greater confidence in the quality of pharmaceuticals produced in a country where national regulations are strictly enforced.

Pharmacy and Poisons Act, Cap 244

The main legislation for the control of pharmacy in Kenya is the Pharmacy and Poisons Act, Cap 244. Its main purpose is to regulate the profession of pharmacy and control the manufacturing, trade, and distribution of pharmaceutical products.

The provisions specific to the licensing of the manufacture of drugs for sale are contained in Part IIIA, section 35A. This provides for the licence to manufacture medicinal substances, and Section 35B provides for compliance with Good Manufacturing Practices. The rule on the manufacture of drugs in Section 16 (5) of subsidiary legislation made under section 44 requires that the premises be licensed under a registered pharmacist, or one with an equivalent qualification.

In the subsidiary legislation, Gazette Notice No. 147/1981, rules for registration of drugs came into operation. The fee for registration of locally produced drugs is US$ 500 compared with US$ 1,000 for imported drugs on first registration. An additional fee of US$ 4,000 is levied for GMP inspection abroad.

New registration guidelines have recently been drafted and finalized. They were due to come into force at the beginning of March 2010 but were, in fact, still under consideration at the time of publication of this report. The Federation of Kenya Pharmaceutical Manufacturers has appealed to the Ministry of Medical Services and the Pharmacy and Poisons Board to delay implementation of some sections and, in particular, the requirement for Bio-Equivalence studies until such time as Kenya has the infrastructure to deal with this aspect.

Industrial Property Act 2001

The Act provides for the promotion of inventive and innovative activities to facilitate the acquisition of technology by granting and regulating patents, utility models, technical innovations and industrial designs. In section 22, an invention is described as new and industrially applicable. It is popularly known as the "Patent Act" and, under section 60, the term of a patent is 20 years from the date of filing the application. The legislation conforms to the international protocols under WTO/TRIPS.

The TRIPS flexibilities on the exploitation of the patented inventions provide for the obligations of the patent owner. The flexibilities within the Act include:

[28] PharmaQuality Catalogue, Issue No 001- 2009: How to control Pharmaceutical Traders/Brokers, by Raffalla Ravinetto, Sandrine Cloez, and Sophie-Marie Scouflaire.

- *Parallel Importation (Section 58 (2))*. This concerns importation into Kenya provided that the rights of the holder have been exhausted in the exporting country through manufacture within that country, importation into that country or otherwise

- *Voluntary Licensing (Sections 64-71)*: This is utilized for acquisition of technology or rights necessary for the manufacture of medicines. It normally starts with an interested person applying for a search at the Kenya Industrial Property Institute (KIPI). The search is intended to establish whether or not the process of manufacture and/or the drugs are patented in Kenya or elsewhere

- *Compulsory Licensing (Section 72-79)*: This measure is taken by governments to ensure that patent rights are not abused by owners or licensees to the detriment of their citizens

- *Governmental Use (Section 80)*: This is a government measure intended to safeguard public interest, in particular with regard to matters concerning national security, nutrition, health, environmental conservation or the development of other vital sectors of the national economy. The Minister for Industrialization may issue an order that a drug be imported or the process of manufacture, or any molecule or substance, be utilized by a government ministry, department, agency or other person as the Minister may designate in the order

Kenya acceded to the TRIPS agreement by enacting this legislation in 2001. The Doha Declaration on the TRIPS Agreement and Public Health in November 2001 recognized the public health problems afflicting developing and Least Developed Countries, especially with regard to HIV/AIDS, tuberculosis, malaria and other epidemics. The Agreement recognized the importance of TRIPS in the development of new drugs but also took into account its impact on access and affordability.

There are many drugs and other pharmaceutical products that are off patent in Kenya, either because the patent has expired or was not sought. This status is usually confirmed upon application for a search at the Kenya Industrial Property Institute

The Industrial Property Act provides that the owner of the patent must receive adequate remuneration taking into account the circumstances warranting the issue of the licence. It should be noted that a compulsory licence is issued only when the applicant has sought—and failed to obtain—a voluntary licence from the owner of the patent.

The Declaration extended the implementation of TRIPS to 2016 for LDCs but, since Kenya is classified as a developing country, it is not eligible for this extension. The term in section 22 on new use has been contested in public fora as a "TRIPS-plus". It provides for a patent holder to apply for new patents, thus preventing generic manufacturers from early patent exploitation and can lead to "evergreen" patents becoming an impediment to local pharma development.

The provision on parallel importation under the Industrial Property Act 2001 provides for flexibility in seeking importation of products still under patent. However, local distributors' activities in importing off-patent products have raised concerns. After consultative meetings between members of the Kenya Association of the Pharmaceutical Industry (KAPI), the Kenya Private Developers Association (KPDA)/retail pharmacies, and the Pharmacy and Poisons Board, a Task Force was formed under the auspices of

the Ministry of Medical Services. This Task Force issued a report in November 2004, containing recommendations on:

- Import controls and elimination of trade in illegally imported drugs from unauthorized sources and by unauthorized person, by:
  - ensuring details of source
  - development of operational procedures on standards
  - publication of lists of authorized importers; and
  - development of software to capture data
- Elimination of trade in counterfeits and stolen drugs by:
  - registration of trade marks
  - impounding and destruction of counterfeits
  - dissemination of information to professionals, and
  - development of comprehensive guidelines
- Strengthening of post marketing surveillance and enhancement of the role of the Pharmaceutical Inspectorate of the PPB in post marketing drug testing by:
  - clarifying job descriptions of personnel in the Inspectorate
  - enlarging the scope of Inspectorate activities to include ports of entry and all fields of pharmacy practice
  - instituting proper procedures for sampling and handling suspect drugs,
  - testing at ports of entry; and
  - encouraging self regulation by the pharma industry
- Improvement of access to and affordability of drugs, through partnerships, pricing policy, and harmonization of the Industrial Property Act
- Conducting awareness and sensitization campaigns by:
  - training of the government staff at the Ministry of Health and involving the judiciary in enforcement; and
  - awareness building on the rational use medicines and the role of the PPB

Anti-Counterfeit Act, December 2008

This Act was legislated to prohibit trade in counterfeit goods, including pharmaceuticals. The definition of counterfeiting has generated controversy because it is broad and over-encompassing and includes substandard products. The emphasis in the WHO definition of counterfeit[29] is somehow lost and a review of the revision would be well worthwhile since there is some concern that it is so broad that legitimate generic medicines could

[29]WHO definition of counterfeit medicine means one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include those with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

also be considered counterfeit. An Anti-Counterfeit Agency under the supervision of the Ministry of Industrialisation is to be set up with a mandate to operationalize the Act.

Kenya Public Procurement and Disposal Act, 2005

This legislation provides for the establishment of procedures for public procurement and for the disposal of unserviceable, obsolete or surplus stores, assets or equipment, in order to:

- Maximize economy and efficiency
- Promote competition and ensure that competitors are treated fairly
- Promote the integrity and fairness of those procedures
- Increase transparency and accountability in those procedures
- Increase public confidence in those procedures; and
- Facilitate the promotion of local industry and economic development

The spirit of this legislation is to promote industrial growth as envisaged in Vision 2030,[30] which includes the development of a robust, diversified and competitive manufacturing sector. The Public Procurement and Disposal regulation[31] states that "the procuring entity may grant a margin of preference of up to 15 per cent in the evaluation of bids to candidates offering goods manufactured, mined, grown, and extracted in Kenya".

The Act also provides for pre-qualification of suppliers: "To identify qualified persons, a procuring entity may use a pre-qualification procedure, or may use the results of a pre-qualification procedure used by another public entity, and the specific requirements based on national or international standards".

Local pharma manufacturers complain of a lack of implementation of these provisions in the case of preferential treatment and pre-qualification of suppliers. Whilst implementation of the provision of 15 per cent local preference would have budgetary implications, it would be beneficial for local industry. Moreover, KEMSA's recent quotations (a form of short term tender)[32] have included specifications which were neither national nor international. For example, a special note in one quotation required that Paracetamol tablets and Sulfadoxine/Pyrimethamine tablets 500/25mg be film-coated. Usually, however, these are plain tablets. Such differing specifications that lock out local manufacturers unaware of the changes stand in the way of the realization of Vision 2030. It would be better for all procurement agents to use the specifications used by the regulatory body, except where an explanation and notice of change has been provided.

There are several other legislations that affect the manufacturing of pharmaceuticals, which come under the purview of various regulations and/or regulatory authorities. They include:

> *The Industrial Registration Act* promulgated for the purpose of registration of industrial undertakings in Kenya and other related purposes. All pharmaceutical manufacturers are to be registered under this Act, as well as Cap 244.

[30] Kenya Vision 2030.

[31] Public Procurement and Disposal Regulations 2006, LN 174, 2006.

[32] KEMSA/OIT 9/2009-2011 Quotation.

The Industrial Property Act, 2001 providing for the promotion of inventive and innovative activities to facilitate the acquisition of technology through the grant and regulation of patents, utility models, technovations and industrial designs; to provide for the establishment, powers and functions of the Kenya Industrial Property Institute; and for all purposes incidental thereto and connected therewith.

The Public Health Act, Cap 242 makes provision for securing and maintaining public health. It is an all-empowering legislation which also establishes a department in the Ministry of Health under the Director of Medical Services whose key function is to safeguard against infections and promote public health and prevention of diseases.

The Food, Drug and Chemical Substances Act, Cap 254 makes provision for the prevention of adulteration of food, drugs, and chemical substances, and for matters incidental thereto and connected therewith.

The Environmental Management and Co-ordination Act, 1999 provides for the establishment of an appropriate legal and institutional framework for the management of the environment, and for matters connected therewith and incidental thereto.

The Narcotic Drugs and Psychotropic Substances (Control) Act, 1994 deals with the control of possession of, and trafficking in, narcotic drugs and psychotic substances, and the cultivation of certain plants. It provides for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, and for all related purposes.

The Labour Act defines the fundamental rights of employees, provides the basic conditions of employment for employers, regulates the employment of children, and provides for matters related to the foregoing.

The Industrial Training Act, Cap 237 is the legislation that deals with the regulation of the training of persons engaged in industry. It established the Training Levy fund under the Directorate of Industrial Training.

4.3 Regulatory environment

In the Afro-regional meeting of WHO in September 2006[33] on Medicines Regulatory Authorities (MRA): Current Status and The Way Forward, it was reported that a study conducted by the WHO Regional Office in 2004 showed that 90 per cent of MRAs in the region lack the capacity to carry out all their regulatory functions and cannot guarantee the quality, efficacy and safety of medicines. A number of recommendations were made as a way forward to strengthen the institutional and organizational framework of the MRAs and their capacities to carry out their regulatory functions. The report, in its conclusion, stated that "Failure to enforce regulations would result in the proliferation of harmful, inefficacious, counterfeit or substandard medicines on the national and international markets".

The Pharmacy and Poisons Board (PPB) is the regulatory body for the pharma sector in Kenya. PPB is facing many challenges and it is quite clear that the WHO

[33] Report of the Regional Director, Fifty-Sixth Session. Addis Ababa, Ethiopia, AFR/RC56/11.

recommendations need to be fast–tracked and implemented in order to make the Board more capable of discharging its regulatory functions. A COMESA study[34] also outlines a number of weaknesses in the legal framework, the regulatory authority, the National Quality Control Laboratory, and the manufacturing sector. In the follow-up plan of action, COMESA's Manual for Minimum Technical Standards of Harmonisation and Tool for NDRA Evaluation[35] was developed. It contains intervention measures recommended to each member state for the implementation of 15 technical standards by the regulatory authorities at country and regional level.

The 15 standards are statements on the countries' obligations and purpose and the scope of measures to be undertaken. They are:

1. *National drug policy*: to ensure that drugs/medicines circulating in the market are safe, efficacious, of good quality, accessible and affordable, and rationally used
2. *National drug legislation*: to provide a legal basis for the control and regulation of the pharmaceutical sector
3. *Quality management systems*: to ensure NDRA (National Drug Regulatory Authority) operations are consistent, reliable, and effective in order to impart confidence in service delivery
4. *Registration of medicines*: to ensure that medicines made available for use meet requirements of quality, safety and efficacy
5. *Quality control laboratories*: to ensure that NDRAs have access to an independent laboratory to verify compliance with the required standards of quality
6. *Good distribution practice*: to ensure compliance with Good Distribution Practice (GDP)
7. *Good manufacturing practice*: to ensure that pharmaceutical production within the country consistently complies with established standards and conditions of product registration
8. *Inspections and audits*: to ensure compliance with GMP, GDP, Good Pharmacy Practice (GPP), and other licensing requirements
9. *Defective product reporting system*: to ensure prompt detection, reporting and effective removal of defective products from the supply chain
10. *Pharmacovigilance system*: to ensure that NDRAs have systems and procedures for detection, assessment, and prevention of Adverse Drug Reactions (ADR)
11. *Anti-counterfeiting measures*: to establish control and enforcement procedures for detecting and preventing counterfeits from entering the distribution chain
12. *Control of donations*: to ensure that all NDRAs have statutory and enforcement measures to monitor, detect, and prevent unregistered substandard or poor quality pharmaceutical products, and also to ensure that only those products with marketing authorization that support rational drug use are allowed into the supply chain

[34] COMSEC/COMESA Report on Development of the Pharmaceutical Sector, June 2005.

[35] Manual: COMESA Minimum Technical Standards of Harmonisation and Tools for NDRA Evaluation June 2009.

13. *Crisis management system*: to prevent known hazards and to reduce the risks that they will occur at specific points in the food chain and drug supply distribution

14. *Drugs and substances legislation*: to have a legal basis for the control of narcotic drugs, psychotropic substances, and precursors. It is the obligation of the member State to ensure the adequate availability of controlled medicines for medical and scientific purposes through an efficient national control regime and to implement programmes to prevent illicit trafficking and diversion of such medicines

15. *NDRA evaluation*: to ensure that each member State within the Mutual Recognition Agreement (MRA) will have the confidence that other NDRAs comply with the Minimum Technical Standards of Harmonisation (MTSH)

Pharmacy and Poisons Board (PPB)

The Pharmacy and Poisons Board is the pharmaceutical regulatory authority in Kenya established by law under the Pharmacy and Poisons Act, Cap 244. The Board regulates the practice of pharmacy and the manufacture and trade of drugs and poisons. The key objective of the Board is to improve the quality of life of Kenyans by ensuring the quality, safety and efficacy of pharmaceutical products and services.

The Chairman of PPB is the Director of Medical Services (DMS) and the Registrar is the Chief Pharmacist. The Board does not have the authority to appoint its own technical staff. The Chairman, Registrar and staff are appointees of the government, seconded by the Ministry of Medical Services (MOMS) for duty at PPB. They can be re-deployed anywhere with different government duties in accordance with the public service guidelines. Although PPB is described as semi-autonomous, all its technical human resources are public servants, making it a government department except for certain operations. Both the Chairman and Registrar also hold policy-making offices at MOMS and government decisions may influence their regulatory role at the PPB.

The major departments at the PPB are Drug Registration, Pharmacovigilance, the Pharmaceutical (GDP) Inspectorate, the GMP Inspectorate, Trade Affairs, and Information Technology (IT).

Drug Registration

There are approximately 13,000 drugs registered with the PPB from 1,250 manufacturers. The Drug Registration Department receives about 30 applications per week for new product registrations, less than a third of which are from local manufacturers. The product in question is not evaluated until a valid GMP certificate is furnished. Registration renewals are more or less automatic on payment of the set fees; no re-testing is done. There is some feeling within the PPB that registration renewals are too easy.

All registered products are listed on the PPB website, and the website is updated every three months. Unfortunately, however, the website continues to shows non-renewed registrations and there is also a recognised problem with the transmission of registration information to other PPB departments. GDP inspectors in the field, for example, do not have ready and easy access to registration information when they encounter suspicious medicines, often in unregistered pharmacies. Software to interlink with other departments would be useful.

There is also a perceived need for more staff, and more hands-on-training of staff on internal evaluation, especially bio-equivalence.

The Department has just finalized new drug registration guidelines which were scheduled for implementation on 1 March 2010. However, the Federation of Kenya Pharmaceutical Manufacturers appealed to the Ministry of Medical Services and the Pharmacy and Poisons Board for a delay in the specific requirement for Bio-Equivalence Testing until such a centre is set up (which should be within five years). In principle, there is an undertaking that a Bio-Equivalence centre should be established in Kenya so that local pharma firms have access to such a facility to carry out the tests. The new guidelines mandate batch testing of all imported medicines and Applied Pharmaceutical Ingredients (APIs) at the Ports of Entry (PoE). Testing is expected to be the responsibility of the National Quality Control Laboratory (NQCL) but it is unclear whether NQCL has the personnel and equipment in place to undertake such testing.

As an indication of the magnitude of the task, 400 consignments of finished medicines come into the Jomo Kenyatta International Airport in Nairobi alone per month, some of them with as many as 10 different products. The testing challenge is considered to be "NQCL's problem", since the laboratory has apparently been adamant about carrying out such testing, if and when required. Should NQCL's testing find an imported product to be defective, then the entire consignment is to be destroyed. The elimination of the defective product is the responsibility of the Pharmaceutical (GDP) Directorate but it is unclear whether the GDP Directorate has the facilities and personnel to discharge this function. Neither NQCL nor the GDP Inspectorate has adequate storage at all PoEs to hold imported products while being tested or awaiting disposal.

Pharmacovigilance (PCV)

The Department of Pharmacovigilance grew out of a donor-funded project started in late 2004 as a result of pressure on the PPB to initiate pharmacovigilance from the Government's public health programmes such as the Malaria Control Programme (MCP), and the anti-TB, and HIV/ AIDS programmes. Some initial co-funding came from these public health programmes and the Department was formally launched in June 2009. It consists of the Department Head, one pharmacist, who is basically responsible for clinical trials, and another pharmacy technologist who is responsible for post market surveillance (PMS) and the pharmacovigilance activities. In recent years, the Department has attempted to generate PCV guidelines and to design a system of alerts and forms for the reporting of poor quality pharma products and suspect adverse drug reactions. In order to increase the impact of the few staff in the Department, a five day comprehensive training programme to sensitize health workers and the public on PCV has been started. To date, nine national-level training courses have been completed by representatives from public health programmes, University of Nairobi lecturers, and parent Health Ministry personnel. A further 277 health workers were trained in the second half of 2009. The Department also works with NGOs and trains Medicines and Therapeutics Committees.

A system has also been introduced under which health workers in the field and members of the public can report suspicious drugs by post, telephone, or e-mail. When such a report is received, the Department first checks the registration of the drug manually by visiting the Drug Registration Department. Samples are then collected by PPB officials and sent to NQCL for analysis. It can take up to four or five months for the test results to come through. If the product is found to be defective, the PCV Department writes

to the local manufacturer or importing agent requesting them to withdraw the drug from the market. Since Good Distribution Practices are not enforced and there are often no batch numbers on medicine packages, suppliers frequently claim that the defective medicine was from a very old batch that was improperly stored by the retailer. If there is no confirmation that the faulty drug has been removed from the market, the PCV hands over the case to the Pharmaceutical (GDP) Inspectorate for follow-up. However, there is no system for closing the loop, i.e. for the PCV Department to be informed by the GDP Inspectorate about the action taken or for the person originally reporting the suspicious drug to learn of any remedial action.

If a reported drug is found to be unregistered, often no information is found on the suppliers of the drug, or on how the drug entered the distribution chain. There is no formulated strategy on post market surveillance although this forms part of the WHO Activity Plan for Kenya. There is also no database and therefore no institutional history of the reports, inspections and actions taken on faulty drugs in the market.

Much more needs to be done in the area of speeding up information flow and alerts in a market where the audit trail of drugs is spotty and counterfeit or substandard medicines can enter through multiple channels (for example, counterfeits have come in as imported furniture).

Further complications may arise because of suspicion and/or reports of corruption at different levels of the monitoring and enforcement structure. Above all, greater coordination within the departments of the PPB and with market players is necessary. To the credit of PPB management, post market surveillance has been identified as a priority and the Board's budget for pharmacovigilance activities was to be increased to KSh 75 million (about US$ 1 million) for 2010-2011.

The Pharmaceutical (GDP) Inspectorate

The Pharmaceutical Inspectorate currently has 40 inspectors to cover the entire country, of whom eight were recruited recently, specifically for Ports of Entry. With this staff, the Inspectorate is expected to monitor all wholesale and retail establishments in Kenya, including hospitals. Thus, it is charged with market surveillance at all levels of the distribution chain. Of the 40 inspectors, 10 are pharmacists, and the rest are pharmacy technologists. Those inspectors who are provincial heads are usually pharmacists. Training consists of induction training for two to three days and those who are assigned to the PoEs are given on-the-job training for a week to familiarize themselves with relevant documentation. Although a refresher course is offered every year, there is a recognized need for specific training on inspection techniques, investigation methods, and prosecution.

Drug inspections in Kenya are, in fact, carried out by two agencies: the Pharmaceutical Inspectorate in the PPB and the older Drug Inspectorate under the Ministry of Health. When the Pharmaceutical Inspectorate was created within the PPB, the harmonization and separation of functions between the two Inspectorates were apparently never fully completed. Thus, there appears to be overlap between the responsibilities of the two Inspectorates, with inspectors from both the Drug and Pharmaceutical Inspectorates conducting joint inspections about four times a year.

The Pharmaceutical Inspectorate has written GDP guidelines but plans to revise them, based on inputs from stakeholders. There is an elaborate checklist for inspection which

is ticked off at the time of registration of new pharmacies but it is not followed up during routine inspections because inspectors do not have the necessary time for this at each inspection. There is, therefore, a need for a simpler form for use during routine inspections. However, although there have been several attempts to develop such a form, one has not yet been finalized.

If unregistered pharmacies or defective drugs are uncovered, the Pharmaceutical Inspectorate follows a "scorched earth" policy. All drugs in the outlet are seized and court action is initiated quickly to allow minimum time for affected parties to counter Inspectorate actions through lobbying. Suppliers of faulty drugs are investigated and brought before PPB's Disciplinary Committee. The feeling within the Inspectorate is that there are sufficient authority and "teeth" under existing statutes to control substandard/counterfeit drugs in the market despite some loopholes in drug classification. The challenge is to ensure adequate enforcement and, in this respect, the Inspectorate is handicapped by a lack of systems, such as formulated guidelines and procedures, and by the lack of the necessary infrastructure.

Inspectors often operate out of space loaned by the local branch of the Department of Medical Services. They do not have offices or a secure location to store seized drugs. Transport vehicles, computers, and communication equipment are not available and this hampers efficiency and broader coverage. Finally, human resources are insufficient and there are not enough trained inspectors.

In a 2006 survey, out of 4,000 retail outlets for medicines (including hospitals, nursing homes, clinics, and pharmacies), only about 1,500 were licensed, meaning that the majority of retail outlets for medicines in Kenya are unregistered. In this context, it is very difficult to close down pharmacies. Occasionally, Inspectorate personnel face hostile opposition from the public in trying to close down an unregistered outlet because it is the only source of medicines for the public in that area.

The Pharmaceutical Inspectorate also receives tips and market complaints about substandard drugs from the Department of Pharmacovigilance but there is no system or procedure to feed back information on the results of investigations conducted by the Inspectorate. Consequently, there is no mechanism to ensure that inspectors on the ground take action on market complaints.

The GMP Inspectorate

The GMP Inspectorate consists of the Department Head and five inspectors. These six officers are responsible for the inspection of all factory premises in Kenya. In addition, GMP inspectors are expected to travel abroad to carry out GMP audits of companies who seek marketing authorization in Kenya. Since there are over 35 local, and more than 1,000 foreign, manufacturing facilities supplying products to Kenya, the number of GMP inspectors is grossly inadequate. Often officials from the Board, MOMS, NQCL and Drug Registration are called upon to augment GMP Inspectorate staff during foreign inspections. The PPB charges a fee of US$ 4,000 for foreign GMP inspections, which is much too low and fails to reflect the actual costs incurred. No clear deadlines exist for inspecting foreign companies still on the waiting list and there are instances of foreign suppliers that have been exporting drugs to Kenya for years but have still not been inspected. The cost/benefit ratio of foreign GMP inspections needs to be assessed against relying on inspection reports of stringent regulatory authorities in the suppliers' home countries and mutual recognition schemes.

Moreover, the Board's GMP Inspectors do not have prior experience in the pharma industry. This limitation, together with the high number of facilities that need to be inspected, underlines the need for the formulation of, and compliance with, detailed guidelines.

Trade Affairs

All importers must apply for an Import Permit with the Trade Affairs Department, detailing the number, quantity, supplier, and price of drugs that are to be imported. The Department issues a permit after ascertaining that the drugs to be imported are registered with the PPB. Similarly, local manufacturers must apply for Export Permits with the Department, detailing the number, quantity, and price of drugs that are to be exported. Consequently, the Department holds detailed information on all import and export of drugs in and out of Kenya. However, this useful information is simply stored within the Department in hard copy and is not readily retrievable. There is little awareness of its existence and it is not disseminated outside the Department or used in any way. Data on import permits for 2007 was only being entered in late 2009 in electronic form, meaning that the electronic record has a time lag of two years.

It should be apparent from the above that the PPB is in need of substantial reform. Its resources and systems are vastly inadequate to cope with its regulatory responsibilities. The Board's staff is overwhelmed by the large number of companies and products that it is expected to regulate, such as unregistered outlets, unregistered medicines, substandard[36] medicines and counterfeits, and manufacturing premises. The system to monitor authorized and unauthorized imports, exports, or locally produced medicines on the market is inadequate. The information capturing and retrieval systems at PPB are not consistent with modern times. The policy and decision-making organs do not receive reliable data on a routine basis and, in the event of a crisis in public health and safety, necessitating withdrawal or recall of a medicine, information on the product name, quantity, price, source, and distribution channels is required. Under the current structure, this information is simply not accessible in a timely manner.

The result of very weak and ineffective regulation has been a flow of substandard medicines onto the domestic market, both imports as well as some locally manufactured products. For example, a baseline study completed prior to nationwide distribution of Artemether-Lumefantine (AL) in Kenya[37] made several observations, viz. that a high proportion of anti-malarials available on the market were unregistered, most of which originated in Kenya and India. The sources of these medicines are known to the PPB but it has done very little to put a stop to this situation. Key recommendations made at the time of the baseline AL study were to:

- Computerize data management systems for medicine registration and to make information accessible to the public
- Enforce compliance by stakeholders with set pharmaceutical regulations
- Support strengthening of key pillars of medicines regulation
- Withdraw non-recommended and substandard anti-malarial products from the market

[36] In this context, substandard medicines means those medicines not conforming to pharmacopoeial standards and/or registration requirements.

[37] Anti Malarial medicines in Kenya. Availability, Quality and Registration Status. December 2007.

Several recommendations contained in the study have not so far been implemented. For example, it identifies the need for regulatory reforms at PPB to safeguard public safety, especially in the context of trade liberalization. Substandard medicines are a continuing health risk that increases the cost of healthcare by necessitating re-treatment at higher costs and engendering drug resistance. They can also cause unnecessary deaths.

There is wide variation in the standard of the facilities in existing Kenyan pharma companies, as well as in new start-ups. Some manufacturers have invested in modern infrastructure that complies with GMP requirements. These companies are concerned that they are operating on a "different level playing field" to others in the same market who are producing in substandard plants. PPB should, therefore, seek to develop premises standards for different formulations (as in liquids, solid state formulations, large and small volume parenterals, and others) and should seek to enforce these premises standards uniformly. However, a "level playing field" will not be achieved unless the PPB also undertakes concurrent measures to enforce the same quality standards on imports as on locally-produced drugs, as well as to stop the import of substandard drugs made in substandard manufacturing facilities outside Kenya.

Regulatory weaknesses and lack of authority to enforce the law could be compounded by fear and self-protection by those in authority and delays in decision-making due to lack of procedures. In the event of a public safety crisis, there are no procedures which have been gazetted for product recall or withdrawal. Similarly, there are no procedures to deal with products which are found by analysis at NQCL to be non-conforming.

In general, there are very strong views in the Kenyan pharma industry that, unless there are deliberate and urgent reforms at the Pharmacy and Poisons Board (PPB), there can be no meaningful programme to strengthen local production. These views are commonly shared among local industry, distributors, importers, and associations,[38] as well as professionals and policy makers. Most stakeholders in the public and private sectors (including civil society) are also of the view that the Board should be de-linked from the parent Ministry of Medical Services and be made autonomous if reform is to be truly meaningful. In the current configuration, there is a disconnect between regulatory authority and policy development and this gives rise to numerous regulatory lapses.

National Quality Control Laboratory (NQCL)

The National Quality Control Laboratory (NQCL) was established as the technical arm of PPB through an amendment of the Pharmacy and Poisons Act (Amendment) 1992, Part IIIB, to provide for the examination and testing of drugs and to ensure quality control. NQCL's core function is the testing of drugs and evaluation of medical devices, post market surveillance, technical advice to the government and the Pharmacy and Poisons Board, training of pharmaceutical personnel both in and outside the country, preparation of secondary standards, and applied research and consultancy.

The Laboratory is a body corporate with a Board of Management but it is not autonomous. The PPB appoints the Board of Management (section 35E), which should appoint the Chief Executive of NQCL, a function currently carried out by government deployment.

[38] Memorandum to Minister of Medical Services, September 2009 on "Issues Affecting the Pharmaceutical Industry in Kenya".

The reasons why a Board of Management is appointed by another Board under the same Act of Parliament are not clear and there appears to have been a legal error at the initial drafting stage. This anomaly of one Board within another has been identified as a factor hampering the functional relationship between the two organizations. The staff at NQCL are also civil servants deployed by the Ministry of Medical Services.[39]

Despite such constraints, NQCL has performed well in recent years and has made key achievements. It is among only six WHO pre-qualified Quality Control laboratories in the whole of Africa,[40] and has additional qualification for microbiology testing.

Whilst the functional relationship between NQCL and PPB is understood, it is not clearly defined. NQCL has the responsibility to test the compliance of products with quality requirements. In recent years, its workload has increased tremendously, with both local and regional clients sending samples for analysis. Space in the Kenyatta National Hospital (KNH) building is a constraint and there is no room for expansion. Consequently, the government has allocated space to develop custom-built premises for NQCL.

The samples sent to NQCL for testing are usually:

- Pre-registration samples from PPB for evaluation before drug registration
- From the Kenya Medical Supplies Agency (KEMSA) for tender-related technical evaluation and surveillance
- From surveillance activities funded by development partners,[41] and
- Occasionally, from pharmaceutical manufacturers

The NQCL is charged with testing drugs and medical appliances for quality. It is reported that quality problems encountered are similar in both local and imported products. The prevalence of counterfeits is thought to be about 20 per cent (based on the WHO definition).[42] Pharmacovigilance activities, coupled with a detailed survey, would be appropriate to establish the level of counterfeits and substandard[43] medicines on the market.

The PPB has not provided guidelines for the handling of NQCL reports when a drug has failed its quality testing, i.e. guidelines for withdrawal from the market, recall, and reprimand of the manufacturer of a pharmaceutical product that fails to comply with specifications, or is found to be counterfeit. Usually, such drugs are already circulating in the market and the public is already exposed to them. There is, therefore, a need for

[39] A person deployed can be transferred without notice by the parent Ministry. If seconded, the terms are clearly stated and the staff member is fully available to the new agency until a written notification of recall.

[40] Other WHO pre-qualified Laboratories in Africa: Adcock, South Africa – January 2008; National QCL, Morocco – July 2008; CENQAM, South Africa – June 2005; RIIP, South Africa – July 2005 and LNCPP, Algeria—2005.

[41] Market surveillance by Prof Kokwaro on antimalarials 2002; WHO/PPB/DOMC study on antimalarials.

[42] According to the WHO definition, a counterfeit pharmaceutical product is a pharmaceutical product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging. The WHO technical committee acknowledges the controversy over the use of the terms counterfeit and substandard product.

[43] Definition of Substandard medicine: Substandard medicines are genuine medicines produced by legitimate manufacturers that do not meet the quality specifications claimed by the producer. For example, they may contain less (or more) active ingredient than stated on the package. This is not necessarily a deliberate intention to cheat but may be due to problems with the manufacturing process.

regulation for the immediate removal from the market of any substandard and/or counterfeit medicines, once NQCL results certify such drugs to be defective. A link, whether electronic or otherwise, must be established for authorization of a withdrawal or recall of medicines, in accordance with the procedures laid down by WHO.

A report by Health Research Action (HERA)[44] found that "local manufacturers want technical assistance from NQCL for training of their Quality Control (QC) and Quality Assurance (QA) personnel and for the procurement of secondary reference standards". Providing training services has the potential to further overload the capacity of NQCL and to promote a conflict of interest in the regulatory role. However, the sale of reference standards would be appropriate and would increase NQCL's revenue, lower costs for local manufacturing companies, and also allow the Laboratory to monitor the use of these standards in manufacturing.

NQCL aspires to be a QC accrediting laboratory for local manufacturers. However, given the potential for conflict of interest if a regulator also acts as an accreditor, such an ambition will need to be carefully considered before it is implemented. The possibility under review would be for NQCL to audit the QC laboratories to ensure compliance with minimum requirements of a quality control laboratory. The World Health Organisation has now published WHO good practices for pharmaceutical quality control laboratories.[45] Should the proposal materialise, NQCL would pre-test drugs presented for registration, and test market samples as part of post market surveillance activities. Its accreditation function would be for the QC labs in the local factories. Moreover, if NQCL were to then find a drug on the market which had been passed by a local pharma company's QC lab to be faulty, then, simultaneously, both the distribution of the drug and the accreditation of that lab would be in jeopardy

NQCL sees its role in strengthening local manufacturers as:

- Acting as a more convenient and geographically closer source of secondary reference standards that would also be cheaper than standards acquired from overseas
- Auditing QC laboratories, and inspection of facility QC labs
- Arranging symposia annually, or every two years, to provide feedback to the industry on quality performance in the market

It has also been suggested that NQCL might form part of the PPB or that PPB should build another QC laboratory. The latter option would increase operational costs with very little impact on regulatory control as it would duplicate the function of the NQCL.

4.4 Options that could benefit the local pharmaceutical industry

The challenges and constraints for the local pharmaceutical industry are diverse and fall into various categories.

[44] Report on Access To Essential Medicines, June 2005 (Health Research Action and PWC).

[45] Forty-fourth report of the WHO Expert Committee on specifications for pharmaceutical preparations. (WHO technical report series; no. 957) released 2010.

Policy

Although the Kenya National Drug Policy (KNDP) 1994 was clear in its support of local manufacturing, it did not put forward a clear plan of action. Industry growth has been largely through private initiative and there is no defined strategy to support the industry (the attainment of PIC/S status by Cosmos, Regal and Universal happened largely as a result of their own initiative, under the auspices of the Public Private Partnership (PPP) project sponsored by GTZ between 2005 and 2008).

The Pharmacy and Poisons Act 1956 has not been amended to expand the provision on manufacturing and it does not include several aspects recommended by WHO on the basic requirements of a pharmaceutical regulatory system. The law remains a stumbling block to local production since it is archaic and does not incorporate current international practices and requirements.

A strategy to strengthen the domestic pharma industry should include:

- Ensuring that the PPB is autonomous, like other government regulatory authorities[46]
- Stronger support, and specific measures, in the KNPP for the local pharma industry
- Revision of the anti-Counterfeit Bill to make a clear distinction between counterfeits, substandard drugs, and generics
- Revision of the Pharmacy and Poisons Act 1956
- Review and harmonization of the industrialization policy with the KNPP
- Creating awareness of the importance of the pharmaceutical sector to economic growth and the supply of quality essential medicines

Regulation

As discussed in earlier sections, the most important development with the potential to improve local production is a reform of the PPB and ensuring improved coordination between PPB and NQCL.

Specifically:

1. *Post market surveillance needs to be significantly enhanced to control substandard drugs on the market and to level the playing field between imports and locally-manufactured products.*

   This should include:

   - Tightening of drug classifications used for registration and the closing of existing loopholes
   - Formulation of an overall strategy for pharmacovigilance
   - Stepping up pharmacovigilance activities, education of health workers, and public education on substandard drugs and the rational use of medicines

[46] Examples: Kenya Revenue Authority; Kenya Airports Authority etc.

- Wider diffusion of market intelligence and information on the health hazards posed by substandard drugs to all stakeholder groups
- Enhancing the capacity of NQCL to test product samples and to provide results on time
- Benchmarking and monitoring the performance of NQCL and boosting the capacity of the Pharmaceutical Inspectorate through adequate systems, infrastructure, and personnel to control substandard drugs at all levels of the distribution chain
- Improving recruitment and training of qualified GDP inspectors
- Formalizing guidelines for GDP inspections, investigations of faulty drug reports, and reporting of field investigations

2. Information flow and coordination—internally between PPB departments and between PPB and NQCL—should be improved

- Registration information should be up-to-date and readily available to all PPB departments and to field inspectors
- Reports of faulty drugs, pharmacovigilance alerts, NQCL testing status and results, and progress of GDP investigations and field actions should be openly trackable (preferably online)
- Trade data should be up-to-date and widely accessible to all interested stakeholders
- Working protocols should be established between the departments of PPB, and between PPB and NQCL
- The respective roles and functions of PPB and NQCL should be clarified, and understood

3. Equivalent GMP standards should be enforced for all Kenyan pharma firms and foreign suppliers

- GMP inspectors should be given special training on inspections and industrial practices in the pharma sector
- GMP inspections should be carried out on all foreign suppliers to the Kenya market
- Standards conforming to minimum international GMP requirements should be formulated and enforced domestically. Following an appropriate period of time (to be determined) to enable local companies to implement these standards, such requirements would be obligatory and would be a prerequisite for certification by the regulatory authority
- Guidelines should be formulated for the setting up of a pharmaceutical manufacturing facility and for assessing the suitability of plants for licence renewal
- GMP Inspectors should be given awareness-building training in matters of ethics, conduct, law, investigation methods, and procedures

4. *A system of checks and balances should be introduced in PPB operations*

This should include:

- Empowering law enforcement and, under the new pharmacy law, setting up a tribunal within the regulatory agency so that malpractices are understood in the context of breach of pharmacy practice and are sanctioned in a timely manner
- Reducing corruption at all levels and deploying zero tolerance measures
- Instituting independent panels and committees of experts to review PPB decisions/actions

Other challenges

Other problems could be solved by the sharing of responsibilities and funding. These are matters of collective responsibility for the industry in which pooling of resources would be beneficial both for the public and private sectors. In this case, public/private schemes would be ideal and should include:

- An establishment for the handling and disposal of pharmaceutical waste

  The pharma sector is at risk of breach of clean environment, and investment in a clean environment project is urgently needed. Such a project could be expanded at a later stage to include other medical waste from private clinics and hospitals

- A central QC laboratory on a joint venture basis to be used by new start up manufacturers for training orientation, as well as to provide services on a batch-to-batch basis. This could also serve as a reference laboratory for already established manufacturers

5. THE INSTITUTIONAL ENVIRONMENT

5.1 Pharmaceutical research bodies

Kenya Medical Research Institute (KEMRI)

The Kenya Medical Research Institute (KEMRI), which was established under an Act of Parliament (Science & Technology (Rev) 1979), is one of the leading health research institutes in Africa. Its mission is "to improve on the quality of health and human life through research". The Centre for Clinical Research (CCR) at KEMRI undertakes clinical studies. There is also a 40-bed research hospital with two outpatient clinics attached. KEMRI also runs the Centre for Traditional Medicines Drugs Research (CTMDR), which carries out research on traditional medicines, especially herbs.

School of Pharmacy (SOP), University of Nairobi (UON)

The School of Pharmacy (SOP) at the University of Nairobi (UON), apart from training undergraduates, hosts the Drug Analysis Research Unit (DARU) and the Pharmacy Practice Centre (PPC). DARU undertakes research work in quality analysis as well as postgraduate training of pharmaceutical analysts, whilst the PPC offers practical training to students in running a pharmacy outlet.

The SOP offers training and consultancy in Drug Analysis (at DARU), Pharmacology (including Pharmacogenetics), Pharmacokinetics, Drug Formulation, Herbal Medicine, and Phytochemistry. It also performs clinical trials, in collaboration with KEMRI, and a concept paper has been prepared on the establishment of a Bio-equivalent Studies Laboratory, also in collaboration with KEMRI. This project needs support in the form of resource mobilisation, partnerships and a strategic plan for implementation.

Kenyatta National Hospital (KNH)

Kenyatta National Hospital is the national teaching and referral hospital and both the School of Pharmacy and School of Medicine are located within its premises. KNH has many scholars carrying out research but their activities could be better coordinated to capture findings on the quality of medicines circulating on the market. Some of the research could focus on the quality of generic medicines and, if disseminated, might assist the local pharma sector to improve the quality of its products. This type of research would also be useful in promoting greater innovation.

African Centre for Clinical Trials (ACCT)

A private research institution, the African Centre for Clinical Trials carries out clinical trials and bio-equivalence studies.

5.2 Business Membership and Sector Governance Organizations

There are several organizations active in the pharma sector. The main ones are:

- *Federation of Kenya Pharmaceutical Manufacturers (FKPM)*: a voluntary corporate membership organization that addresses policy, taxation issues, and other regulatory concerns
- *Kenya Association of Pharmaceutical Industry (KAPI)*: membership is also voluntary. It is mainly a grouping of research-based pharmaceutical companies, most of them multinationals based in Kenya
- *Kenya Association of Manufacturers (KAM)*: voluntary membership for all manufacturing industries. It is a strong lobbying body that influences policy change and engages at all government levels. It provides the services of a Secretariat and coordinates the pharmaceutical sector group meetings
- *Kenya Private Sector Alliance (KEPSA)*: this is a strong lobby group that engages the government at round table meetings, especially the quarterly Prime Minister's Round Table. KEPSA's membership consists of industry organizations and professional bodies
- *Kenya Health Federation (KHF)*: a recent body formed after the establishment of KEPSA, specifically focusing on health-related concerns and participating in Ministerial Sector Task Force Meetings as the technical arm of KEPSA. Its membership is industry organizations, professional bodies and corporate organizations
- *PPP-Health Kenya*: membership is MOMS; MOPHS; Ministry of Planning; and NGOs (including faith-based NGOs)
- *The Pharmaceutical Society of Kenya (PSK)*: a professional body with voluntary membership for pharmacists. It has an office and operational secretariat

Several organizations, and especially KHF, feel strongly that FKPM's mandate should be reviewed with a view to strengthening the institution. The establishment of a permanent secretariat in a reformed FKPM is important. There is new thinking in certain quarters of the pharma sector (KAPI) about forming a Kenya Generic Manufacturers' Association, whose membership would be based on corporations that meet certain GMP criteria and would allow joint inspection of premises as a condition of membership.

5.3 Drug procurement and distribution

KEMSA: Procurement for the public health system

The Kenya Medical Supplies Agency (KEMSA) is established by law as the primary public procurement agency for medicines, medical supplies, and medical devices and equipment. It is funded by direct allocation in the national budget and by development partners. The procurement process starts with the receipt by KEMSA of procurement requests from the relevant department in the Ministry of Health. It then prepares a procurement plan, with descriptions, specifications, and quantity of items required by the public institutions. KEMSA's mode of purchase is through open tender or quotations for urgent supplies. For regular procurement, a decision is made by the user department and

the funding agency on the mode of tendering, i.e. whether it should be local open tender or international open tender. Interested companies domiciled in Kenya are eligible for local tendering.

The next step is the publication of tender notices. These describe the required items and quantities; the procedures to be followed for bidding, receipt of samples, and technical evaluation; and the conditions of award. The tender notice also provides an opportunity for bidders to seek clarifications and offers the possibility of amendments before the tender deadline. There are technical specifications for tender qualification: pharmaceutical manufacturers need certification by the national authority with regard to conformance to the WHO certification scheme and GMP. All products must be currently registered with the Pharmacy and Poisons Board. Evidence is required for bio-availability and/or bio-equivalence for certain critical items, upon request. There are several other requirements with regard to packaging, labeling, etc.

At the close of the tender period, KEMSA carries out commercial and technical evaluation of the bids. Before an award is made, it appoints a technical evaluation committee to assess the bids' compliance with product specifications and other GMP/certification requirements. The assessments are submitted to a tender committee which awards the contract on the basis of lowest price amongst the bids of acceptable quality.

Supplies are delivered to KEMSA warehouses where they are again evaluated on receipt and before storage. KEMSA, in conjunction with the user department, prepares a distribution list. Distribution is made mainly to public health institutions and KEMSA outsources transport for deliveries to the health facilities.

The pattern of procurement at KEMSA has recently been changed following the emergence of various problems in the process in recent years. In the past, KEMSA had, in some years, procured above budget. This resulted in unpaid bills from one year having to be carried over and settled out of the following year's budget allocation. This procedure then created budgetary shortfalls in the succeeding year. Moreover, money allocated by Treasury for purchase of pharmaceuticals but not spent in a budgetary year automatically reverts back to the Treasury on 30 June each year. To avoid this situation, transfers were made to KEMSA's account from the Ministry of Health before financial year-end so that it would appear that the funds had already been spent. In order to resolve this anomaly, both KEMSA and the Task Force report recommend the establishment of a special fund as already provided for in the Act establishing KEMSA. In an attempt to resolve this problem, tenders covering a two year period—instead of just one—are now advertised. There is also provision to procure only a portion of the total quantity specified in the tender, according to the needs, priority and available funds.

A joint survey funded by USAID, the Millennium Challenge consortium, and Management Sciences for Health was carried out in 2007/8 to compare KEMSA's procurement prices with those of the Mission for Essential Drugs and Supplies, Kenyatta National Hospital, and local manufacturers and distributors. One of the purposes was to determine whether KEMSA and the Ministry of Medical Services were getting value for money in public procurement. The conclusion was that, for the most part, KEMSA prices are more competitive than for similar products purchased by health facilities from all the other entities surveyed, and that KEMSA was indeed achieving value for public-funded procurement of medical commodities (as shown in table 22 below).

Table 22. Procurement price comparisons among public institutions

Indicator items	*KEMSA price ratio*	*MEDS price ratio*	*KNH Price Ratio*
Amox Cap 250mg	1.00	1.01	1.51
Amoxicillin Syr	1.00	0.89	0.96
Paracetamol Tab 500mg	1.00	1.14	1.03
Cotrimox. Tab 480mg	1.00	1.05	0.99

Source: Report on 2007/8 Medicines & Medical Supplies Price Survey in Public Health Sector.

As mentioned in Section 4.2, there is already legislation (the Kenya Public Procurement and Disposal Act 2005)[47] which allows a "margin of preference of 15 per cent" in public procurement for goods manufactured in Kenya. Nonetheless, this provision is not currently being applied. In an interview with KEMSA, the Acting Chief Executive Officer stated that the reason for the non-implementation of this provision in KEMSA tenders was the lack of guidelines from the Finance Ministry. Exact figures on the proportion of KEMSA procurement that is supplied by local pharma manufacturers are not available since KEMSA does not disaggregate its spending to reflect purchases from local producers separately.

Table 23 shows the components of KEMSA's Essential Medicines Supply budget of 2007/2008. The total value of this budget was KSh 2,653,733,047 (US$ 35.4 million) and it represents the purchase of essential medicines, excluding anti-malarials, ARVs and anti-TBs, which are supplied through donor funds. Of this total, 55.47 per cent was for Rural Health Kits (RHK). In tendering for the supply of RHKs via KEMSA, it is a requirement that the bidder should be a manufacturer of about 50 per cent of the products in the Kit.

Locally registered companies largely supply the Rural Health Facility (RHF) requirements and, in 2007/2008, 10 out of 14 suppliers of RHKs[48] were locally incorporated, although this figure includes local importers. KEMSA does not distinguish between local pharma producers and local distributors of imported products in its information gathering and reporting.

Table 23. Government allocation for essential medicines 2007/08

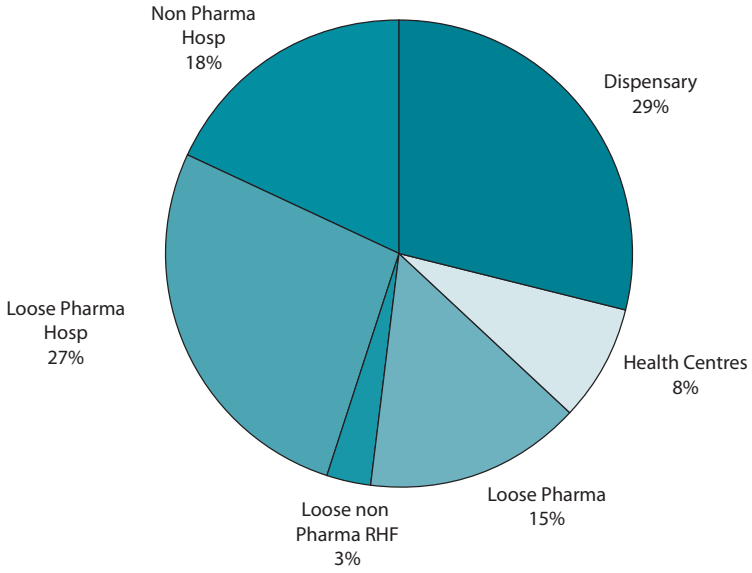
	KSh	*per cent*
Grand Total	2,653,733,047	100.00
Total Rural Health Kits	1,472,008,219	55.47
Dispensary	777,003,995	29.28
Health Centre	224,962,697	8.48

[47]The Public Procurement and Disposal Regulations 2006: Section 28 (2) The margin of preference (a) for the purposes of section 39 (8) (b) (i) of the Act, shall be 15 per cent of the evaluated price of the tender.

[48]A Rural Health Facility Kit contains a number of medicines and non-pharmaceutical items as single units of supply.

	KSh	per cent
Loose Pharma RHF	384,968,440	14.51
Loose non Pharma RHF	85,073,087	3.21
Total Hospital	**1,181,724,828**	**44.53**
Loose Pharma Hosp	711,336,432	26.81
Non Pharma Hosp	470,388,396	17.73

Source: UNIDO Survey.



To support government spending, donors/development partners provide around 31 per cent of the funds needed by the public health system [49]. Since local pharma plants do not meet WHO pre-qualification standards and this is a donor requirement, these manufacturers are locked out of most donor-funded procurement in KEMSA's open international tenders. It is ironic that during stock-outs and emergencies, companies like Cosmos have supplied urgently needed ARVs, for which local companies could not bid during the normal procurement process. KEMSA provides no incentives to procure pandemic drugs from local pharma which would ensure sustainable sources of supply. Consequently, local suppliers have little opportunity to supply the public sector other than in the case of emergency supplies.

Distribution System

The drug distribution system in Kenya can be classified into public (government), NGO, and private channels. The private sector is served by distributors (distributing both imports and locally-manufactured goods) and directly by local manufacturers.

[49] From National Health Accounts study, HMIS 2008.

In a workshop on Private-Public Partnership in April 2009,[50] some observations were outlined as core problems in the Kenyan health product supply chain. The key points raised by participants included:

- Need to strengthen regulations governing supply. This includes exploring mechanisms to reduce the number of counterfeit drugs in the health supply, enforcing prescription guidelines, etc.
- Need to consolidate and rationalise the pharmaceutical market and supply chain
- Need to place greater importance on the role of pharmacists and other players in the pharmaceutical sector. Some participants greatly extolled private pharmacists' involvement in improving health in Kenya and stressed the need to better recognize their contribution
- Need for greater clarity in defining the roles of pharmacists and pharmacist technicians with regard to the extent and limits of their competence
- Need to continue with reforms of KEMSA that would allow a greater public-private mix and enhance performance

Wholesalers-Retailers/Pharmacies

The procurement of medicines in the private sector is not centralized. There are many distributors and wholesalers registered by the Pharmacy and Poisons Board and some of them are retailers as well. A large number of unregistered outlets, currently estimated between 3,000 and 4,000, also exists and these source their wares by various means, including registered wholesalers and other retailers.

Distributors purchase medicines based on customer needs, which are established through marketing activities focused on prescribers, pharmacies and, sometimes, promotional activities in conferences and public media. The various categories of medicines are marketed in different ways:

- Original prescription brands: these are sold mainly through prescriptions originating from medical practitioners although patients regularly request renewal of their prescriptions directly at their pharmacies to save costs on consultation
- Branded generics: these are also sold like original brands. The wholesalers/distributors maintain stocks, and prices and promotional activities are factors that influence stocking strategy. Deliveries from the manufacturer/distributor to the outlet are by courier or by company vans. Smaller outlets buy and carry medicines as parcels. Transport costs are met by the buyer
- Unbranded Generics: these are mainly low-cost and are usually available in rural settings

All medicines in the distribution chain must be registered by the PPB and should meet quality requirements. Each manufacturer is responsible for the quality of its medicines in the distribution chain. The manufacturers, together with the distributors, are responsible for the mode of distribution, pricing, and promotion. In many cases, they employ medical representatives who provide detailed information on the products to prescribers, medical institutions, pharmacies and other medical workers. Pharmacists and more experienced medical representatives also provide continuing education seminars. Most upmarket

[50] Public Private Partnership Workshop, Naivasha April 2009.

hospitals prefer to receive product information through such seminars, whereas others prefer to get information in one-on-one sessions with medical representatives.

Drug Pricing

The pricing structure norm for medicines is built on tradition and is supposed to allow for a 10 per cent mark-up for the drug manufacturer over production cost; a 15 per cent margin for the distributor/wholesaler over the manufacturer's or importer's price; and a 33 per cent margin for the retailer above the wholesale price. However, due to competitive pressures, these norms are breaking down. It is difficult to discern the true manufacturer mark-up without accurate knowledge of production costs, and wholesalers/retailers do not adhere strictly to the pricing principle either. Discounting from the usual pricing norms is common. Since the Kenyan market for medicines is open and price sensitive, some manufacturers/importers opt for different schemes of price discounting. For example, "buy 10 items and get one free (10 + 1)" or "buy six and get one free (6 + 1)" are schemes offering effective discounts of 10 per cent to 16 per cent. In some cases, items are discounted by over 30 per cent at the retail outlet.

Since pharma products are dated, stocks may expire if they do not move. Consequently, some distributors/wholesalers discount to increase the purchase volume at particular times. Where a product has a shorter shelf life, the discount may even be larger to avoid the expiry of products on the shelf because the conditions of sale usually stipulate no compensation for expired or near-expiry medicines. The retail outlet, on its own, may also sell some products at cost in order to attract and retain customers.

All this means that prices vary considerably. The prices of original brands tend to be very high, especially before patents expire. However, prices drop once generics are introduced on the market although the price of the original brand still remains higher than the generic. The prices of branded generics are usually a fraction of the original brand price.

Quite often, the price is not related to the cost of production. There is a general perception in the market that, if a product price is low, the quality of such a product is doubtful. On the other hand, manufacturers report that some of their products are sold below production cost without compromising on quality although there are currently no data to support this supposition. A case in point is the pricing of Paracetamol. Some prices on generic Paracetamol are very low compared with original brands, and appear to barely cover the cost of the API amounts supposedly included (1,000 tablets at KSh150, compared with 20 tablets of original brand at KSh 92.00, or 100 tablets of original brand at KSh 312.00). Some local manufacturers, like Cosmos, sell 100 Paracetamol tablets in blister packs at KSh 105.00. Others claim that having such a low price on the product list is a sales draw for other products.

5.4 Options that could benefit the local pharmaceutical industry

1. Local industry could lobby for preferences in public procurement, as provided for in the law. The government, through KEMSA, is the single largest buyer of drugs in the country. Were the "margin of preference" to be implemented for local manufacturers, this would provide an immediate boost to local companies with regard to non-donor-funded public procurement. Local industry could lobby aggressively for the formulation of the required guidelines and rapid enforcement of this law.

2. *The pharma industry needs a "strong voice"*. Many of the possible options for the pharma sector in Kenya to meet existing challenges should be tackled jointly by local companies with a sector-wide approach. A prerequisite for this is that the industry should be able to speak with a single, strong voice, and to be an effective lobby with the regulatory authorities and in political circles. That voice is lacking today, since the trade body for the local producers, the Federation of Kenya Pharmaceutical Manufacturers, is weak and disorganized and lacks effective leadership. In view of this, producers need to be more pro-active in promoting increased dialogue among themselves to arrive at joint positions for which they can then lobby.

Activities which the FKPM could consider include:

- Focused position papers with data analysis
- Training programmes at managerial, supervisory and operational level
- GMP standard as a criterion for membership

the introduction of joint supplier audits; since such an exercise would be too expensive for individual firms, the reports on the joint exercise could be shared, based on an agreed audit procedure between manufacturers and/or PPB.

6. STRENGTHENING LOCAL PHARMACEUTICAL PRODUCTION: RECOMMENDATIONS FOR ACTION

The economic and public health benefits of local production of essential medicines have already been discussed in section 1.7. In subsequent sections of this report, the pharma sector has been analysed from various perspectives—from a focus on local manufacturing, the business environment, and the institutional environment, respectively. In each case, particular options or areas for action have been identified which would help to enhance local production. These are outlined in sections 3.8, 4.4, and 5.4.

This report does not aim to present an exhaustive list of issues facing the local pharma industry. Rather, it aims to point out the complexity of the pharma market and the inter-relationship of the multiple variables in the business and regulatory environments which create the paramount need for a coordinated approach to achieving enhanced capabilities for local pharma. Progress through ad hoc actions focusing on one or more aspects of the market or production is likely to be difficult. What is required is a holistic strategy for the sector.

Based on a review of possible steps towards improvement derived from the analyses in earlier sections, the following is a set of recommended interventions at the regulatory level, at the sector/enterprise level, and at the policy level.

6.1 Regulatory level

6.1.1 The Pharmacy and Poisons Board (PPB)

- Strengthen post market surveillance in order to control substandard and counterfeit drugs in the Kenyan market by:

  Enhancing pharmacovigilance

  Strengthening the capacity of the Pharmaceutical Inspectorate with adequate systems, infrastructure, and human resources

  Instituting guidelines and protocols, and proper information access/sharing for the Departments of Pharmacovigilance, Pharmaceutical Inspectorate, and Drug Registration to work together effectively

- Design and instal an Information Technology (IT) system to capture and allow easy retrieval by appropriate personnel (including field inspectors) of data on:

  Updated drug registrations

  Reports of substandard drugs in the distribution chain

  Pharmacovigilance alerts

  Tracking of decisions/actions on substandard drug complaints/withdrawals

  The source/quantity/price of all imports and exports

- Establish minimum international GMP standards as the target for the Kenyan pharma industry and a holistic plan to achieve this in order to:

  Improve the skills and exposure of GMP inspectors to industrial manufacturing pharmacy

  Train GMP Inspectors in matters of ethics, conduct, law, and investigation procedures

  Establish GMP inspections procedures, including reporting and follow-up

  Tighten GMP enforcement to ensure it is consistent with WHO inspection guidelines and ensure regular follow-up and remedial measures

  Develop minimum requirements for new plant registration with regard to suitability of premises according to type of formulation produced in order to enhance quality assurance aspects

6.1.2 The National Quality Control Laboratory (NQCL)

- Build capacity (i.e. increase equipment and human resources and provide training) for NQCL to adequately support PPB in testing drugs at Ports of Entry and on request from PPB Departments
- Benchmark response times on test results and institute performance criteria for NQCL functions
- Create a mechanism for monitoring and review of NQCL performance against set criteria

6.1.3 PPB/NQCL

- Develop joint procedures/linkages for efficient testing of suspect drugs to ensure fast withdrawal of non-compliant products from the market
- Set up a forum for top management of both institutions to regularly coordinate joint activities and to iron out problems

6.2 Sector/enterprise level

- Build capacity for the pharma trade association, the Federation of Kenya Pharmaceutical Manufacturers (FKPM), by:

  Reforming the governance structure of the FKPM and making membership more attractive to all Kenyan pharma manufacturers

  Refining the positions and priorities of the Federation so that it establishes itself as an effective lobby and "voice" for the industry

- Train personnel of pharma companies in industrial pharmacy practices and take up training opportunities through the UNIDO South-South Cooperation Centre
- Improve efficiency in plant operations in order to reduce production costs
- Establish linkages for technology and know-how transfer at local, regional and international level

6.3 Policy level

- Implement existing regulation on 15 per cent margin of preference for local manufacturers in public procurement of medicines
- Establish a package of incentives (in terms of taxes, duties) to encourage development of the Kenyan pharma industry
- Review measures to improve possibilities for local firms to raise finance for upgrades and/or encourage foreign investment into the sector
- Fast track harmonization of regulation within the EAC/COMESA, especially the recommendations on strengthening the PPB
- Modify the existing legal framework so that the PPB can become autonomous

6.4 Other actions

- Set up an industrial training curriculum at schools of pharmacy in Kenya
- Establish an independent Kenya Bioequivalence Study Centre of international standard with the School of Pharmacy and KEMRI, preferably as a Private Public Partnership and in collaboration with development partners
- Establish a waste management project for proper handling and disposal of pharmaceutical waste
- Lobby for linkages with donor-supported programmes associated with procurement of essential medicines in order to encourage prompt and good quality local supply

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