

KENYA'S PHARMACEUTICAL INDUSTRY 2005



KENYA

EXPORT PROCESSING ZONES AUTHORITY



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TABLE OF CONTENTS

1	INDUSTRY OVERVIEW.....	1
1.1	INTRODUCTION	1
1.2	NATIONAL POLICIES ON HEALTHCARE AND PHARMACEUTICALS	2
1.3	TRADITIONAL / HERBAL MEDICINES	3
2	INDUSTRY STRUCTURE.....	4
2.1	MANUFACTURERS.....	4
2.2	DISTRIBUTORS	5
2.3	RETAILERS.....	5
2.4	HEALTH INSTITUTIONS.....	5
2.5	MEDICAL PERSONNEL.....	6
3	PRODUCTION OF PHARMACEUTICAL PRODUCTS	7
4	MARKET CONDITIONS.....	8
4.1	EXPORTS.....	9
4.2	IMPORTS	9
5	MEDICAL RESEARCH & DEVELOPMENT	10
6	LEGAL & REGULATORY FRAMEWORK.....	10
6.1	MOH / PHARMACY AND POISONS BOARD ROLE AND OBJECTIVES....	11
6.2	PHARMACEUTICAL SOCIETY OF KENYA ROLE AND OBJECTIVES.....	11
6.3	KENYA MEDICAL ASSOCIATION ROLE AND OBJECTIVES	11
6.4	KEMSA ROLE AND OBJECTIVES	12
6.5	KENYA BUREAU OF STANDARDS ROLE AND OBJECTIVES	12
6.6	NHIF ROLE AND OBJECTIVES.....	13
7	REASONS TO INVEST IN KENYA’S HEALTH AND PHARMACEUTICAL INDUSTRY	13
8	INVESTMENT OPPORTUNITIES	14
9	KEY PLAYERS IN THE INDUSTRY	15
9.1	COMPANIES	15
9.2	INSTITUTIONS AND COLLABORATING AGENCIES.....	15
10	USEFUL CONTACTS	15
11	SOURCES OF INFORMATION AND GLOSSARY	16



List of Tables

	Page	
Table 1:	List of company and locations	4
Table 2:	Health Institutions – Kenya, 2002-2003	6
Table 3:	Number of registered medical personnel in Kenya, 2002-2003	6
Table 4:	Approximate market shares for pharmaceutical Products by therapeutic category in Kenya	7

List of Charts

Chart 1:	Value of principal exports, 1999 – 2003 (Kshs million)	9
Chart 2:	Quantity of imports & exports of medicinal and Pharmaceutical products (Tonnes)	10

List of Abbreviations

▪ KEBS	Kenya Bureau of Standards
▪ KShs	Kenya Shillings
▪ MOH	Ministry of Health
▪ WHO	World Health Organisation
▪ MOTI	Ministry of Trade & Industry
▪ IPC	Investment Promotion Centre
▪ CBS	Central Bureau of Statistics
▪ ITS	International Trade Statistic
▪ KEMSA	Kenya Medical Supplies Agency

Annual Average Exchange Rates (KShs to US\$)

Year	Rate
1998	60.4
1999	70.3
2000	76.2
2001	78.6
2002	78.4
2003	75.9
2004	80.0 (As at 31st August 2004)

For latest rates click on <http://www.centralbank.go.ke/cbk/FXrates/archives.html>



1 Industry Overview

1.1 Introduction

Kenya spends about 8% of its GDP on health. Per capita expenditure per person stood at about US\$ 11 per person in 2003. Out of this, US\$ 6 came from budgetary resources, which also included donor contributions and the balance of about US \$5 came mainly from out-of-pocket expenditure. This expenditure fell far below the WHO's recommended US\$34 per capita.

Out-of-pocket expenditure thus accounted for 53% of the total cost of healthcare, with the remainder being Government contributions from general taxation (25%), Social Health Insurance (15%), private prepaid health plans (5%) and non-profit institutions expenditure at 2%. The above scenario means the current healthcare financing system depends mainly on out-of-pocket expenditure and therefore 75% privately financed.

The health system in Kenya is organized and implemented through a network of facilities organized in a pyramidal pattern. The network starts from dispensaries and health clinics/ posts at the bottom, up to the health centers, sub-district hospitals, district hospitals, provincial general hospitals and at the apex there is the Kenyatta National Hospital, and more recently the Moi Referral Hospital, Eldoret.

The Ministry of Health (MoH) is the major financier and provider of health care services in Kenya. Out of all the health facilities in the country, the MoH controls and runs about 52% while the private sector, the mission organizations and the Ministry of Local government runs the remaining 48%.

The public sector controls about 79% of the health centers, 92% of the sub-health centers, and 60% of the dispensaries. The NGO sector is dominant in health clinics, maternity and nursing homes controlling 94% of the total while also controlling 86% of the medical centers in the country.

In urban rural distribution, the health sector is faced with inequalities. 70% of urban population has access to health facilities within 4 km, as opposed to 30% of the rural population.

The health sector in Kenya is one of the sectors that has experienced remarkable development in the recent years. The country has made great efforts in controlling diseases like Malaria, TB and Cholera while actively fighting the AIDS/HIV pandemic. Similar efforts have been made in controlling communicable diseases like poliomyelitis, neonatal tetanus and measles. The targets for eradication of the guinea worm disease and elimination of lymphatic filariasis and leprosy have been attained. Other parasitic diseases of epidemiological concern such as schistosomiasis, helminthiasis and leishmaniasis are seriously being addressed.

The efforts at different levels to control diseases have seen the adoption of the Directly Observed Treatment Short-course (DOTS) as a national strategy in Kenya to contain Tuberculosis. The treatment success rate had improved to about 80% by end of 2003. During the same period, Kenya had attained a national zero-prevalence rate of 6.7% for its population affected by HIV/AIDS.

In order to control Emerging diseases and epidemics the government has put into place strategies that include the Participatory Hygiene and Sanitation Transformation (PHAST), Healthy Cities initiative, Hazard Analysis Critical Control Points (HACCP), water quality surveillance and occupational health strategies.



The Pharmaceutical sub sector

The pharmaceutical industry consists of three segments namely the manufacturers, distributors and retailers. All these play a major role in supporting the country's health sector, which is estimated to have about 4,557 health facilities countrywide.

Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the regions' market. Out of the region's estimated of 50 recognised pharmaceutical manufacturers; approximately 30 are based in Kenya.

It is approximated that about 9,000 pharmaceutical products have been registered for sale in Kenya. These are categorized according to particular levels of outlet as free-sales/OTC (Over The Counter), pharmacy technologist dispensable, or pharmacist dispensable/ prescription only.

1.2 National policies on healthcare and pharmaceuticals

1.2.1 National Health Sector Strategic Plan (NHSSP) 1999-2004

The Kenya Health Policy Framework (1994) sets out the policy agenda for the health sector up to the year 2010. To operationalize this framework paper, the National Health Sector Strategic Plan (NHSSP, 1999-2004) was developed in 1994.

The tasks specified in the plan include:

- Strengthening of the central public policy role of the Ministry of Health.
- Adoption of an explicit strategy to reduce the burden of disease.
- Definition of an essential cost effective health care package.
- Emphasis on decentralization of health care delivery through redistribution of health services to rural areas.
- Special focus on essential key priority packages based on the burden of disease and the required support systems to deliver these services to Kenyans.

Currently, medical care is a pre-requisite among employers; the law requires that every employer ensure the provision of proper medicines and attendance to employees, unless otherwise provided for by the government.

Policy on pharmaceuticals

The patent protection of pharmaceuticals in Kenya is based on the African Regional Industrial Property Organization (ARIPO) patent system. Kenya's patent laws have been revised from the traditional British based format to the ARIPO system, which was created by the Lusaka agreement in 1976.

ARIPO is based in Harare, Zimbabwe; the organisation was mainly established to pool the resources of its member countries in industrial property matters together in order to avoid duplication of financial and human resources.

Additionally, the Kenyan government passed the Kenya Industrial Property Bill in 2001. This bill allows Kenya to import and to produce more affordable medicines for HIV/AIDS and other diseases.

1.2.2 The National Social Health Insurance Fund (NSHIF)

The NSHIF is a proposed health scheme that seeks to waive charges at the district hospitals. The scheme is part of a wider policy reform programme initiated by the government to ensure all Kenyans have access to health care. It forms part of the



economic reform strategy operating under the theme: 'Ensuring Provision of Basic Health Package to All Kenyans and increasing Coverage of Quality Healthcare for the Poor.' The scheme is approximated to cost Sh5 billion, targeting about 9 million poor Kenyans.

The scheme is yet to be implemented, and is under review following implementation procedure and funding concerns raised by several groups that included among others, the National Nurses Association of Kenya (NNAK), the Kenya Medical Association (KMA), the Kenya National Union of Teachers (KNUT), the Central Organisation of Trade Unions (COTU) and the Federation of Kenya Employers (FKE), among others.

1.2.3 National Hospital Insurance Fund (NHIF)

The NHIF is Kenya's single largest financier of health services apart from the Government. It was established by an act of parliament in 1966 as a department of the MOH. In 1972, the NHIF Act was amended to incorporate voluntary membership. In 1990, the Act was repealed to allow contribution on a graduated scale of income. In 1998, the old Act was repealed and in its place is NHIF Act of 1998, which also transformed NHIF into a state corporation, delinking it from the Ministry of Health, thus ceasing to be a government department.

The fund facilitates members' access to quality health services. It works closely with public and private health care facilities countywide and professional medical associations. Currently, about 400 hospitals and health providers that offer generalized, specialised and emergency healthcare services are accredited by the Fund. The NHIF Act gives the fund power to declare/accredit hospitals where contributors can seek services.

NHIF membership is open to Kenyan residents aged 18 years and above from either the formal or the informal sectors. The formal sector membership is drawn from the government and NGOs, corporate firms etc. Members are required to pay a monthly premium of KShs 30 – KShs 320 depending on one's basic salary.

1.2.4 Health Management Organizations (HMOs)

Health Management Organizations (HMOs) are health insurance agencies that provide health facilities and services to registered members at a fee. Kenya is estimated to have about 10 large and medium sized HMOs, who between them support about 200,000 medically covered persons.

For registration, the capitalisation requirements of HMOs are Kshs 25 million for organisations that conduct total business below Kshs 250 million annually. HMOs whose annual business is over Kshs250 million need to top up their capital base at a ratio of Kshs 1 million for every Kshs 10 million of business, maintaining capitalisation at 10 per cent of collected premiums.

1.3 Traditional / herbal medicines

Traditional medicine (TM) refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.

In Africa, up to 80% of the population use traditional medicine for primary health care. In industrialized countries, adaptations of traditional medicine are termed "Complementary" or "Alternative" Medicine (CAM).



The World Health Organization (WHO) launched its first ever-comprehensive traditional medicine strategy in 2002. The strategy is designed to assist countries to:

- Develop national policies on the evaluation and regulation of TM/CAM practices
- Create a stronger evidence base on the safety, efficacy and quality of the TM/CAM products and practices
- Ensure availability and affordability of TM/CAM including essential herbal medicines
- Promote therapeutically sound use of TM/CAM by providers and consumers
- Document traditional medicines and remedies

WHO estimates the global market for herbal medicines to currently stand at over US \$ 60 billion annually and is growing steadily.

The roles of traditional and herbal forms of healthcare are important and cannot be underestimated in Kenya's healthcare system. The government is looking at ways to bring some practices used in traditional medicine into mainstream healthcare. Already, the government offers licenses to healers from China and India to open traditional health-care practices.

2 Industry structure

The pharmaceutical industry in Kenya consists of manufacturers, distributors and retailers, who all actively support the Ministry of Health and other key players in developing the health sector.

2.1 Manufacturers

The pharmaceutical sector consists of about 30 licensed concerns include local manufacturing companies and large Multi National Corporations (MNCs), subsidiaries or joint ventures. Most are located within Nairobi and its environs. These firms collectively employ over 2,000 people, about 65% of who work in direct production.

The industry compounds and packages medicines, repacking formulated drugs and processing bulk drugs into doses using predominantly imported active ingredients and excipients. The bulk of locally manufactured preparations are non-sterile, over-the-counter (OTC) products.

The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continue to expand, driven by the Government's efforts to promote local and foreign investment in the sector. Table 1 below lists some of the leading pharmaceutical manufacturing companies in Kenya.

Table 1: List of Companies and locations

Company Name	Location
Alpha Medical Manufacturers	Nairobi
Aventis Pasteur SA East Africa	Nairobi
Bayer East Africa Limited	Nairobi
Beta Healthcare (Shelys Pharmaceuticals)	Nairobi
Cosmos Limited	Nairobi
Dawa Pharmaceuticals Limited	Nairobi
Didy Pharmaceutical	Nairobi
Diversey Lever	Nairobi
Eli-Lilly (Suisse) SA	Nairobi
Elys Chemical Industries Ltd	Nairobi



Company Name	Location
Glaxo SmithKline	Nairobi
High Chem East Africa Ltd	Nairobi
Ivee Aqua EPZ Limited	Athi River
Mac's Pharmaceutical Ltd	Nairobi
Manhar Brothers (Kenya) Ltd	Nairobi
Novartis Rhone Poulenc Ltd	Nairobi
Novelty Manufacturers Ltd	Nairobi
Pfizer Corp (Agency)	Nairobi
Pharmaceutical Manufacturing Co (K) Ltd	Nairobi
Pharmaceutical Products Limited	Nairobi
Phillips Pharmaceuticals Limited	Nairobi
Regal Pharmaceutical Ltd	Nairobi
Universal Pharmaceutical Limited	Nairobi

Source: Kenya Factbook 16th Edition, 2001 & The Kenya Telephone Directory 2004.

2.2 Distributors

The Kenya Medical Suppliers Agency (KEMSA), a division of the Ministry of Health, largely carries out the distribution of pharmaceutical products in Kenya. It distributes drugs to government public health facilities and private health facilities.

KEMSA has been an autonomous body since 1st July 2003. Its policy is to make available essential drugs and equipment primarily but not exclusively, to public facilities. KEMSA competes with other suppliers, e.g. the mission based medical supply facility (MEDS) and private wholesalers.

2.3 Retailers

Pharmaceutical products in Kenya are channelled through pharmacies, chemists, health facilities and shops. There are about 700 registered wholesale and 1,300 retail dealers in Kenya, manned by registered pharmacists and pharmaceutical technologists.

The drugs on sale in Kenya are sold according to the outlet categorization, which can be described as free-sales/OTC, pharmacy technologist dispensable, or pharmacist dispensable/prescription only.

2.4 Health institutions

The country continues to have remarkable expansion in the number of health facilities in all provinces. This is in line with the government's effort to avail accessible health facilities and services to all Kenyans.

The number of health institutions grew from 4,499 in 2002 to 4,557 in 2003, a marginal increase of 1.3%. Rift valley reported the highest number of health facilities, with a total of 1,267 (27.8%), while North Eastern province, with 88 health facilities had the least number, accounting for 1.9% of the total. Table 2 below illustrates the distribution of health facilities in the country by province.



Table 2: Heath Institutions in Kenya 2002-2003

Province	Hospitals, H/Centers and H/Sub Centers & Dispensary	
	2002	2003
Nairobi	485	493
Central	517	526
Coast	435	440
Eastern	831	837
North Eastern	83	88
Nyanza	539	548
Rift Valley	1259	1267
Western	350	358
Total	4,499	4,557

Source: Economic Survey 2004 by Central Bureau of Statistics, Ministry of Planning and National Development

The World Health Organization estimates the global market for herbal medicines to currently stand at over US \$ 60 billion annually and is growing steadily.

2.5 Medical Personnel

The country continues to lay emphasis on continuous training of more medical personnel to compliment the growth in the health sector. The number of registered medical personnel rose by 2.6% from 59,049 in 2002 to 60,603 in 2003. Enrolled nurses accounted for half of the registered medical personnel. Table 3 below gives an overview of the registered medical personnel in Kenya.

Table 3: Number of registered medical personnel in Kenya, 2002-2003

Type of Personnel	2002		2003	
	Number	No per 100,000 population	Number	No per 100,000 population
Doctors	4,740	15.1	4,813	15.3
Dentists	761	2.6	772	2.7
Pharmacists	1,866	5.9	1,881	5.8
Pharmaceutical Technologists	1,399	4.3	1,405	4.3
Registered Nurses	9,753	31	9,869	33.1
Enrolled Nurses	29,094	94.6	30,212	100.2
Clinical Officers	4,778	15.2	4,808	15.7
Public Health Officers	1,174	3.3	1,216	3.6
Public Health Technicians	5,484	17.3	5,627	19.4
Total	59,049	189.3	60,603	200.1

Source: Health Management Information System, Ministry of Health, 2004



3 Production of pharmaceutical products

The products manufactured by the pharmaceutical companies in the country for both local and international markets include Antibiotics, Antimalarials, Antiamoebics, Analgesics, Antidiarrheals, Antacids, Tranquillisers, Antispasmodics, Vitamins and Antiulcers. These drugs are used in various medical areas including Anti-Infective, Gastrointestinal, Analgesic/Anti-inflammatory, Cardiovascular and Respiratory therapeutic segments

The pharmaceutical sector in Kenya is also engaged in assembling capsules, disposable syringes, paracetamol, and surgical gauze amongst others.

Development in production of pharmaceuticals has been enhanced by the decision by Glaxo SmithKline PLC (GSK) to license Cosmos Ltd, a Kenyan company to produce generic versions of two of its life-prolonging AIDS drugs Zidovudine and Larnivudine, as well as a combination of the two, for sale in Burundi, Kenya, Rwanda, Tanzania and Uganda. Kenya becomes the second African country after South Africa to start producing generic antiretroviral drugs in the continent. Production of these drugs by Cosmos Ltd. will start in the course of October 2004 although Glaxo SmithKline will also continue manufacturing Zidovudine and Larnivudine in Kenya

Table 4 below gives a breakdown of the market share approximations for the various pharmaceutical products in therapeutic categories. 40% of all the pharmaceutical products are anti-infectives, while central nervous system category has a share of 30%. Respiratory system products, gastrointestinal and metabolic organ products, and other pharmaceutical products have a share of 10% each.

Table 4: Approximate market shares for pharmaceutical products by therapeutic category in Kenya.

Therapeutic Category	Pharmaceutical products	Market Share
Anti-infectives	Antibiotics, antimalarials, sulphonamides, anti-tuberculosis preparations, antiamoebics, antivirals, antifungals, vaccines, sera and immunoglobulins,	40 %
Products acting on the central nervous system (CNS)	Analgesics and antipyretics, anti-inflammatory agents, hypnotics, sedatives and tranquilizers, anticonvulsants, CNS stimulants, muscle relaxants, antihistamines, antidepressants, anaesthetics, etc	30 %
Products acting on the respiratory system	Expectorants and cough suppressants, inhalations, bronchial spasm relaxants, respiratory stimulants, etc	10 %
Products acting on gastrointestinal and metabolic disorders	Stomatological preparations, antacids, tonics, hepatic preparations, laxatives, antidiarrheals, insulin preparations, vitamins, mineral supplements, anabolic agents for systemic use, etc -	10 %
Other pharmaceutical products	Products acting on the cardiovascular and genito-urinary systems, cytotoxins, vaccines, dermatological preparations, ophthalmic drugs, hormonal products, diagnostic and contraceptive agents, etc	10 %

Source: Industrial Sector Analysis Report , Ministry of health, 2001

Raw material availability & Locations

Kenya has minimal raw materials for pharmaceutical products and relies a lot on imported sources. The industry imports over 95% of the raw materials. The



availability of raw materials locally is limited to only about 5% of the total industrial requirements. The locally sourced raw materials include:

- Maize starch
- Refined sugar
- Glucose syrup
- Rectified spirit and ethanol
- Sodium chloride
- Packaging materials

In efforts to increase supply, the Government has embarked on specific growth measures, which include:

- Drug development from natural sources for the local industry
- Continued research by institutions like Kenya Medical Research Institute (KEMRI) and the University of Nairobi on extracts from medicinal and aromatic plants.
- Supplementing mainstream research with herbal medicine by involving local traditional health practitioners and biomedical researchers in research processes.

NGOs and AIDS/HIV work

Kenya is estimated to have around 2.3 million adults living with HIV; with about 700 people dying daily of HIV related infections. One of the key factors affecting Kenyans is the high cost of anti-retrovirals (ARVs) and other essential medicines.

In 2001, the Kenyan parliament passed the Kenya Industrial Property Bill 2001, which greatly impacted on the health sector, allowing the importation and production of more affordable medicines for HIV/AIDS and other diseases.

The bill includes most of the WHO recommended 'safeguards', which include:

- Parallel importing - the right to shop around the world for the cheapest patented drug
- Compulsory licenses - issuing licenses for the production or importation of cheaper generic medicines - the new Kenya IP Bill specifically mentions high drug prices as a ground for issuing compulsory licenses
- The 'Bolar provision' - which allows generic manufacturers to do the appropriate trials, registration process etc, to be ready to roll off the production line as soon as the patent expires.

The deadline for developing and least developed countries to amend the laws to make them WTO/TRIPS compliant is 2000 and 2006 respectively.

4 Market Conditions

The market for pharmaceutical products in Kenya is estimated at KShs 8 billion per annum. The government, through Kenya Medical Supplies Agency (KEMSA) is the largest purchaser of drugs manufactured both locally and imported, in the country. It buys about 30% of the drugs in the Kenyan market through an open-tender system and distributes them to government medical institutions.

There are about 700 registered wholesale and 1,300 retail dealers in Kenya, manned by registered pharmacists and pharmaceutical technologists. These pharmacies are accorded a 25% mark-up on retail drugs.

Anti-infective products (chiefly antibiotics, antimalarials, sulfonamides), analgesics, antipyretics, bronchial relaxants and cytotoxins account for the bulk of government and private sector purchases of medicines in the Country.



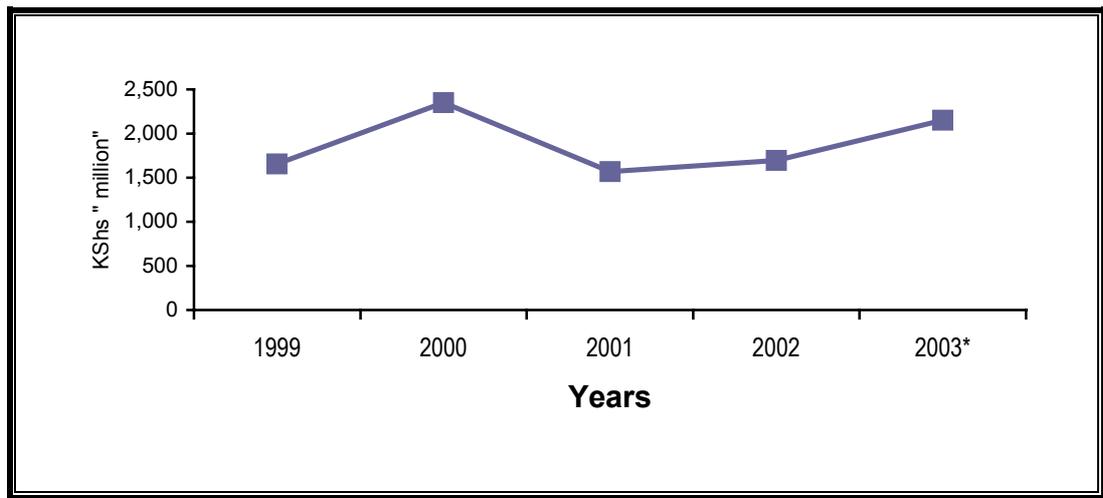
4.1 Exports

Kenya enjoys preferential access to the regional market under a number of special access and duty reduction programmes related to the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA) among others.

The country exports its medicinal and pharmaceutical products to Tanzania, Uganda, DRC, Rwanda, Burundi, the Comoros, Ethiopia and Malawi among other destinations.

The value of Kenyan medicinal and pharmaceutical products exported increased from KShs 1.6 billion in 1999 to 2.1 billion in 2003.

Chart 1: Value of principal exports, 1999 – 2003 (Kshs million)



Source: *Economic Survey 2004 by Central Bureau of Statistics, Ministry of Planning and National Development*

4.2 Imports

Control of the profession of pharmacy and the trade in pharmaceutical products is administered by the Ministry of Health (MoH), through the Pharmacy and Poisons Board, as provided for by Chapters 244 (The Pharmacy and Poisons Act) and 245 (The Dangerous Drugs Act) of the Laws of Kenya.

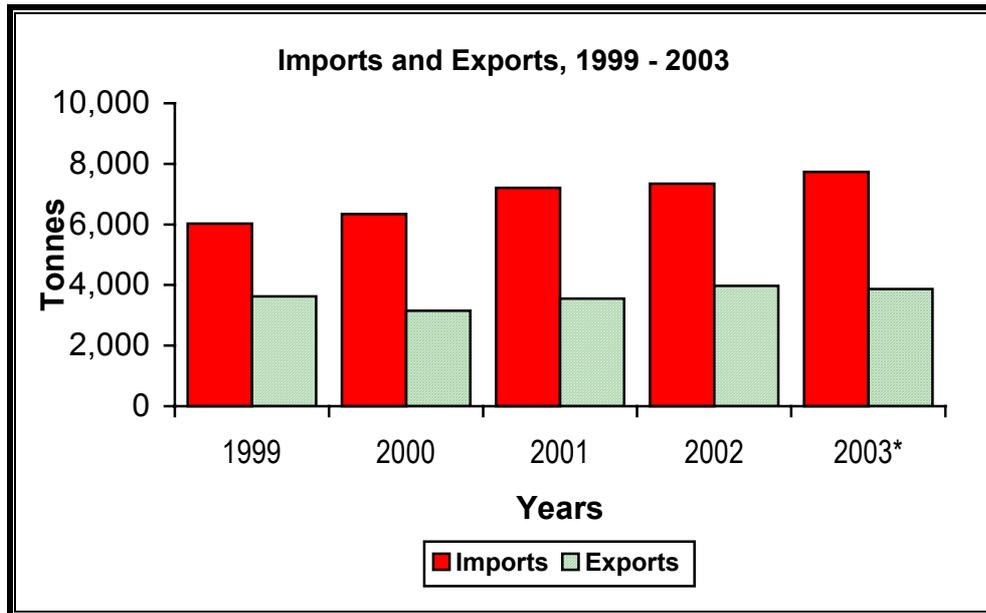
Kenya largely imports medicinal and pharmaceutical products from sources such as Great Britain, India, Germany, France, the USA and Switzerland.

Importers are expected to meet legal requirements, which include:

- Provide samples to the Kenya Bureau of Standards (KEBS) for quality checks and registration
- Meet the regulations of the national policy, which has been adopted by the MOH. This includes an essential drugs list, using WHO guidelines, whose objective is to promote the availability of quality pharmaceutical products at affordable prices.
- Pass regulatory quality control, monitoring and market surveillance as stipulated by the Pharmacy and Poisons Board and the National Drug Quality Control laboratory.



Chart 2: Quantity of Imports & Exports of medicinal and pharmaceutical products (Tonnes)



Source: Economic Survey 2004 by Central Bureau of Statistics

5 Medical research & development

There are great efforts being made in the area of research and development in the field of pharmaceutical and healthcare development in Kenya.

Research institutions undertaking or supporting medical research in Kenya include Kenya Medical Research Institute (KEMRI), Kenya Industrial Research and Development Institute (KIRDI), African Medical Research Foundation (AMREF) and academic institutions like Moi University's School of Medicine, the Medical faculty of the University of Nairobi among others.

6 Legal & regulatory framework

The organization of Kenya's health care delivery system revolves around three levels, namely:

The MoH headquarters - The headquarter sets policies, coordinates the activities of NGOs and manages, monitors and evaluates policy formulation and implementation.

The provinces - The provincial tier acts as an intermediary between the central ministry and the districts. It oversees the implementation of health policy at the district level, maintains quality standards and coordinates and controls all district health activities. In addition, it monitors and supervises District Health Management Boards (DHMBs), which supervise the operations of health activities at the district level.

The districts - district level concentrates on the delivery of health care services and generates their own expenditure plans and budget requirements based on the guidelines from the headquarters through the provinces.

Other key players in the healthcare sector include the private sector, which consists of the churches, private healthcare providers, pharmaceutical companies, NGOs, and the traditional herbal medical practitioners.



6.1 *MOH / Pharmacy and Poisons Board role and objectives*

The Ministry of Health (MoH) has the responsibility of overseeing both the pharmacies and the trade in pharmaceutical products. This is done through the Pharmacy and Poisons Board, as provided for by Chapters 244 (The Pharmacy and Poisons Act) and 245 (The Dangerous Drugs Act) of the Laws of Kenya.

- Product registration is effected after a thorough evaluation of efficacy, safety and quality. As part of a national drug policy, the MoH has adopted an essential drugs list, using World Health Organization (WHO) guidelines.
- Kenya, like all other developing nations adopted the 'Alma Alta' declaration of 'Health for all by the Year 2000', setting various policy measures to achieve this goal, which included the establishment of a national drug policy.

The Pharmacy and Poisons Board was established by the Pharmacy & Poisons Board Act. The Act also confers, to the Board, the right to declare an epidemic. Breaking of any of the Boards' rules is illegal and criminal under the Act.

The Pharmacy and Poisons Board ensures:

- For Manufacturers:
 - Manufacturers register their premises
 - The products are registered with the Board
 - Product labelling in either English or Kiswahili
 - Ensures Batch Number, Date of manufacture, Expiry Date and Address of Manufacture is labelled
- For Pharmacists:
 - All pharmacists have practising licenses
 - Register their premises with the Board
 - Employ qualified personnel
 - Observe the laid down professional ethics

6.2 *Pharmaceutical Society of Kenya role and objectives*

The society issues licenses to pharmacists, as well as ensuring the drug store managers are members of the Pharmaceutical Society of Kenya (PSK) and have sworn allegiance to the pharmacy practitioners' professional oath.

PSK equally plays the role of raising queries as and when they believe its members are committing malpractices.

It ensures standards, which include:

- Monitoring and advising its members on new disease control programmes
- Promotes increased quality training of pharmacy personnel
- Ensure proper distribution of pharmaceutical and non-pharmaceutical products
- Compound sterile and non-sterile pharmaceutical products according to guidelines
- Compound extemporaneously – that is to compound any non-sterile pharmaceutical product prepared in a single item for patients;
- Undertake pharmacy management

6.3 *Kenya Medical Association role and objectives*

The Kenya Medical Association, founded in 1968, is the representative body for medical doctors licensed to practice in the Republic of Kenya. Elected officials who serve on a voluntary basis run KMA.



KMA's objectives include:

- To promote and uphold medical ethics and practice of medicine in Kenya.
- To advise the Government, other medical bodies and the general public on matters related to health and medicine.
- To support Continuing Medical Education through its publications, the East African Medical Journal and Medicus, monthly seminars and scientific conferences.
- To maintain the honour and interests of the medical profession.
- To liaise with other medical associations around the world.

6.4 KEMSA role and objectives

Kenya Medical Supplies Agency (KEMSA) is a semi-autonomous unit in the Ministry of Health. Its policy is to make available essential drugs and equipment primarily but not exclusively, to public facilities. It is the largest purchaser of drugs in the country, through an open-tender system and distributes them to public medical institutions. The tendering system for drugs is open to both local and foreign manufacturers and distributors.

KEMSA gets its funding from the MoH, which in turn receives an annual budget from the Exchequer for drugs and medical supplies based on an estimate of national public health delivery requirements. This budget is available for payment to both foreign and local suppliers as and when required. The medical supplies comprise both proprietary and generic pharmaceutical products.

KEMSA faces the challenge competing with other suppliers, e.g. the mission based medical supply facility (MEDS) and private wholesalers.

6.5 Kenya Bureau of Standards role and objectives

The Kenya Bureau of Standards (KEBS) was established by an Act of parliament, THE STANDARDS ACT, chapter 496 of the Laws of Kenya. It started its operations in July 1974.

The aims and objectives of KEBS include preparation of standards relating to products, measurements, materials, processes, etc. and their promotion at national, regional and international levels; certification of industrial products; assistance in the production of quality goods; quality inspection of imports at ports of entry; improvement of measurement accuracies and dissemination of information relating to standards.

The services offered by KEBS include:

- Sale of Kenya's and foreign standards
- Product certification (Issuance of Diamond Mark of Quality)
- Handling consumer complaints
- Calibration of measuring instruments
- Maintenance of standards of measurements
- Quality inspection of imports at port of entry
- ISO 9000 certification
- ISO 14000 Certification
- Training Programmes and Technical advice
- Laboratory Testing
- Standards Development and Implementation
- Standards Information Resource Centre

Quality Inspection of Imports started in Kenya on 1st July 1995 after the gazettelement of Legal Notice No. 227 of 14th June 1995, while Legal Notice No. 66 of 10th June



1999 declares all imports into Kenya which do not meet the requirements of Kenya Standards or any other standards approved by KEBS as prohibited imports.

6.6 NHIF role and objectives

Apart from the government, the NHIF is Kenya's single largest financier of health services. It is a statutory social insurance fund, whose public responsibility is to provide health insurance coverage for its members and their dependents. The fund currently reimburses only in-patient care.

NHIF pays fixed rates for in-patient days, covering the bed costs. All other fees for treatment, diagnosis and pharmaceuticals have to be paid out-of-pocket by the NHIF-insured patient.

7 Reasons to invest in Kenya's health and pharmaceutical industry

Kenya is one of the most stable democracies in Africa. The Government welcomes, promotes and protects private enterprise. In addition, Kenya's competitive advantage for the health and pharmaceutical sector investment is supported by various investor friendly factors that include:

Trademark and patent protection

Kenya is a member of most major international and regional intellectual property conventions – the World Intellectual Property Organization (WIPO), the African Regional Industrial Property Organization, the Paris Convention on the Protection of Industrial Property, and the Berne Convention on the Protection of Literary and Artistic Works.

Access to the regional market

Exports from Kenya enjoy preferential access to world markets under a number of special access and duty reduction programmes. These include regional markets (EAC, COMESA), EU-African-Caribbean-Pacific/Lome Convention and the African Growth & Opportunity Act (AGOA).

Stable political climate

Kenya has been one of the very stable countries in Africa since independence. The country has had three presidents with smooth transition taking place from one government to the next and peaceful elections held regularly. This is also manifested in the number of international and regional organizations headquartered in Nairobi including the UN, IGAD etc.

Investment insurance

The Constitution of Kenya provides guarantees against expropriation of private property. In addition, capital repatriation, remittance of dividends and interest are guaranteed to foreign investors under the Foreign Investment Protection Act (FIPA) (Cap 518).

Kenya as a member of MIGA (Multilateral Investment Guarantee Agency) provides investors with an opportunity to insure their investment in Kenya against a wide range of non-commercial risks. Kenya is also a member of the African Trade Insurance Agency (ATI), a multilateral export credit and political risk agency for COMESA member states as well as the International Council for Settlement of Investment Disputes (ICSID).



Strategic location

Located on the East African coast and having the port of Mombasa, Kenya is strategically located for investors wanting to access the East and Central African market. Kenya is also a regional hub for airlines allowing for easy access from and to any part of the world.

Investor friendly arrangements

The Kenya government can guarantee investor friendly arrangements such as:

- the Export Processing Zones (EPZ) program which offers attractive incentives to export-oriented investors and EPZ Authority to provide one-stop-shop service for facilitation and aftercare
- the Investment Promotion Centre (IPC) to promote all other investment in Kenya including in Manufacturing under Bond (MUB) program
- the Tax Remission for Export Office (TREO), a program for intermittent imports for export production
- Generous investment and capital allowances
- Double taxation, bilateral investment and trade agreements

Availability of affordable labour

Kenya provides potential investors with an abundant supply of affordable labour. Kenya also has a well-trained labour force that is capable of handling all sorts of pharmaceutical procedures.

Good quality of life

Kenya hosts a number of international organizations and foreign embassies and provides very good and up to standard living conditions for foreign investors wishing to reside in Kenya. With recognized international hotels, airports and entertainment centres, Kenya provides as much comfort for foreigners as in any European capital.

8 Investment opportunities

Opportunities for investment in the health/pharmaceutical sector in Kenya include:

- Manufacture of disposable surgical gloves, latex gloves and condoms.
- Commercial processing of traditional medicines, considering the diverse flora available in the country.
- Multipurpose chemical plant for bulk production of intermediate inputs such as paracetamol, aspirin, etc.
- Processing of locally available sugar, salt (sodium chloride) and ethanol to pharmaceutical grade for pharmaceutical industry use.
- Chemical plant to manufacture anti tuberculosis, anti-leprosy, antibiotic rifampicin from the penultimate state.
- Manufacture of Quinine by extraction from Cinchona bark and subsequent purification and synthesis to Quinine sulphate.
- Extraction of Hecogenin from sisal waste and synthesis of Betamethasone from Hecogenin.
- Manufacture of medical supplies e.g. syringes, catheters, gauzes, etc, and medical equipment for the regional market.

Prospects for the pharmaceutical industry in Kenya

- Export of high quality products
- Increased quantity of production
- Expand product portfolio and intensify the search for new markets and marketing opportunities
- Support for medical research



- Ensure strict adherence to the national code of conduct and the industry's code of practice.

9 Key Players in the industry

9.1 Companies

The key players in the industry include MNCs like Glaxo SmithKline, Boots Pharmaceuticals, Bayer, Pfizer, Aventis, Novartis, Astra Zeneca, Eli Lilly, Pharmacia, Roche, and local establishments like Dawa Pharmaceutical Ltd and Cosmos Pharmaceuticals among others.

9.2 Institutions and collaborating agencies

- Pharmaceutical Society of Kenya (PSK)
- Kenya Medical Association (KMA)
- Kenya Medical Suppliers Association (KEMSA)
- Kenya Association of Manufacturers (KAM)
- Ministry of Health (MoH)
- Kenya Bureau of Standards (KBS)
- Kenya Forestry Research Institute (KEFRI)
- National Health Insurance Fund (NHIF)

10 Useful Contacts

Ministry of Health
Afya House, Cathedral Road
P.O. Box 30016, Nairobi, Kenya
Tel: 254-20-2717077
Web: www.health.go.ke

Ministry of Trade and Industry
Telposta Towers,
Kenyatta Avenue
P.O. Box 43137 Nairobi, Kenya
Tel: 254-20-315001-4
Fax: 254-20-315011
Web: www.tradeandindustry.go.ke

Pharmacy and Poisons Board
Masaba Road
P.O. Box 27663, 00506 Nairobi
Fax: 254-20-2713431
Email: ppb@africaonline.co.ke

Pharmaceutical Society of Kenya
P.O. Box 44290, Nairobi, Kenya
Tel.: 254-20-556-455
Fax: 254-20-552-046

Kenya Revenue Authority (KRA)
Times Towers Bldg., Harambee ave.
P.O. Box 48240, 00100 GPO Nairobi,
Kenya.
Tel: +254-20-310900/315553
Email: info@kra.go.ke
Web: www.kra.go.ke

Kenya Bureau of Standards
Bellevue Area, Off Mombasa
Rd
P.O Box 54974 City Square
Fax: 254-20-503293
Tel: 254-20-502210/502211
Email: info@kebs.org
Web : www.kebs.org

Investment Promotion Center
(IPC)
National Bank Building, 8th
Floor, Harambee Avenue
P.O. Box 55704-00200 Nairobi,
Tel: 254-20-2211401-4
Fax: 254-20-336663
Email:
info@investmentkenya.com
Web:
www.investmentkenya.com

Export Processing Zone
Authority (EPZA)
Administration Building
Athi River EPZ, Viwanda Road
Off Nairobi - Namanga
Highway
P.O Box 50563, 00200 Nairobi
Kenya
Tel: 254 45 26421-6
Fax: 254 45 26427
Web: www.epzakenya.com
Email: info@epzakenya.com



11 Sources of Information and Glossary

- Ministry of Health
- World Health Organisation
- Ministry of Trade & Industry
- Kenya Revenue Authority
- Investment Promotion Centre
- Central Bureau of Statistics
- International Trade Statistic
- Kenya Export Promotion Council
- Kenya Medical Supplies Agency
- SciDev.Net 2002

Reference:

- Economic Survey 2004 by Central Bureau of Statistics and Ministry of Planning
- Kenya Factbook 2001 by Kul Burshan
- Statistical Abstract 2003 by Central Bureau of Statistics and Ministry of Planning.
- Kenya Bureau of Standards (KEBS)
- Kenya Coalition on Access to Essential Drugs
- The East African Standard Newspapers –29th September 2004

Note: The Kenya Coalition on Access to Essential Medicines includes: Action Aid, The Association of People living with AIDS in Kenya (TAPWAK); Health Action International (HAI Africa); Network for people living with HIV/AIDS (NEPHAK); Women Fighting AIDS in Kenya (WOFAK); Society for Woman and AIDS in Kenya (SWAK); Nyumbani; International Federation of Women Lawyers Kenya (FIDA); CARE International; Médecins Sans Frontières (MSF); DACASA; Pharmaciens Sans Frontières (PSF); Kenya Medical Association (KMA); Consumer Information Network; Campaigners for AIDS Free Society.

NB: Social Health Insurance (SHI) includes NHIF and Community Based Health Initiatives; Private Prepaid Health Plans (PPP) includes HMOs and private health insurance.