Ministry of Medical Services

# KENYA NATIONAL PHARMACEUTICAL POLICY 2008

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2008

# Contents

# Foreword

Kenya published the first National Drug Policy (KNDP) in 1994, addressing important issues impacting on pharmaceutical services. However, there was no clear and sustainable strategy for its implementation, and monitoring and evaluation of its impact were minimal. External assessments of the pharmaceutical sub-sector, supported by development partners such as the World Bank and WHO, have highlighted the challenges that need to be addressed and made recommendations.

Various regional and international trends impact on pharmaceutical services in Kenya, and require elaboration of government commitments and policy directives: - growth and sophistication of the global pharmaceutical market and the local pharmaceutical industry, and Kenya's growing participation in regional and international trade in pharmaceuticals. All these affect access to medicines by the population and shape investments and human resources development in the pharmaceutical sub-sector.

At the national level, ongoing comprehensive health sector reforms require concurrent reform of the pharmaceutical sub-sector, in order to fully realize health and development goals. The private sector continues to play an increasing role in pharmaceutical service delivery and out-of-pocket financing for medicines remains a barrier to access. The use of traditional medicines also requires special attention. Pharmaceutical services therefore need to be adequately re-defined, with regulatory mechanisms that respond to current and emerging needs and challenges.

The Government recognizes that access to essential medicines is a basic human right. Access to essential medicines on a sustainable basis is one target of the Millennium Development Goals (MDGs), to which Kenya is firmly committed. This revised policy aims to address the needs and trends in pharmaceutical service delivery and to

ensure harmony with other health and development policies.

Overall, the Policy focuses on strengthening the management and delivery of pharmaceutical services through relevant legislative and institutional reforms; strengthening national institutions for medicines procurement, supply, regulation and quality control; developing and appropriately managing pharmaceutical human resources; and enhancing collaboration with other sectors and with partners.

It is my sincere hope that this National Pharmaceutical Policy will facilitate the much-needed reform in the pharmaceutical sub-sector, towards achieving the policy goal of ensuring *'…the provision to all Kenyans of efficient, effective pharmaceutical services that are sustainable, equitable, accessible and affordable with safe, efficacious and high quality medicines, which are appropriately used'.*

Finally it is important to note that the KNPP is not just a policy for pharmaceutical personnel. It is a national guide to effective health sector reform. Implementation of the Policy will require the full participation of all those with a stake in the correct development, management and use of medicines for the benefit of our people.

**Hon. Prof. Peter Anyang' Nyong'o, EBS, MP**
**Minister for Medical Services**

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We are indebted to the members of the Technical Working Group for sharing their insights and experience, and for their hard work during the course of two policy review and formulation retreats at Nyeri Outspan Hotel 8-12 May 2006 and/or Naivasha Country Club 4-6 September 2006 (for list of members see Annex 2).

We are also grateful for the valuable insights and contributions of the following from WHO: Dr Hans Hogerzeil, Dr Gilles Forte and Dr Moses Chisale, as well as Dr Paul Spivey, WHO Pharmaceutical Consultant who carefully reviewed the first draft and assisted the Task Force in preparation of an advanced draft during the course of a special 3-day meeting in Nairobi in January 2007.

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| | |
|---|---|
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# Abbreviations & Acronyms

| | |
|---|---|
| AIDS | Acquired Immunodeficiency Syndrome |
| AOP | Annual Operation Plan |
| AMU | Appropriate Medicines Use |
| cGMP | current Good Manufacturing Practice |
| DMS | Director of Medical Services |
| DoP | Department of Pharmacy |
| EML | Essential Medicines List |
| EMMS | Essential Medicines and Medical Supplies |
| GDP | Good Dispensing Practice |
| GDP | Gross Domestic Product |
| GPDP | Good Pharmaceutical Distribution Practice |
| GPPP | Good Pharmaceutical Procurement Practice |
| HIV | Human Immunodeficiency Virus |
| IEC | Information, Education and Communication |
| INN | International Non-proprietary Name |
| KEDL | Kenya Essential Drugs List |
| LMIS | Logistics Management Information System |
| KEMSA | Kenya Medical Supplies Agency |
| KEML | Kenya Essential Medicines List |
| KEMSL | Kenya Essential Medical Supplies List |
| KEPH | Kenya Essential Packages for Health |
| KNDP | Kenya National Drug Policy (1994) |
| KNPP | Kenya National Pharmaceutical Policy |
| MDGs | Millennium Development Goals |
| MEDS | Mission for Essential Drugs and Supplies |
| M&E | Monitoring and Evaluation |
| MoH | Ministries of Health |
| MTC | Medicines and Therapeutics Committee |
| MTI | Medicines and Therapeutics Information |
| NHSSP | National Health Sector Strategic Plan |
| NSHIF | National Social Health Insurance Fund |
| NQCL | National Quality Control Laboratory for Drugs and Medical Devices |
| PPB | Pharmacy and Poisons Board |
| QA | Quality Assurance |
| QC | Quality Control |
| R&D | Research and Development |

| | |
|---|---|
| STG | Standard Treatment Guidelines |
| SWAp | Sector Wide Approach |
| TB | Tuberculosis |
| TCAM | Traditional, Complementary/Alternative and Herbal Medicines |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| TWG | Technical Working Group |
| WHO | World Health Organization |
| WTO | World Trade Organization |

**Note:** underlined items are defined in the Glossary

# Methodology used for Policy Review and Revision

A Technical Working Group (TWG) of the MoH undertook the first stages of KNPP development. The TWG comprised representatives of various MOH departments, health institutions, as well as the private sector, training institutions, professional associations, and civil society.

Several key documents informed the review process, and the key ones are listed in Annex 3. In undertaking the review, the TWG strived not merely to update the existing policy, but to develop a coherent, comprehensive and appropriate policy responsive to the current and expected future situation and context.

The TWG held two consultative retreats, in March and September 2006, to develop the draft document. This was further edited and enhanced following further inputs arising from WHO review and in the course of a special 3-day meeting of the Task Force and WHO consultant held in January 2007.

An advanced draft incorporating the many amendments was presented to the senior management of MoH for review and endorsement in May 2007. Following incorporation of further amendments, the revised advanced draft was then disseminated and discussed during a stakeholder consensus meeting in August 2007. The final draft of the KNPP, which incorporated final amendments arising from the consensus meeting, was submitted to the Minister for Health for formal adoption.

## Scope of the Policy

The Kenya National Pharmaceutical Policy (KNPP) encompasses the key elements for revitalizing the pharmaceutical sub-sector in Kenya. It outlines relevant policy direction and strategies touching on pharmaceutical products, personnel for provision of pharmaceutical services and the key institutional framework and processes required

to ensure access to medicines for the population. The term pharmaceutical has been adopted in the title instead of 'drug' or 'medicine', to signify the Government focus on comprehensive reform of the entire sub-sector, with the ultimate goal of making medicines[1] and pharmaceutical services more accessible to all Kenyans.

## Presentation of the KNPP

Part 1 provides **background information** upon which the policy is based, relating to the current status of the health sector and the pharmaceutical sub-sector.

Part 2 states the **Principles, Vision, Goal and Objectives** guiding policy formulation and implementation.

Parts 3, 4 and 5 constitute the main **policy areas** namely:

Part 3: **Pharmaceutical sub-sector Management**

Part 4: **Pharmaceutical Supply System**

Part 5: **Appropriate Medicines Use**

Each of these has an introductory section summarizing key issues and challenges relating to that area of policy.

Within each of these areas, there are a number of components covering specific aspects or areas of activity. For each component, there is a policy **AIM** highlighted in a box. Next follows a general statement of intent, i.e. what will be done to achieve the AIM. Finally there is a list of specific necessary **Actions to Implement Policy** which will be used to prepare strategic policy implementation plans and annual action plans.

A **Glossary** at the end of the document (Annex 1) provides an explanation of key terms as used in the policy document.

[1] See Glossary for definition of 'medicines' and 'pharmaceuticals' as used in this Policy

# 1. Introduction

## 1.1 Country Socio-Economic and Health Profile

Since the first National Drug Policy (KNDP) was developed in 1994, Kenya's population has grown from 26.8 million to the current 34 million. Fifty-six percent of the population lives below the poverty line. Substantial resource inputs to the health sector by the Government and development partners have resulted in specific gains and various improvements, but overall, key health indicators have been on the decline and a significant number of Kenyans cannot reliably access the medicines they need.

The **overall health** of the population is threatened by AIDS, malaria, tuberculosis and other diseases. An estimated 1.5 million Kenyans are living with HIV. Malaria is the main contributor to morbidity and mortality in Kenya, causing 34,000 deaths annually in children below 5 years of age. Kenya is ranked tenth in the world for tuberculosis burden in countries, and the case-load continues to increase. Medicines, medical devices and diagnostics to manage these and other diseases are expensive, and present great challenges for access, monitoring and regulation. This has put a significant demand on the health system overall and the pharmaceutical sub-sector specifically, including on pharmaceutical personnel, procurement and supply management.

The public health care system remains the major **provider of health services**, accounting for 58% of health facilities, 52% of hospital beds and 70% of health personnel. The private for-profit sector and the private not-for-profit providers complement the public sector health services.

## Country Health Indicators

| Indicator | Value (Year) |
|---|---|
| Total population | 34.3 million (2005) |
| Urban population (% of total) | 34% (2002) |
| Gross Domestic Product (GDP) per capita (in international dollars) | 1,586 (2004) |
| Life expectancy at birth (M/F) (years) | 51/50 (2004) |
| Healthy Life Expectancy at birth (M/F) years | 44/45 (2002) |
| Child mortality (M/F) per 1,000 (probability of dying under age 5 years) | 115/110 (2004) |
| Adult mortality (M/F) per 1,000 (probability of dying between 15-59 years) | 477/502 (2004) |
| Total health expenditure per capita (in international dollars) | 65 (2003) |
| Per capita total health spending (US$) | 6.2 (2005) |
| Total expenditure on health (% of GDP) | 5.0% (2006) |
| Percentage of total government budget spent on health | 8.6% (2005/06) |
| Percentage of out-of-pocket expenditure spent on medicines | 69% (2003) |
| Percentage of MOH budget spent on medicines and medical supplies | 9% (2005/06) |

***Sources:*** *MOH National Health Accounts (2003); WHO Statistical Information System (WHOSIS)[2] (Feb 2007); PPB (2007)*

Public **financing of the health sector** through the exchequer is about US$ 6.2 per capita, or 5% of GDP, which falls below the WHO recommended level of US$ 34 per capita (of which a minimum of $2.5 should be on essential medicines), and far short of the Government's commitment to spend 15% of the national budget on health, as agreed in

[2] http://www3.who.int/whosis/core/core_select_process.cfm

the Abuja Declarations of 2001 and 2006. This under-funding has reduced the sector's ability to ensure an adequate level of service provision to the population, and has led to significant out-of-pocket payments. For example, cost sharing, accounted for 7.4% of the Ministry's recurrent expenditures in 2005/2006[3]. This contributes to inequity in access to healthcare for the poor and disadvantaged groups. The proposed National Social Health Insurance Fund (NSHIF) is intended to ensure that basic health services are equitably available to all Kenyans. These factors put Kenya at risk of not achieving the Millennium Development Goals (MDGs), to which the Government has made a commitment. Thus additional resources need to be committed to health together with more focused strategies to address inequities in the sector.

The Government's **policy reforms** are outlined in the Economic Recovery Strategy for Wealth and Employment Creation (2003-2007), where the focus is to restore economic growth, generate adequate employment, and reduce high levels of poverty. Within this framework, the focus of health reforms is on improving access to healthcare by improving financing, infrastructure, and procurement and distribution of medicines. In addition, Kenya is a signatory to several international treaties and conventions, including the International Covenant on Economic, Social and Cultural Rights, which confer responsibility on the Government to address and protect human rights in national health policies. Kenya is also an active member of the East African Community, which has committed to full integration into a federation by 2013, and thus there is need to align health policies with the goals of regional integration.

*Kenya Vision 2030: Transforming National Development* launched in 2006 is a long-term plan to create a 'globally competitive and prosperous nation with a high quality of life by 2030', anchored on transforming the nation's economic,

[3] Adopted from the Health Sector Report 2007

social and political aspirations. Under this plan 'pro-poor spending proposals, particularly in health and education are important in reducing the state of inequality'[4].

Kenya's Health Policy Framework (1994)[5] outlines the goal of the health sector policy to 2010 as: *To promote and improve the health of all Kenyans through the deliberate restructuring of the health sector to make all health services more effective, accessible and affordable*. This Framework outlines comprehensive **health sector reforms**, amongst them strengthening the policy role of the central MOH; decentralization and capacity strengthening of provincial and district levels; re-orientation, re-training and re-deployment of health manpower; and adoption and implementation of the **National Drug Policy** as the guide for legislative reforms, staff development and management improvements in pharmaceutical services.

Based on experiences in implementing the first plan covering 1994-2004, the second **National Health Sector Strategic Plan** (NHSSP II: 2005-2010), outlines a new results-based approach to service delivery, with the Kenya Essential Package for Health (KEPH) as a core element. KEPH focuses on delivery of a defined service package at five stages of the human life cycle. Within the principles of a Sector-Wide Approach (SWAp), KEPH also focuses on harmonization and alignment between the Government and its development partners, with the various health interventions integrated through the 'three ones', i.e. one sector plan, one implementation framework (outlined in the Joint Program of Work and Funding (JPWF) and Annual Operation Plans (AOPs), and one Monitoring and Evaluation (M&E) framework. The NHSSP II defines six levels for service delivery of the Kenya Essential Package for Health (KEPH), with the community level as the foundation for priority setting in health interventions.

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[4] http://www.nesc.go.ke/News&Events/KenyaVision2030Intro.htm
[5] Reprinted in 1997

## 1.2 Pharmaceutical sub-Sector Profile

Since the adoption of the KNDP in 1994, demands on the health system have continued to increase with the growth in population. Although the number of public and private health facilities has also increased, the health system remains overburdened, perhaps most significantly due to the ongoing burden of HIV, TB and malaria. The pharmaceutical sub-sector has experienced the same challenges affecting the health sector. Following incomplete implementation of the KNDP, there are many areas in need of attention in order to strengthen the sub-sector and improve key indicators.

### Key Pharmaceutical Sub-sector Indicators

| Indicator | Value (Year) |
|---|---|
| Date of National Drug Policy | 1994 |
| Date of National Essential Medicines List | 2002 |
| Date of Standard Treatment Guidelines | 2002 |
| Public sector medicines expenditure (US$) | 16 million (2002/3) |
| Public sector per capita medicines expenditure (US$) | 0.51 (2002/3) |
| Percentage of MOH recurrent budget spent on medicines & medical supplies | 11.3% (2006/2007) |
| Pharmaceutical sub-sector value (US$) | 130 mill (2004) |
| Number of registered pharmaceutical manufacturers | 35 (2006) |
| Number of registered pharmacies (including 208 wholesalers) | 1,153 (2006) |
| Number of registered pharmacists | 1,895 (2006) |
| Number of enrolled pharmaceutical technologists | 1,436 (2006) |
| Ratio of pharmaceutical personnel/population (per 1,000) | 0.08 (2006) |

***Sources:*** *MOH National Health Accounts (2003); WHO Statistical Information System (WHOSIS) (Feb 2007); PPB (2006)*

Public sector **pharmaceutical services** are provided by the MoH through the Division of Pharmacy headed by the Chief Pharmacist who is also by law the Registrar of the medicines regulatory authority. The current MOH structure and the dual roles of some MOH officers is not conducive to effective pharmaceutical sub-sector management and does not facilitate effective delivery of services.

The numbers of **pharmaceutical personnel** (pharmacists and pharmaceutical technologists) has increased with time, but they are still insufficient relative to the population in need (1 for every 10,300 persons or approximately 0.1 for every 1,000 population). Moreover, these personnel are inequitably distributed across the country with the majority concentrated in the private sector and in urban areas, and there are notable skills gaps in key areas, such as management, pharmaceutical procurement and supply, etc. As a result, the quality of pharmaceutical services is compromised. In this respect, key areas of focus for this policy are: - building and promoting a coherent pharmaceutical care program, standardizing curricula and training of personnel, and developing and retaining of pharmaceutical human resources.

The Government has established **key institutions** for pharmaceutical supply (KEMSA), regulation (PPB) and quality control (NQCL) of medicines. However their full potentials are yet to be realized and many opportunities exist to consolidate and strengthen their roles and functions.

The government and its bilateral partners contribute significantly to health sector strengthening and **financing** but currently this is insufficient to ensure equitable access to essential medicines for all Kenyans. Significant factors (such as national debt, inflation, economic growth and unpredictable donor support) and lack of required budget-planning information make concrete budget projections difficult. This contributes to major gaps in funding and

consequently, access to medicines and resources for the pharmaceutical sub-sector and medicines supply remain grossly inadequate.

The Government is rationalizing the health financing system, with public financing priority on primary health care, coupled with other appropriate health insurance and risk-pooling mechanisms involving the public and private sectors, including the informal sector and community schemes. The scrapping of the user fees/cost recovery system in 2005 and the introduction of the 10/20[6] system of nominal fixed fees for services at rural health facilities was a major step towards this aim.

There has been an enormous development of the local **pharmaceutical market** over the last decade, with an estimated 8,500 products currently marketed in Kenya. A vibrant pharmaceutical manufacturing industry has been established in Kenya, with great potential and opportunities to serve the East African and COMESA sub-regions. Trade liberalization and a challenging local manufacturing environment must be addressed to ensure the effectiveness and sustainability of this vital resource. Furthermore, medicines regulation and post-market surveillance need strengthening to ensure consumer confidence in the medicines originating from, and those circulating in the Kenyan market.

[6] Kshs 10 for dispensaries and Kshs 20 for health centers

# 2. Principles, vision, goal and objectives

## 2.1 Policy Principles

The KNPP is based on four guiding principles:

a) **Human Rights**
The right to health is a fundamental human right. Access to essential medicines is an integral part of this right, as an important prerequisite for the provision of effective health services to the population. In order to secure these rights and prerequisites, the KNPP addresses inter alia the following issues:

- regular updating of the national lists of essential medicines and supplies, to define minimum needs,
- consultation with and involvement of all stakeholders,
- clear policy objectives and obligations of the stakeholders,
- baseline and target indicators to measure progress in implementation, and
- ensuring equitable access to essential medicines for all vulnerable and marginalized groups

b) **The Essential Medicines Concept**
The World Health Organization defines essential medicines 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"* [7],

c) **The Pharmaceutical Care Approach**
This involves the responsible provision of medicines to achieve definite outcomes that improve or maintain a patient's quality of life, and a continuous, collaborative process to prevent, identify and solve medicines-related problems and improve medicines utilisation

d) **Effective Partnerships** for delivery of pharmaceutical services, including partnerships within the public sector as well as Public Private Partnerships in the context of the Sector Wide Approach (SWAp), which is the health sector coordinating framework.

## 2.2 Policy Vision

Well-managed coherent pharmaceutical services making Essential Medicines accessible to all Kenyans

## 2.3 Policy Goal

To ensure the provision to all Kenyans of efficient, effective pharmaceutical services that are sustainable, equitable, accessible and affordable with safe, efficacious and quality Essential Medicines, which are appropriately used

## 2.4 Policy Objectives

1. To ensure equitable access to affordable medicines through the public, private, and other sectors.
2. To ensure continuous availability of safe and effective Essential Medicines especially in the public sector.

[7] WHO Policy Perspectives on Medicines — Equitable access to essential medicines: a framework for collective action (WHO, March 2004)

3. To promote appropriate medicines use through good prescribing and dispensing practices and correct use by consumers.
4. To ensure appropriate regulation and control of human and veterinary medicines
5. To ensure that the quality of medicines for human and veterinary use in Kenya meets internationally acceptable standards.
6. 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.
7. To encourage self-sufficiency in local manufacture of Essential Medicines for the domestic market and promote growth in pharmaceutical exports.
8. To ensure integration of useful traditional, complementary/alternative and herbal medicines into the national health-care system.
9. To strengthen and institutionalize pharmaceutical care as a key component of the healthcare system.
10. To increase and strengthen institutional, technical and human resource capacity for the effective provision of pharmaceutical services.

## 2.5 Policy Implementation Arrangements

The following will be key features of the KNPP implementation process and associated structures and arrangements:

a) The master plan for implementation will be a 5-year strategic **KNPP Implementation Plan** (KNPP-IP) developed consultatively with stakeholders

b) The **KNPP-IP** will link closely with the **NHSSP-II** in order to ensure the correct focus on identified health sector priorities. From the **KNPP-IP** will derived **annual operational plans** (AOPs), which are the main instruments guiding implementation of policies and strategies, for the MOH together with its development and implementing partners.

c) Successful implementation of this Policy will hinge on: (i) incorporation of the relevant components of the KNNP-IP into the **institutional development plans** and **monitoring frameworks** of the respective stakeholder institutions and (ii) adequate resource allocation by Government and partners.

d) Monitoring and Evaluation of the KNPP-IP will follow the framework of the NHSSP II, and will comprise: (i) **quarterly performance reports** to be shared with all actors; (ii) **annual reports** on implementation of each AOP; (iii) external **Mid-Term Review (MTR)** after 3 years of implementation and (iv) a Final External Evaluation of the KNPP-IP after 5 years.

e) In order to assess the ultimate goal of the policy, i.e. access to medicines and pharmaceutical services for the population, standardized WHO tools[8,9] will be applied to assess access to medicines, during the first year and the 5th year respectively, of the policy implementation period.

f) The final evaluation and assessments will inform subsequent review and revision of this Policy, which is anticipated after 5 years.

[8] Using Indicators to Measure Country Pharmaceutical Situations: Fact book on WHO Level I and level II indicators (WHO, 2006)
[9] WHO Household Survey Tool to measure access to medicines (2007)

# 3. Pharmaceutical sub-Sector Management

**Administration:** The current pharmaceutical management structure was devised in the 1960s when pharmacy was seen merely as a supply and dispensing function. It is no longer appropriate for management of the pharmaceutical sub-sector in the 21st century. Key changes in the sector include:- commercialization and globalization of trade in pharmaceuticals; intellectual property provisions and their implications on access to medicines; increasingly complex issues of quality and safety; spread of counterfeits and other illegal practices; increased sophistication of disease management with associated costs; increasing demand for information and advice on appropriate medicines use; and the enhanced role of the pharmacist in public health and in the clinical environment.

There is a persistent misconception that pharmaceutical services comprise only procurement and supply of 'commodities'. International management trends are towards clear separation of policy, regulation and supply functions, with the MOH providing oversight.

There is therefore an urgent need to redefine and strengthen pharmaceutical sub-sector management within the Ministry of Health and enhance its capacity for policy making, regulation and oversight, in order to effectively address the above changes and misconceptions and correct the chronic sector under-performance.

**Supply system:** The Kenya Medical Supplies Agency (KEMSA) has been reorganized and is currently in the midst of a programme to further strengthen its structure and functioning.

**Legislation and regulation:** The primary legislation governing the pharmaceutical sub-sector is *The Pharmacy and Poisons Act 1957 (Cap. 244)*, with its subsequent

amendments and associated regulations covering such matters as rules for medicines supply, establishment of the NQCL, and transformation of the PPB[10]. Fifty years after enactment of the *Pharmacy and Poisons Act*, the pharmaceuticals scene has changed drastically, and consequently there is need to overhaul existing legislation and enact a modern medicines act, encompassing the entire scope of human and veterinary products, and key elements of quality, efficacy, safety and appropriate use.

The process of restructuring the PPB is underway, towards the goals of attaining the required autonomy and full realization of its regulatory role.

**Human and financial resources** for the pharmaceutical sub-sector remain a significant challenge. Even with increasing inputs by the Government and its partners, neither resource is sufficient to meet the needs of the sector. Furthermore, there are distributive and operational inefficiencies of the available resources, which lead to inequity and inefficient utilization. In particular there is a chronic deficiency of pharmaceutical capacity at lower KEPH Levels.

**Medicine prices** and mark-ups are not regulated in Kenya, and there are significant price variations across regions and sectors. Surveys of medicine prices show that public and mission procurement attains competitive prices below international reference prices[11], but patient prices are relatively high compared with neighbouring countries and international reference prices. Accordingly, given the prevalence of poverty in the country, and the high out-of-

[10] Other relevant legislation includes the *Narcotics & Psychotropic Substances Act (1994), Food, Drugs and Chemical Substances Act (Cap. 254), Use of Poisonous Substances Act (Cap 247), Medical Practitioners and Dentists Act (Cap 253),* and *Trading in Prohibited Goods Act (Cap 519).*

[11] International Drug Price Indicator Guide, Management Sciences for Health/WHO (2005)

pocket health expenditures, most medicines are unaffordable for the majority of the population[12].

**Research and development** if strategically directed can improve the health of Kenyans through addressing their priority health needs, including poverty-related diseases. Operational research can be used to document and help solve ongoing operational challenges in the effective management and delivery of health care including the appropriate use of medicines. The potential for operational and clinical research exists in Kenya, but is constrained by various factors, including: insufficient human and financial resources; limited investment in health related research; poor coordination; lack of prioritization of research issues; poor dissemination of findings; and no recognition of quality research.

**Intersectoral collaboration and technical cooperation** is necessary to achieve KNPP goals in the most efficient and cost-effective way. Cooperation between all the interested partners can help optimize outcomes of planned initiatives by making use of the strengths and comparative advantages of each partner, fostering a collaborative approach to dealing with issues and avoiding confusion and duplication of effort.

**Management information**. Significant data is generated on various aspects of pharmaceutical services, but the challenge remains to ensure it is systematically collected and compiled, suitably analysed and then made readily available for management purposes. The current Health Management Information System (HMIS) is not performance-based or output-oriented. Performance indicators and targets are not comprehensive enough for the pharmaceutical sub-sector and there are no mechanisms for the collection of disaggregated data on access to medicines (eg. by gender or vulnerable groups).

[12] Medicines Price Monitor, Kenya Ministry of Health, April 2006

Unless rectified, these constraints may impede appropriate monitoring and evaluation of KNPP implementation.

## 3.1 National Pharmaceutical Services Administration & Institutional Structures

**AIM**
Effective and transparent administration, coordination and regulation of the pharmaceutical sub-sector

Pharmaceutical management structures and institutions will be re-defined and strengthened to make them more responsive to current and future health sector demands

**Actions to Implement Policy**

1. Establish and fund a pharmaceutical policy implementation unit within the MOH
2. De-link the offices and functions of the regulatory authority from that of pharmaceutical services administration
3. Assign MOH pharmaceutical services a status commensurate with the fundamental importance of pharmaceuticals in stated national development goals and health sector commitments
4. Undertake appropriate restructuring of pharmaceutical services at all levels
5. Operationalize the PPB (national medicines regulatory authority) as an autonomous body corporate within government
6. Ensure technical autonomy of the NQCL and facilitate its accreditation for effective operation
7. Enact legislation to establish KEMSA as the primary public medicines procurement agency
8. Redefine internal management structures and relationships for MOH DoP, PPB, NQCL and KEMSA.

## 3.2 Legislation and Regulation

**AIM**
Effective regulation of the pharmaceutical sub-sector (personnel, premises, practices and products)

All legislation affecting the sector will be reviewed and harmonized to ensure that it is responsive to sector needs, and that adequate sanctions for non-compliance are provided for.

Effective implementation and enforcement of the legislation will require enhanced capacity of the regulatory authority, a transparent enabling environment and the active collaboration of all participating bodies and agencies.

**Actions to Implement Policy**

1. Update and harmonize as required all medicines legislation, regulations and rules.
2. Develop PPB capacity to adequately control and regulate traditional, complementary/alternative and herbal medicines, nutraceuticals, chemicals[13], medical supplies and cosmetics.
3. Strengthen PPB role in regulation of post market surveillance, pharmacovigilance, clinical trials and other studies involving medicines.
4. Review, update and enforce the medicines scheduling system.
5. Participate in regional and international initiatives to harmonize pharmaceutical regulatory systems and their implementation.
6. Consolidate and strengthen all pharmaceutical inspectorate functions under the PPB.
7. Develop and implement legislation and mechanisms to effectively deal with counterfeit medicines

[13] i.e. as required for provision of health services; and any others which may have an impact on human and veterinary health

8. Strengthen the role of relevant professional bodies and enhance linkages with MOH to effectively monitor and enforce professional ethics, practice and standards.
9. Review and revise legislation related to licit use of controlled and psychotropic substances including precursors to facilitate their access and appropriate use
10. Enhance PPB capacity to regulate medicines for veterinary use, establishing effective linkages with veterinary stakeholders

## 3.3 Financing and Pricing

**AIMS**

Financial resources mobilized for effective KNPP implementation and sustainable pharmaceutical service delivery. Prices of medicines are regulated and affordable

The Government will mobilize adequate financial resources, and appropriately allocate them for equitable provision of pharmaceutical services. Priority will be given to primary health care, vulnerable groups[14] and public health issues (e.g. malaria, HIV and TB). A mechanism for regulation of medicines prices will be developed and implemented to ensure their affordability.

**Actions to Implement Policy**

1. Evaluate and prioritize existing medicine financing schemes (such as revolving drug funds, NSHIF, and cost sharing) with the aim of determining the most equitable and sustainable mechanism.
2. Allocate adequate financial resources for public-sector medicines procurement and for provision of pharmaceutical services with a focus on equity and efficiency

[14] e.g. children <5yrs, women, prisoners, the poor, elderly, and marginalized groups

3. Strengthen financial management and pharmaceutical supply systems to enable effective operation and monitoring of resource utilization.
4. Develop and implement a National Medicines Pricing Policy to guide ethics and practices in pricing, with the overall aim of improving affordability of medicines.

## 3.4 Human Resources

**AIM**
Development and effective management of human resources required for delivery of pharmaceutical services

The number of appropriately trained pharmaceutical personnel will be increased to respond to existing gaps and increased demand. Appropriate skills will be developed and maintained at all levels of care and roles clearly defined. Within the public sector, personnel will be rationally deployed to meet service delivery demands.

**Actions to implement policy**

1. Develop and implement a pharmaceutical human resource development plan with an appropriate scheme of service that recognizes specialization.
2. Recruit and retain adequate numbers of pharmaceutical personnel in the public service.
3. Explore options to increase the number of pharmaceutical training opportunities at colleges and universities for basic and relevant postgraduate training, and institute mechanisms for progression from diploma to degree level.
4. Devise an appropriate system for continuous professional development.
5. Define the competencies, roles and responsibilities of pharmaceutical practitioners and effectively regulate their training and practice.
6. Develop capacity for the delivery of pharmaceutical services at all KEPH levels.

## 3.5 Research and Development (R&D)

**AIM**
Promote research on medicines and their use to address priority health issues

The MoH will stimulate and coordinate research primarily directed at effective implementation of the KNPP.

**Actions to Implement Policy**

1. Identify priority research areas to address key health needs and establish required collaborative links
2. Support and facilitate appropriate operational research and utilize research findings to further develop pharmaceutical policies and practices.
3. Encourage, motivate and support health institutions and professionals to conduct R&D on medicines including Traditional Medicine.
4. Establish and maintain a medicines research database.

## 3.6 Intersectoral and Technical Cooperation

**AIM**
Effective and sustainable technical collaboration for optimum utilization of resources in order to achieve desired health outcomes

Pharmaceutical policy implementation will be undertaken within the context of National Health Sector Strategic Plan and the Sector Wide Approach (SWAp) which is the health sector coordinating framework.

**Actions to Implement Policy**

1. Establish formal coordination mechanisms for inter-agency and inter-sectoral collaboration in pharmaceutical sub-sector initiatives and interventions.

2. Collaborate fully in regional and international initiatives for improving delivery and quality of pharmaceutical services.
3. Develop appropriate linkages between the public sector and other sectors (Faith Based Health Services, Non-Governmental Organisations and private) to enhance equitable access to medicines.
4. Develop appropriate intersectoral linkages to ensure adequate control and appropriate use of medicines for veterinary use.
5. Enhance linkages with relevant institutions and Departments to effectively address issues of drug and substance abuse.

## 3.7 Monitoring and Evaluation (M&E)

**AIM**
Effective M&E to guide pharmaceutical sub-sector development

A functional, standardized and well-resourced M&E system will be established focused on priority areas (eg. equitable medicines access for vulnerable groups) to guide and inform KNPP implementation and future revision.

**Actions to Implementation Policy**

1. Develop, implement and sustain a reliable Pharmaceutical Management Information System
2. Develop and implement guidelines for KNPP M&E, including the necessary tools and appropriate performance indicators.
3. Allocate adequate resources for M&E
4. Arrange for periodic external evaluation of KNPP implementation.

# 4. Pharmaceutical Supply System

The management of the pharmaceutical supply system varies according to the sector. In the **public sector**, essential medicines for KEPH levels II to V are procured according to the Kenya Essential Drugs List (KEDL), stored and distributed by KEMSA on behalf of the MOH. Facilities also procure using user fees especially for EMMS not available through KEMSA or items for special needs. Level VI facilities (Teaching and Referral Hospitals) procure independently. In the **private not-for-profit** sector, EMMS are procured, stored and distributed by MEDS and other not-for-profit agencies on behalf of faith-based and other health facilities. In the **private for-profit sector**, supply of medicines is managed by wholesalers and distributors.

Opportunities to strengthen the pharmaceutical supply system include updating the EDL, improving efficiency in medicines quantification, streamlining procurement procedures and processes, fully utilizing WTO TRIPS flexibilities, improving storage conditions, improving distribution functions, strengthening cGMP inspections and QC testing, establishing effective pharmacovigilance and post market surveillance systems, improving medicines disposal procedures, and controlling and integrating Traditional Medicine (TM) into the health system.

**Selection** of medicines is anchored to the KEDL and the Standard Treatment Guidelines (STGs), both updated in 2002 but not widely distributed. It is necessary to distribute them and to sensitize health workers on their importance. The **National Medicines and Therapeutics Committee** (NMTC) needs to be re-established and supported, to regularly revise these policy guides, taking into account emerging and re-emerging diseases and the changing disease management protocols.

The accuracy and applicability of **quantification** of drug needs in any system is dependent on complete,

comprehensive and reliable data. In the public sector, quantification does not generally reflect the current context and actual needs, leading to risks of medicine stock-outs, expiries and losses.

**Procurement** and **distribution** of medicines are key pillars of an effective healthcare system. KEMSA undertakes procurement and distribution centrally for Kenya's public sector, and is undergoing reform to streamline and strengthen this important function, focused on changing from the quarterly kit ('push') supply to a monthly demand-based ('pull') supply system. The process is complete for all hospitals, and is currently being implemented for rural health facilities. This requires capacity strengthening for procurement and supply management at all levels, and concurrent integration of existing parallel distribution systems that are uncoordinated, and often duplicative and wasteful. Furthermore, there is need to establish supportive linkages with the NGO and private sectors. The procurement of medicines for priority public health conditions requires special attention, in line with global and national disease control targets.

The overall **storage infrastructure** for medicines needs improvement in terms of capacity, design, maintenance and security. In the public sector, there is an on-going program to refurbish medicines storage facilities. This requires concurrent development of **guidelines and tools** and comprehensive training in medicines management, in order to improve the performance of personnel to better manage stocks and prevent losses through expiry and pilferage.

Kenya has enormous capacity for the **manufacture** of Essential Medicines both for the local and regional markets, and the local pharmaceutical industry is an important national economic component. A substantial and increasing proportion of generic medicine requirements are supplied to all sectors by local manufacturers. Incentives for the local industry have included exemptions from taxes and duties on

raw materials, excipients and packaging materials. Other possible incentives include encouraging technology transfer and international accreditation of local pharmaceutical manufacturers and full implementation of TRIPS flexibilities. Priority for these incentives should be essential medicines, and consumers should be the primary beneficiaries.

Regardless of their origin, all medicines marketed in the country must be registered by the PPB. **Quality assurance** involves a combination of current Good Manufacturing Practices (cGMP) inspections, Good Pharmaceutical Procurement Practice (GPPP) by the procurement agencies, and quality control (QC) testing by recognized QC institutions. The PPB has the central role of assuring the quality of all pharmaceuticals on the Kenyan market. Strengthening of this QA function would focus on appropriate standardization and enforcement of quality standards, increasing awareness of quality issues among consumers; and establishing a QA system for the entire pharmaceutical service delivery system, including training, dispensing, prescribing, and pharmaceutical care.

In the public sector, **disposal** of unwanted EMMS is guided by MoH guidelines and the 2005 Procurement and Disposal Act. However, the guidelines are complex and cumbersome, thus most medicines disposal is still an *ad hoc* activity undertaken only when there is an urgent need to deal with accumulated, expired or otherwise unwanted items. There is need to streamline the procedures for medicines disposal, and to enhance collaboration between MOH and other relevant authorities.

**Traditional medicines** (TM) are an essential part of the national culture and WHO estimates that 80% of people in Africa use traditional medicines as part of primary health care. Despite their widespread use, comprehensive documentation on TM use, safety, efficacy and quality is lacking. The MOH wishes to integrate TM into the healthcare system, and the policy and legislative framework necessary

to guide their use are under development. Therefore all the requirements, procedures and practices applicable to the EMMS are also relevant for the supply of traditional, complementary & alternative (CAM) as well as herbal medicines.

## 4.1 Selection

**AIM**
Evidence-based selection of medicines
to meet public health needs

The Ministry of Health will determine the range of medicines to be marketed in the country, based on defined criteria[15]. The Essential Medicines concept as defined by WHO will be the basis for medicines selection.

**Actions to Implement Policy**

1. Establish and effectively support the functioning of national and institutional Medicines and Therapeutic Committees (MTC).
2. Review and regularly update the KEML, develop the KEMSL and promote their use at all levels of the health system.
3. Develop an IEC programme to improve the understanding of the Essential Medicines concept amongst health workers, patients and the public.
4. Incorporate the Essential Medicines concept in training curricula for health workers to support the evidence-based selection process and appropriate medicines utilisation
5. Promote the Essential Medicines concept and evidence-based selection of medicines in the private sector

[15] Safety, efficacy, quality, therapeutic need, level of care, affordability and appropriateness

## 4.2 Quantification

**AIM**
Reliable quantification of medicines needs at all levels as the basis for rational procurement

Quantification is an integral part of the supply process. Adequate capacity will be developed at all levels to enable reliable estimation of needs.

**Actions to Implement Policy**

1. Develop an effective LMIS to support quantification
2. Operationalize an appropriate and reliable quantification system at all levels of care, and enhance linkages with the private sector.

## 4.3 Procurement

**AIM**
Required Essential Medicines procured at the best possible price in a timely and transparent manner

Medicines procurement will follow GPPP and applicable laws and regulations, taking full benefit of the relevant TRIPS provisions and safeguards.

**Actions to Implement Policy**

1. Strengthen and sustain a centralized, coordinated, autonomous, primary procurement agency for integrated public-sector bulk medicines procurement and supply.
2. Integrate and harmonize existing public sector parallel procurement activities to optimize procurement efficiency and effectiveness, and secure consistent access to medicines for priority public health needs.
3. Define and implement an effective financing system to support rational procurement.

4. Develop and support pharmaceutical procurement capacity, including application of relevant TRIPS provisions, at all relevant KEPH service delivery levels.
5. Prepare national and institutional procurement plans based on reliable quantification.
6. Review, update and effectively implement medicines donation guidelines.
7. Develop an effective system for the procurement of medicines for disasters and emergencies.
8. Encourage linkages between procuring agencies including pooled procurement at institutional and sub-regional levels.

## 4.3 Storage and Inventory Management

**AIM**
Quality, security and appropriate stock of medicines maintained at all levels of the supply chain up to the point of use

Pharmaceutical storage infrastructure will be improved and maintained. An effective storage and inventory management system will be developed and applied at all levels.

**Actions to Implement Policy**

1. Assess pharmaceutical storage infrastructure; develop and implement an infrastructure improvement and maintenance plan.
2. Develop an effective LMIS to support inventory management
3. Develop and implement standard operating procedures for storage and inventory management.
4. Upgrade and standardize tools, equipment and systems for effective inventory management

## 4.4 Distribution

**AIM**
The continuous availability of required medicines at all levels in accordance with Good Distribution Practice (GDP)

Pharmaceutical distribution systems will maintain the quality and security of medicines throughout the supply chain and generate required records.

**Actions to Implement Policy**

1. Develop an effective LMIS to support distribution
2. Operationalize guidelines and procedures for GDP including an efficient pharmaceutical recall system
3. Enhance compliance with legal requirements for medicines transportation

## 4.5 Local Production

**AIM**
Self-sufficiency in Essential Medicines production and growth in pharmaceutical exports

To improve domestic accessibility of Essential Medicines and promote pharmaceutical exports, the government will ensure an enabling environment for local pharmaceutical production.

**Actions to Implement Policy**

1. Strengthen capacity for cGMP compliance and encourage international accreditation for local manufacturers.
2. Provide incentives for local pharmaceutical production of essential medicines to improve their affordability and availability
3. Effectively utilize WTO/TRIPS flexibilities to promote local manufacture of Essential Medicines and other products and technologies of public health importance.

## 4.6 Quality Assurance (QA)

**AIM**
Quality, safe and efficacious medicines are provided according to legal requirements and professional standards

Medicines shall meet internationally acceptable standards of quality, safety and efficacy, and shall be provided according to legal requirements and professional standards.

**Actions to Implement Policy**

1. Develop and implement a coherent national pharmaceutical QA system.
2. Enhance the capacity for, and collaboration in, pharmaceutical quality control
3. Develop and promote the use of quality management principles with regard to pharmaceutical quality assurance in the public and private sectors.
4. Enhance the participation of the pharmaceutical industry, the private sector, health professionals and consumers in post-market surveillance and pharmacovigilance.

## 4.7 Disposal Management

**AIM**
Safe, environmentally-appropriate disposal of pharmaceutical waste

Pharmaceutical waste shall be disposed of according to nationally and internationally acceptable standards.

**Actions to Implement Policy**

1. Assess the nature and extent of pharmaceutical waste.
2. Review, revise, disseminate and implement guidelines on safe disposal of pharmaceutical waste.

## 4.8 Traditional Medicines[16]

**AIM**
Appropriate use of safe, quality and efficacious traditional medicines

The MOH will ensure appropriate utilization of TM in such a way as to reduce the risks and maximize the benefits involved in their use.

**Actions to Implement Policy**

1. Establish a unit within the MOH to coordinate TM activities.
2. Identify key risk areas in TM utilization and develop mechanisms to mitigate them.
3. Develop and implement guidelines on provision and use of human and veterinary TM.
4. Promote the local production of useful and commercially viable TM for human and veterinary use.

[16] Traditional Medicines includes Traditional, Complementary/Alternative & Herbal Medicines (TCAM)

# 5. Appropriate Medicines Use (AMU)

In 1985 the historic '*Conference of Experts on Rational Use of Medicines'* was convened in Nairobi, and the importance of rational prescribing, appropriate dispensing and use of medicines were highlighted on the international stage. Concepts of 'inappropriate use' were agreed upon, including overuse of antibiotics, unnecessary use of injections, and unwarranted polypharmacy. Such practices were shown to lead to significant wastage of scarce resources for health, poor patient outcomes, and increased adverse effects.

Since the landmark meeting in 1985, various strategies have been identified globally for improving prescribing and dispensing by health workers, clinical practices of pharmaceutical personnel and the use of medicine by consumers. These include:

- **Medicines and Therapeutic Committees (MTCs):** National and institutional level MTCs can guide proper prescribing and medicines use.
- **Pharmaceutical Care:** A comprehensive model for patient-focused practice of pharmacy that ensures the most appropriate medicines are effectively used and the patient is actively involved in ensuring successful therapeutic outcomes.
- **Consumer Empowerment:** Knowledgeable consumers are more likely to proactively participate in their health care. The health system can benefit from opportunities for consumer feedback on medicines issues, through appropriately supported channels.
- **Information, Education and Communication (IEC):** A coherent national level campaign targeting the community with unbiased, relevant and practical information on medicines use.

**Appropriate Medicines Use** leads to improved patient care and safety, and is a crucial requirement in managing scarce resources for health. In Kenya the various contributing factors to be addressed to improve medicines use include:

- Evidence based selection from the wide range of products available on the market, to minimize challenges for prescribers and patients
- effective regulation and standardization of dispensing practices
- access to objective, practical information on medicines and their proper use
- Appropriate training of health workers on appropriate medicines use
- Addressing equity issues in the provision of medicines, to minimize out-of-pocket financing for medicines

There are **initiatives** to implement these strategies in Kenya, with varying results. These need to be consolidated and expanded into a comprehensive programme that addresses AMU throughout the entire health system.

Many **consumers** today are knowledgeable about the diseases that affect them, the therapeutic alternatives, and their right to participate in decisions about their care. **Pharmaceutical care** has been widely acknowledged as the most comprehensive practice approach for pharmaceutical personnel to provide patient-centered, outcome-based care, and it is applicable in hospital and community pharmacy settings.

To institutionalize pharmaceutical care requires committed and motivated pharmaceutical personnel, adequate support and capacity building (including financial and human resources, tools and training), promotion and advocacy and commitment from professional associations, the government and training institutions. Also important is a comprehensive **medicines information** system,

incorporating regulation of medicines promotion and advertising, and a dedicated national centre for medicines and poisons information, as a source of unbiased medicines information for health providers and consumers.

**Prescribing** is a professional function that must focus on the patient's best interest in terms of appropriate therapy, safety, efficacy and cost effectiveness. Prescribing practice benefits from monitoring and feedback mechanisms that promote adherence to treatment guidelines and positive lists. STGs and the KEDL are key tools for good prescribing, and their impact needs to be enhanced through adequate dissemination, sensitization and an effective system for monitoring and enforcing their use.

Appropriate **dispensing** is should ensure patient safety; promote patients' understanding of, and the appropriate use of medicines. Appropriate tools, proper training and standardization of practice, and an effective regulatory framework are important pillars for good dispensing practice. Of importance is ensuring that consumers access medicines only from authorized dispensing outlets.

Consumers are vulnerable to receiving biased information and inappropriate claims often emanating from unauthorized medicines outlets, unscrupulous producers and distributors of medicines and uninformed media sources. Accurate, accessible, objective and practical information about medicines, including prices can greatly improve **medicines use by consumers**. At the national level, this would require an IEC strategy for medicines use, communicated in a culturally appropriate manner. Appropriate linkages between the PPB and relevant consumer organizations could assist in the implementation of such a strategy.

## 5.1 Pharmaceutical Care

**AIM**
Patient-centered pharmaceutical service for improved therapeutic outcomes

Pharmaceutical personnel will be key members of the therapeutic team, with the patient as the primary focus in pharmaceutical service provision.

**Actions to Implement Policy**

1. Develop and implement a strategy for institutionalization of pharmaceutical care, including guidelines, tools and skills
2. Promote the application of pharmaceutical care principles throughout the health system

## 5.2 Medicine and Therapeutics Information (MTI)

**AIM**
Access to medicines and therapeutics information that is unbiased, accurate and practical

Relevant, practical and unbiased information will be made readily accessible to health professionals to optimize therapeutic outcomes and use of resources

**Actions to Implement Policy**

1. Develop, review and disseminate required MTI, including national EMLs, clinical guidelines, formularies and bulletins, with an initial focus on primary care levels.
2. Support institutional MTCs for improved therapeutic practice and medicines utilization
3. Establish and support an effective National Medicines and Poisons Information Service

## 5.2 Prescribing

**AIM**
Appropriate prescribing contributing to optimal therapy

Prescribing will be according to legal provisions and Good Prescribing Practice

**Actions to Implement Policy**

1. Develop and promote guidelines for Good Prescribing Practice including prescribing by International Non-proprietary name (INN).
2. Support assessment and improvement of prescribing practices in line with the guidelines and coordinated by institutional MTCs.
3. Collaborate with the relevant ministries to ensure that veterinary prescribing conforms to this policy.

## 5.3 Dispensing

**AIM**
Appropriate dispensing contributing to optimal therapy

Dispensing will be according to legal provisions and Good Dispensing Practice. Generic substitution will be used as a means of increasing accessibility and affordability of essential medicines

**Actions to Implement Policy**

1. Develop and promote guidelines for Good Dispensing Practice (including generic substitution) in all sectors.
2. Support assessment and improvement of dispensing practices in line with the guidelines and coordinated by institutional MTCs.
3. Develop and implement standard operating procedures for the operationalisation of GDP at all KEPH levels and in all medicines outlets.

## 5.4 Medicines Use by Consumers

| **AIM** |
| --- |
| Appropriate use of medicines by consumers |

Relevant and unbiased information will be made available to enable consumers to use prescribed and 'over the counter' medicines in order to maximize the therapeutic benefits and minimize any associated risks.

**Actions to Implement Policy**

1. Formulate and implement an effective IEC strategy for the promotion of AMU by consumers.
2. Strengthen regulation of medicines advertising and promotion including TM and veterinary medicines.
3. Establish an effective mechanism for consumer feedback and complaints on medicines issues.
4. Involve consumers and other relevant stakeholders in AMU and provision of medicines information.

# Annex 1: Glossary

**Appropriate Medicines Use (AMU):** this occurs when consumers receive medicines:

- meeting their clinical need (i.e. the right medicine for the right condition)
- in a suitable form for administration (i.e. the right dose-form)
- in doses meeting their individual requirements (i.e. the right dose)
- for an adequate period (i.e. the right duration)
- with all the necessary advice on correct use and storage (i.e. the right information)
- at the lowest possible cost to them and their community (i.e. the right price)

. . . and adhere to the recommended treatment

**Complementary / Alternative Medicines (CAM)** is a group of diverse medicines not presently considered to be part of the conventional medicine system. For most CAM there is no scientific evidence of safety or efficacy. Those which are proven to be safe and effective may become adopted into conventional health care. **Complementary medicine** is used *together with* conventional medicine, e.g. use of aromatherapy to help lessen a patient's discomfort following surgery; **Alternative medicine** is used *in place of* conventional medicine, e.g. using acupuncture to relieve pain instead of taking medicine.

**Generic substitution** is the statutorily permitted substitution of a prescription medicine as prescribed by an authorized (registered) medical, dental or veterinary practitioner using a trade or brand name with a therapeutically equivalent generic medicine. This may only be done by an authorized (registered) pharmacist within the context of dispensing practice.

**Good Dispensing Practice** encompasses:

- Appropriate premises (safety, security, size, design, environment, condition, tidiness)
- Required equipment, consumables (e.g. containers, labels) and reference materials
- Effective and reliable medicines supply management system including stock management
- Complete and accurate stock and dispensing records
- Systematic, methodical and safe dispensing procedures including patient counseling
- Use of generic names and appropriate generic substitution
- Complete adherence to regulatory requirements including medicines schedules
- Proper pharmaceutical waste management
- Effective prescription monitoring and incident recording/reporting systems
- Provision of relevant and practical medicines and health-related information for consumers and health professionals
- Commitment to continuing professional development
- Professional and productive relationships with consumers and other health care professionals
- Sound administration and management structure to ensure efficiency and clear lines of accountability

**Good Pharmaceutical Distribution Practice** encompasses:

- Efficient storage facilities network with fewest number & levels appropriate to geography
- Appropriate delivery strategy
- Reliable stocks & consumption records
- Supplies allocation based on actual workload & treatment needs
- Maintaining accountability procedures & storage security at each level
- Construction/renovation of appropriate storage facilities
- Reliable transport arrangements
- Effective reporting & supervision arrangements

**Good Pharmaceutical Procurement Practice** encompasses:

- Purchasing only registered KEML, KEMSL and KVEML items by generic name
- Order quantities based on reliable needs quantification
- Complete, comprehensive and accurate technical specifications for items to be procured
- Competitive tendering from pre-qualified suppliers
- Thorough technical evaluation of bids by competent professionals including quality control testing where required
- Separation of key procurement functions and regular audits
- Prompt payment of suppliers
- Formal supplier qualification & monitoring system

**Good Manufacturing Practice (GMP):** involves meeting performance standards established by WHO and the Government including criteria for: - Personnel, Facilities, Equipment, Materials, Manufacturing operations, Labeling, Packaging, Quality control and Stability testing.

**Good Prescribing Practice** means prescribing medicines by generic name in accordance with evidence-based guidelines to ensure safe, effective and economic use. This will ensure that the correct medicine in the most appropriate presentation (dose-form) is prescribed in the correct dose regime (dose quantity, frequency and duration) together with complete, practical patient counseling to ensure appropriate use and adherence to the treatment regime.

**Healthy Life Expectancy** (HALE) or Disability Adjusted Life Expectancy is a WHO summary measure of the level of health that captures the full health experience of the population, and not just mortality. It is a measure of life expectancy adjusted for non-fatal outcomes, and is used to assess health systems performance. It is most easily understood as the lifespan in full health, i.e. without

disability.
(see http://www.euro.who.int/document/ehr/e76907d.pdf)

**Herbal medicines** include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations.

**International dollar** is a hypothetical unit of currency with the same purchasing power of that the US dollar has in the United States at a given point in time, i.e. the US dollar converted at purchasing power parity (PPP) exchange rates. It shows how much a local currency unit is worth within the country's borders and is used to make comparisons both between countries and over time. While not in widespread use, the term is sometimes used by international organizations such as the World Bank and the International Monetary Fund in their published statistics. Figures expressed in international dollars cannot be converted to another country's currency using current market exchange rates; instead they must be converted using the country's PPP exchange rate used in the study.

**International Non-proprietary Name (INN) or Generic name** is the official (WHO-assigned) name of a medicine, regardless of who makes or sells it. Use of generic names (rather than a brand name) facilitates identification, simplifies purchasing, may lead to cost savings (generic products are often cheaper than their branded equivalents), and use in prescribing enables generic substitution

**Medicines:** The term ‘medicines’, as used throughout this document, supersedes the term ‘drugs’ and is taken to mean medicines and medical supplies, e.g. surgical consumables such as dressings, syringes and catheters. It is used synonymously with the term ‘pharmaceuticals’.

**Medicines outlet** denotes any place where medicines are made available to the public. They include hospitals, clinics,

health centres, dispensaries and pharmacies. General outlets (e.g. groceries and supermarkets) may also function as medicines outlets, but only for defined 'over-the-counter medicines', e.g. Aspirin and paracetamol

**Medicines Regulatory Agency (MRA)**[17]
This is the agency established by law with responsibility for ensuring effective implementation of all laws and regulations related to:- licensing, inspection and control of pharmaceutical professionals, practice and facilities; availability, marketing, prescribing, labeling, dispensing of human, veterinary, traditional/herbal, complementary/alternative medicines and medical supplies; and conduct of clinical trials.

In performing its mandate the MRA in Kenya would undertake the following:- registration, post-market surveillance and quality control of medicines and medical supplies; inspection and licensing of local pharmaceutical premises and operations (retail, wholesale & manufacturing); cGMP inspection of foreign pharmaceutical manufacturing premises and operations; inspection, approval and licensing of pharmaceutical training institutions and monitoring/maintenance of training standards; monitoring of adverse drug reactions; provision of pharmaceutical regulatory information and monitoring and control of medicines import and export

**Nutraceutical** is a food or part of a food that provides or is claimed to provide medicinal or health benefits, including prevention and treatment of disease

**Pharmaceuticals:** the term 'pharmaceuticals', as used in this document, is synonymous with the term 'medicines', as defined elsewhere in the glossary.

[17] In Kenya, this is the Pharmacy and Poisons Board

**Pharmaceutical Care** may be defined as the responsible provision of pharmacotherapy to achieve definite outcomes that improve or maintain a patient's quality of life[18]; a collaborative process to prevent or identify and solve medicines and health problems and a continuous quality improvement process for the use of medicinal products

**Pharmaceutical services** are the sum total of all the practices, procedures and processes required to obtain medicines, provide them to the consumer and ensure their appropriate use. In the Kenya public health sector these services relate specifically to Essential Medicines and Medical Supplies.

**Quality Assurance**: is the sum total of all pharmaceutical management activities required to ensure that a medicine reaches the patient is safe, effective and acceptable to the patient. This includes such areas as procurement, manufacturing and **quality control** testing (testing of medicines samples against specific quality standards).

**Total Quality Management** is a comprehensive and structured approach to organizational management that seeks to improve the quality of products and services through ongoing refinements in response to continuous feedback from consumers. TQM requirements can be applied to any type of organization, and they may be defined separately for a particular organization or may be in adherence to established standards, such as the International Organization for Standardization's ISO 9000 series.

**Traditional medicines (TM)** are those medicines based on the theories, beliefs, and experiences *indigenous* to different

[18] Hepler CD & Strand LM. Opportunities and responsibilities in pharmaceutical care. American Journal of Health Systems Pharmacy 1990; 47: 533-543

cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. They include indigenous herbal medicines.

# Annex 2: Technical Working Group Contributors

Following are the participants of the two KNPP Technical Working Group policy review and formulation retreats which took place at (1) Nyeri Outspan Hotel 8-12 May 2006 and/or (2) Naivasha Country Club 4-6 September 2006:

1. Dr Josphat Mbuva, Deputy Chief Pharmacist MoH(1)(2)
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3. Dr Michael Thuo, Regional Technical Advisor, MSH RPM-plus (1)(2)
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7. Dr Chris Forshaw, Pharmaceutical Advisor, MoH/Danida HSPS (1)(2)
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10. Mr Erastus Ndumbi, Acting Chief Pharmaceutical Technologist, MoH (1)(2)
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15. Dr Mwenda Riungu, MEDS (1)(2)
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35. Dr Abel Nyakiongora, District Medical Officer of Health, Mt Elgon (2)
36. Dr Benedict Munyaka, Pharmacist Mwingi District Hospital (2)
37. Dr Joseph Mukoko, MSH-RPM PLUS (2)
38. Dr William Mwatu, Kenya Association of Pharmaceutical Industry (2)

# Annex 3: Key Documents

The primary documents utilized in the development of the KNPP were as follows:

1. Kenya National Drug Policy (KNDP) Ministry of Health (1994)

2. WHO Guidelines for Developing National Drug Policies (1998)

3. Consultancy to Review The National Drug Policy, Law and Regulation: Final Report (Eurohealth 2005)

4. Consultancy on Access and Institutional Capacity Assessment in Kenya: Final Report Vol 1: Access to Essential Medicines (HERA/ETC/PWC 2005)

5. Consultancy on Pharmaceutical Institutional Capacity Assessment in Kenya: Final Report Vol 2: Institutional Capacity of MOH, PPB, KEMSA (HERA/ETC/PWC 2005)

6. Consultancy on Evaluating/Improving Quality Assurance and Sustainability in the Medical Supplies Sub-Sector in Kenya: Final Report Vols 1 and 2: Quality Assurance (HERA/ETC/PWC 2005)

7. Consultancy to Strengthen the Rational Use of Drugs in Kenya (Final Report) (HERA/ETC/PWC 2005)

8. Kenya Pharmaceutical Review - Procurement and Logistics (Final Report) (HERA/ETC/PWC 2005)

9. Towards a Strategic Framework for Reforming the Pharmaceutical Sector in Kenya (Fastmed Pharma Health Consultants, gtz 2005)

10. National Health Sector Strategic Plan II (2005-2010), Ministry of Health

11. Annual Operational Plan (AOP) 1, Ministry of Health (2005/6)

12. Reversing the Trends, The Second National Health Sector Strategic Plan of Kenya, Annual Operational Plan 2, 2006/07 (MoH June 2006)

13. Kenya Health Policy Framework (MOH 1994)

14. Baseline Survey of the Pharmaceutical Sector (WHO/HAI/MOH 2003)

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