REPUBLIC OF KENYA

MINISTRY OF MEDICAL SERVICES AND
MINISTRY OF PUBLIC HEALTH AND SANITATION

# Sessional Paper No 4 of 2012

# on

# NATIONAL PHARMACEUTICAL POLICY

**Reforming the pharmaceutical sector to ensure equitable access to Essential Health Products and Technologies for all Kenyans**

**JULY 2012**

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CONTENTS

## ABBREVIATIONS

| | |
|---|---|
| ADR | Adverse Drug Reaction |
| AMU | Appropriate Medicines Use |
| API | Active Pharmaceutical Ingredient |
| ARVs | Anti-Retroviral (medicines) |
| AWP | Annual Work Plan |
| CDF | Constituency Development Fund |
| cGMP | current Good Manufacturing Practice |
| COMESA | Common Market for Eastern and Southern Africa |
| CPD | Continuous Professional Development |
| DMS | Director of Pharmaceutical Services |
| DP | Development Partners |
| DPS | Director of Pharmaceutical Services |
| DVS | Director of Veterinary Services |
| EAC | East African Community |
| EMMS | Essential Medicines & Medical Supplies |
| ERBs | Ethical Review Boards |
| FBHS | Faith-Based Health Services |
| FDA | Food and Drug Authority |
| FKPM | Federation of Kenya Pharmaceutical Manufacturers |
| FTAs | Free Trade Agreements |
| HPT | Health Products and Technologies |
| ICC | Inter-Agency Coordinating Committee |
| ICT | Information and Communication Technology |
| IDF | Import Declaration Form |
| INN | International Non-proprietary Name |
| IP | Intellectual Property |
| GDP | Good Dispensing Practice/Good Distribution Practices/ Gross Domestic Product |
| GHE | Government Health Expenditure |
| GPP | Good Pharmaceutical Procurement (principles) |
| GSPOA | Global Strategy and Plan of Action (on public health, innovation and IP) |
| HSSF | Health Sector Services Fund |
| ISO | International Organization for Standardization |
| KEBS | Kenya Bureau of Standards |

| | |
|---|---|
| KEML | Kenya Essential Medicines List |
| KEMRI | Kenya Medical Research Institute |
| KEMSA | Kenya Medical Supplies Agency |
| KEMSL | Kenya Essential Medical Supplies List |
| KEPH | Kenya Essential Package for Health |
| KHSSP | Kenya health Sector Strategic Plan |
| KNDP | Kenya National Drug Policy (1994) |
| MEDS | Mission for Essential Drugs & Supplies |
| MDGs | Millennium Development Goals |
| MDR TB | Multi-Drug Resistant Tuberculosis |
| MoU | Memorandum of Understanding |
| MTC | Medicines and Therapeutics Committee |
| MTEF | Medium Term Expenditure Framework |
| NACADA | National Campaign Against Drug Abuse Authority |
| NCDs | Non-Communicable Diseases |
| NMTC | National Medicines and Therapeutics Committee |
| NQCL | National Quality Control Laboratory |
| OTC | Over-The-Counter (medicine) |
| OIE | World Organization for Animal Health (formerly Office International des Epizooties) |
| PHI | Public Health Inspector |
| PICC | Pharmaceutical Interagency Coordinating Committee |
| PPDA | Public Procurement and Disposal Act |
| PPB | Pharmacy & Poisons Board |
| PSK | Pharmaceutical Society of Kenya |
| QA | Quality Assurance |
| R&D | Research and Development |
| SWAp | Sector-Wide Approach |
| THE | Total Health Expenditure |
| TM | Traditional Medicine |
| TRIPS | Trade-related aspects of Intellectual Property Rights |
| USFDA | United States Food and Drugs Agency |
| VMTC | Veterinary Medicines and Therapeutics Committee |
| WHO | World Health Organization |
| WTO | World Trade Organization |



## FOREWORD

Kenya adopted the first National Drug Policy (KNDP) in 1994, concurrently with the Health Policy Framework (KHPF), to guide much-needed reform on pharmaceuticals. However implementation of the KNDP was severely hampered by subsequent lack of the requisite legal, administrative and financial support. Over the years, the urgency to reform the sector steadily increased, as documented in extensive sector reviews and assessments.

The process of developing this pharmaceutical policy started in 2006, informed by the existing evidence and guided by global technical norms; and was characterized by extensive stakeholder consultations and consensus building at multiple levels. The draft policy was adopted by national stakeholders in August 2007, and subsequently, in response to the renewed momentum of political and constitutional reforms in the country, it was further reviewed and adopted in April 2009. Subsequently, this Sessional Paper was developed and aligned to the new Constitution; and approved for presentation to Parliament at the Cabinet meeting held on 19th January 2012.

The scope of the Policy encompasses medicines and other health products and technologies – for human and veterinary use - whose development, production, sale and distribution are the mainstay of the pharmaceutical and allied sectors. It provides for the legal and institutional reforms necessary to radically improve the performance of the pharmaceutical sector in Kenya, in particular to enhance governance of pharmaceuticals across sectors; regional and international arenas; restructure national institutions for the procurement, supply, regulation and quality control of medicines and other health products; develop adequate human resources for the diverse needs and functions, and enhance partnerships and collaboration aimed at universal access to Essential Health Products and Technologies.

This Policy was developed in the context of, and aligned to, a concurrent revision of the Health Policy Framework (1994) and subsequent harmonization of national health laws. Consequently, implementation of the health policy, legal and strategic framework is expected to fully integrate the KNPP provisions. In addition, it is important to note that the KNPP is a national guide for policy actions across many sectors. The policies outlined herein apply not only to pharmaceuticals, but to all health products and technologies intended for use or application in the attainment of health. We recommend that all relevant ministries, departments,

partners, NGOs and other stakeholders focus their efforts on implementation of this Policy, in order to attain the policy goal of "*Universal Access to quality essential health products and technologies; and pharmaceutical services in Kenya*".

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## PREAMBLE

This Policy, to be known as the Kenya National Pharmaceutical Policy (KNPP) succeeds the Kenya National Drug Policy (KNDP) of 1994. It builds on the strengths of the KNDP, and expands the scope by capturing the complexities and dynamics of the pharmaceutical sector, and defining a policy framework that is integrated within overall government policy framework. The Policy is a guide for reforms that are necessary to be undertaken on pharmaceuticals, so as to attain national health and economic goals, in particular, equitable access to essential medicines, health products and technologies for the population.

The Policy is premised on the principles of human rights, good governance, partnerships, effective regulation and international collaboration. The Policy upholds fundamental human rights, in particular the right to health, including the right to access essential medicines. It defines the scope of essential medicines, and outlines key strategies to ensure that they are available and affordable; that they meet defined standards of quality, efficacy and safety; and that they are appropriately utilized.

The Policy recognizes that the pharmaceutical sector is a distinct economic entity, with multi-dimensional aspects that have a direct impact on the health and safety of the population, as well as on the national economy, international trade and cooperation. Therefore, enhanced government focus, institutional and regulatory strengthening and development of specialized technical skills are critical for the development of this sector. Regional and international trends continue to impact on the sector in Kenya, such as growth of the local industry; the country's role in regional and international trade in pharmaceuticals; technological advancements in the pharmaceutical industry; and the global focus on control and elimination of diseases. All these factors shape the direction of sector investments and human resources development, and impact on access to essential health products and technologies by the population.

This Policy has been developed in the context of Kenya's Vision 2030, the Kenya Health Policy (2012-2030) and the relevant health sector strategic plans; as well as trends in regional integration. It provides for broad restructuring of governance structures for HPT, including the necessary de-linking, upgrading and decentralization, and alignment with health sector orientations. It further outlines the health and development goals; objectives and targets; and key strategies to guide its implementation.

Implementation of this Policy will be through a multi-sectoral and integrated approach. In this regard, the Government will provide the necessary enabling environment and infrastructure for its implementation; and collaborate with the faith-based, NGO and private sector players; communities and civil society; as well as other governments, and relevant regional and international bodies. In particular, restructuring of governance and institutional structures will be prioritized, through enactment of relevant legal instruments, to facilitate implementation of the various strategies and attainment of the Policy Vision.

**A Note on Scope and Application of the KNPP (2012):** The Kenya Health Policy (2012-2030) adopts the health systems framework, in which the health sector is organized around seven 'health systems building blocks' as the key policy orientations for health investment: i.e. i) health leadership & governance ii) health financing iii) service delivery systems iv) health products & technologies v) health infrastructure vi) health workforce and vii) health information. Within this framework, *health products and technologies* (HPT) encompasses those products intended for use or application in the attainment of health, with pharmaceuticals as the core HPT. In this context, the principles and norms applicable to pharmaceutical policies are equally adaptable to other HPT and the critical pharmaceutical sector issues outlined in the KNPP cut across all the health systems building blocks. Therefore the KNPP has broad application as a policy guide on issues affecting HPT within the Health Policy and reference to 'pharmaceuticals' or 'medicines' in these policy documents should be interpreted - as far as is applicable - within the broad health systems context of HPT.



# 1 INTRODUCTION

## 1.1 THE PROBLEM

1. Pharmaceuticals are critical to the economic and social development of Kenya. Medicines treat diseases, save lives and promote health, and they are a core component of the Right to Health. However, medicines can be poisonous and have the potential to cause serious harm or death - if prescribed, dispensed or taken inappropriately; or if their quality and safety are not assured. Pharmaceuticals are specialized and costly goods, being a major component of local and international trade; a major health investment for Government and development partners; and key health expenditure for households.

2. The pharmaceutical sector in Kenya is part of a specialized and highly globalized industry, in which pharmaceutical *research, products, trade, personnel* and *services* are intrinsically linked in a complex and dynamic matrix of health, economic and political issues; each with national, regional and global dimensions. This multi-dimensional nature encompasses numerous externalities, often conflicting with public health principles for ensuring equitable access to essential medicines.

3. Ensuring access to medicines is one of the targets of the Millennium Development Goals (MDGs). Access has multiple dimensions, i.e. *availability, geographical proximity, affordability, safety, efficacy, quality*; *appropriateness and rational use*. These dimensions apply equally to medicines, medical supplies and other health technologies; and similar principles apply to veterinary medicines. A critical step towards the attainment of universal access to medicines is a comprehensive policy guidance encompassing all access dimensions.

4. Kenya adopted its first national drug policy in 1994. Although the policy realized some achievements, its implementation was constrained by lack of an enabling legal and institutional framework. Therefore, policy and strategic direction for the pharmaceutical sector has remained weak, with low prioritization in health decision making and failure to address the rapid development and externalities of the sector. Pharmaceutical sector problems have manifested in stock-outs of essential medicines, high medicine prices, incidences of counterfeit and substandard medicines,

unauthorized dispensing and unlicensed outlets; and inappropriate medicines utilization leading to wastage and poor health outcomes. These hinder universal access to human and veterinary essential medicines in Kenya, and consequently, lack of attainment of national health goals.

## 1.2 POLICY PRINCIPLES

5. The Policy is based on the following guiding principles:

a) The **Right to Health:** Access to essential medicines is an integral part of the fundamental right to health enshrined in the Constitution. The Policy provides for strategies to ensure equitable access to essential medicines, particularly for vulnerable population groups.

b) The concept of **Essential Medicines:** defined as "*those that satisfy the priority health care needs of the population; 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*" [1].

c) **Good Governance:** The medicines and health products supply chain is vulnerable to inefficiency and unethical practices, with adverse consequences for Government, individuals and healthcare providers. **Good Governance** in the pharmaceutical sector entails efficiency, transparency, accountability, institutional integrity and moral leadership. Checks and balances are required at each step in the product development and supply chain.

d) **Effective Partnerships:** The Policy affirms the importance of stakeholder involvement and coordination; aligns partnership coordination on pharmaceuticals with the current health sector coordinating framework and outlines key roles and obligations

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*WHO Policy Perspectives on Medicines - Equitable access to essential medicines: a framework for collective action* (WHO, March 2004)



of stakeholders, as well as a framework for measuring progress in policy implementation.

e) **Multi-Sector and International Collaboration:** The pharmaceutical sector is a distinct economic entity with linkages across several sectors and operating in a highly globalized and interconnected manner. Multi-sector and international collaboration and cooperation are essential to comprehensively address the intricate and complex issues; and to safeguard public health and safety.

f) **Regulation:** The process by which consumers obtain pharmaceuticals is complex. It involves several intermediaries and has inherent moral hazards and information asymmetries. Pharmaceutical systems do not always guarantee rational decision-making that primarily benefits the consumer. Therefore, strong regulatory enforcement is required to safeguard the interests of the consumer.

## 1.3 VISION, GOAL, OBJECTIVES AND STRUCTURE OF THE POLICY

### 1.3.1 Vision of the Policy

6. To be a well-governed pharmaceutical sector making essential medicines and health technologies accessible to all Kenyans and contributing to social and economic development.

7. Universal Access to quality essential medicines, essential health technologies and pharmaceutical services in Kenya

8. The overall objective of the Policy is *to ensure equitable access to essential medicines through the public, faith-based, NGO and private providers.* Specific objectives are to:

1. Ensure continuous availability of safe and effective essential medicines and medical supplies especially in the public sector.
2. Ensure the quality, safety and efficacy of human and veterinary drugs in Kenya, in line with internationally acceptable standards.
3. Ensure appropriate regulation and control of biological products, medical devices, tobacco products, cosmetics and

products that emit radiation, to ensure their safety to humans and animals.

4. Encourage local manufacture of essential medicines for self-sufficiency in the domestic market and to promote growth in pharmaceutical exports.
5. Promote good prescribing and dispensing of medicines and their appropriate use.
6. Encourage development and appropriate regulation of traditional/herbal medicines in line with national health goals.
7. Develop adequate and appropriate human resources to meet the needs of the pharmaceutical sector.
8. Increase and strengthen institutional, technical and human resource capacity for the effective provision of pharmaceutical services.
9. Enhance transparency, accountability and good governance on pharmaceuticals.
10. Promote and effectively regulate pharmaceutical research and innovations that make medicines and health technologies more effective, safer and more affordable.
11. Increase and strengthen institutional, technical and human resource capacity for effective management and regulation of veterinary pharmaceutical products.

### 1.3.4 Structure of the Pharmaceutical Policy

9. This Policy is organized into five Chapters.

**Chapter 1:** Introduces the need for a pharmaceutical policy and outlines the problem, policy principles, vision and objectives.

**Chapter 2:** Focuses on the pharmaceutical sector in Kenya, and the justification for the pharmaceutical policy reform; outlines the rationale for the pharmaceutical policy, highlighting past efforts, constraints and challenges faced to date.

**Chapter 3:** Constitutes the main body of the Policy, outlines the key challenges in each policy area, and sets out the policy statements. Institutional and legal arrangements specific to each policy area are addressed within the relevant sub-section.



**Chapter 4:** Outlines the requisite legal and institutional reform expected on implementation of the Policy.

**Chapter 5:** Outlines the implementation arrangements for ensuring integration of this Policy within existing health governance and coordinating framework.

**Annexes:** Key facts and figures, glossary of terms and the policy development process.

### 1.3.5 Review of the Pharmaceutical Policy

10. The National Pharmaceutical Policy provides a framework for reform and governance of the pharmaceutical sector. Because the sector is dynamic, there will be need to review the Policy within 10 years to align developments within the sector to the future needs of the country.

# 2 BACKGROUND AND CONTEXT

## 2.1 COUNTRY BACKGROUND

11. Kenya's population has grown from 26.8 million in 1994 when the KNDP was developed, to about 39 million in 2009. The country's Human Development Index (HDI) for 2011 is 0.509, ranking it 143 out of 187 countries[2], whereas the Human Poverty Index (HPI-1) of 29.5% ranks the country 92nd among 135 developing countries for which the index has been calculated[3]. However, these development trends are characterized by wide disparities in key indicators in all sectors, across socio-economic, geographical and gender strata; and are a major contributor to health inequalities. The national absolute poverty - the proportion of Kenyans with levels of consumption that are insufficient to meet basic food and non-food needs - declined from 52.3% in 1997 to 45.9% in 2005/06[4].

## 2.2 PHARMACEUTICAL SECTOR AND NATIONAL DEVELOPMENT

### 2.2.1 Pharmaceutical Sector Structure and Overview

12. The global pharmaceutical industry has developed tremendously, becoming increasingly globalized and technologically advanced.

[2] *UNDP Human Development Report, 2011*
[3] *UNDP Human Development Report, 2008 Update*
[4] *Kenya Integrated Household Budget Survey, 2005*

Kenya's pharmaceutical sector has been evolving since independence and today, with a sector value of about US$ 230 million in 2008[5], pharmaceuticals are a significant contributor to the economy and a key component of healthcare delivery. The pharmaceutical sector functions entail the following:

- pharmaceutical manufacturing for local consumption and import
- local trade (wholesale and retail) and international trade (import and export)
- pharmaceutical procurement, supply and distribution (public sector and FBHS)
- pharmaceutical care services (comprising prescribing, dispensing, patient advice and monitoring of therapy)
- regulation and control of products and markets (internal and cross-border control)
- monitoring drug efficacy, safety and quality; drug and poison information
- training and development of pharmaceutical personnel in colleges and universities
- drug research and development, including clinical trials and bioequivalence studies

13. Inherent in the pharmaceutical sector functions are critical and highly complex issues, such as intellectual property rights, counterfeit medicines, taxes and tariffs, registration, licensing and inspection, pricing and affordability, and unbiased consumer information.

## 2.3 POLITICAL, ECONOMIC, SOCIAL AND REGIONAL CONTEXT

14. The Constitution of Kenya (2010) provides a transformational change in governance and public administration. From a health perspective, the *Right to Health* for every Kenyan is affirmed through a comprehensive Bill of Rights. Governance structures fundamentally changed from a previously centralized structure to a two-tier system comprising the National Government and 47

[5] *Pharmaceutical Sector Profile Kenya,* UNIDO (2010)



delivery and resource allocation. These orientations require restructuring of health governance and healthcare delivery systems to align with the Constitution, and this is outlined in the *Position Paper on Implementation of the Constitution in the Health Sector.*[6]

15. Vision 2030 is Kenya's political and economic blueprint, through which the country aims to transform into a newly industrialized, middle income country, providing a high quality of life to all its citizens by the year 2030. The Vision has three pillars - economic development, social development and political reform. It places a high premium on maintaining a stable macroeconomic environment, driven by constitutional, legal reforms; and real time structural and institutional reforms, through which the country aims to increase annual GDP growth rates to an average of 10% over the Vision horizon.

16. Pharmaceutical sector issues cut across the three pillars of Vision 2030, i.e. political, economic and social.

### 2.3.1 Political Context

17. On the **political pillar**, pharmaceuticals attract a high level of political interest, due to their high economic value, the large public and private investment and their impact on the health and well-being of society. Consequently, many pharmaceutical issues are high on the political agenda of society, being the subject of intense political and trade discussions in forums such as the World Health Assembly, the World Trade Organization, as well as in bilateral and multilateral trade negotiations. Because of the high value of medicines, the pharmaceutical sector is particularly vulnerable to corrupt and unethical practices, and hence there is a critical need for strong governance and regulatory oversight structures to foster transparency; and an effective legal framework with adequate sanctions for handling non-compliance.

### 2.3.2 Economic Context

18. Macroeconomic factors play a vital role in the pharmaceutical sector. On the **economic pillar**, the pharmaceutical industry is a key player in manufacturing and trade, producing and distributing a wide range of medicines and health supplies for local consumption and for export. Pharmaceutical production and trade are major economic activities involving manufacturers, importers, exporters, wholesalers

[6] Ministry of Medical Services & Ministry of Public Health & Sanitation (2011)

and retailers. This provides medicines for healthcare and much-needed employment, thus contributing to the GDP. A properly regulated pharmaceutical sector contributes to national development and to the health of the population through improved access to essential medicines, health products & technologies.

19. Furthermore, the nature and scope of pharmaceuticals is constantly evolving, driven by research and innovation. Drugs and drug delivery systems are increasingly sophisticated, and what constitutes a 'medicine' is no longer obvious. Diverse technologies converge to influence how chemical and biological entities (new or existing) are formulated to solve specific health problems. A chemical entity can be used alone or in combination (e.g. in a tablet) or integrated into a device that delivers the drug under controlled conditions[7]. Added to this complexity is the emergence of genetics as a source of diverse health products.

20. The result is that 'medicines' and technology are intricately entwined - right from the molecular level; and no single terminology can fully define the health products and technologies produced by the pharmaceutical and related (biomedical, genetic, etc.) sectors[8]. Investment in these sectors is largely private and therefore profit driven. Consequently, intellectual property and trade must be balanced with public health considerations. From a policy perspective, critical pharmaceutical sector issues are largely applicable to the myriad products and technologies associated with this complex healthcare solutions industry. The attendant policy and strategic imperatives must be anchored on sound science, appropriate technology and public health considerations.

### 2.3.3 Social and Demographic Context

21. On the **social pillar**, pharmaceuticals are critical inputs into healthcare, taking a significant proportion of the health budget for Government and households. Pharmaceutical personnel are a key component of the healthcare workforce, providing the full range pharmaceutical services such as procurement and supply, dispensing and patient advice, monitoring adherence to treatment and adverse drug reactions (ADRs).

[7] e.g. pre-filled insulin syringes, contraceptive implants or insecticide-treated mosquito nets

[8] In this respect, the term 'pharmaceuticals' serves as a flagship for the broader category of products referred to in the Health Policy as Health Products & Technologies (HPT)



22. Poverty is a major contributor to low utilization of health services, as the poor are more likely than the rich to let an illness go untreated, or to incur catastrophic expenditures on medicines. Recent measures by Government such as reduction in user fees and improved public supply of essential medicines has led to increased utilization of health services, especially among the poor. Pro-poor spending in health is therefore critical to the attainment of national health goals.

### 2.3.4 Regional and International Context

23. Kenya plays a prominent role on the global and regional political arena and is an important economic hub in Africa. Therefore, national pharmaceutical sector issues have much broader regional context and implications. As a partner state of the EAC and COMESA, Kenya has the largest economy among the EAC countries; a large capacity for pharmaceutical production and a balance of trade surplus with the rest of Africa.

24. The EAC regional economic bloc - with a combined population of more than 125 million people and a combined estimated GDP of $60 billion in 2008 - bears strategic and geopolitical significance and prospects for the country's pharmaceutical sector. As part of the regional integration agenda, the EAC countries are working towards harmonization of pharmaceutical policies and standards to facilitate access to pharmaceutical goods and services within the region. As a major exporter of pharmaceuticals to other EAC and COMESA countries, the harmonization initiatives would enhance access to regional markets, as well as more effective cross-border regulation of pharmaceuticals.

25. Kenya plays a major role in shaping key issues affecting developing countries in international trade, including pharmaceutical trade. Issues of innovation, IP and health are a key health agenda in international forums such as the World Health Assembly and the World Trade Organization, with major implications on the country's ability to provide universal access to affordable medicines and to develop fully its pharmaceutical industry. Kenya is a strong voice for developing countries in multilateral negotiations on matters of trade and health. Pharmaceuticals have a critical place in these negotiations, hence the need to fully integrate pharmaceuticals in the national capacity and direction for trade policy decision making.

26. The country also bears the ramifications of prolonged civil strife within some neighboring countries, which contribute to outbreaks of communicable diseases; as well as entry of illegal goods like counterfeit medicines or narcotics. Many international NGOs and UN agencies provide humanitarian assistance - including supply of locally sourced medicines - to refugees in Kenya and other affected populations in the region.

## 2.4 NATIONAL HEALTHCARE CONTEXT

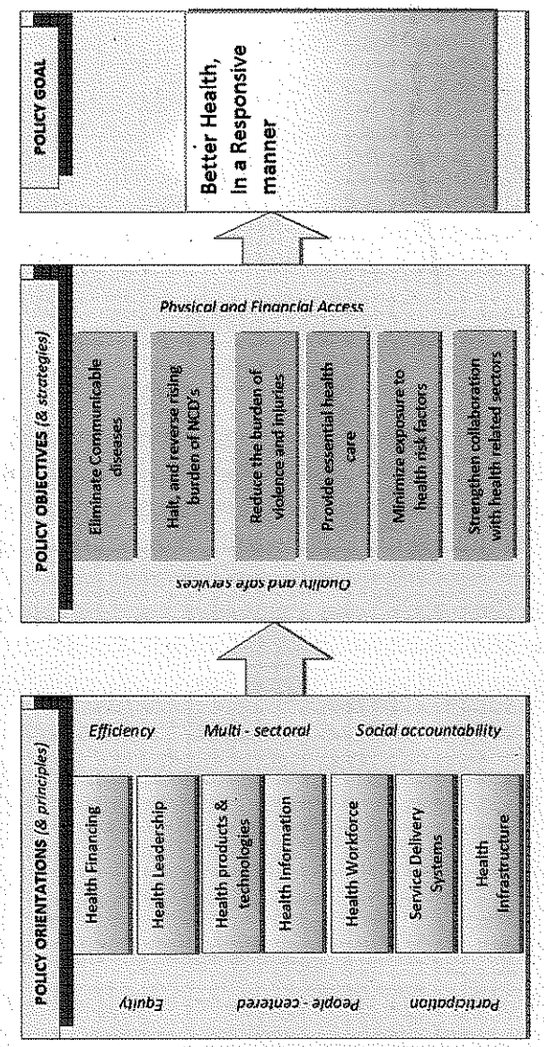
### 2.4.1 Health Policy and Legal Framework

27. The Kenya Health Policy (2012-2030) - replacing the Kenya Health Policy Framework (KHPF 1994-2010) - will guide the country towards '*attaining the highest possible health standards in a manner responsive to the population needs*'. The Policy is anchored on a health systems framework, defined in terms of six policy objectives to be attained through investment across seven policy orientations. The **target** of the Health Policy is to attain *a level and distribution of health commensurate with that of a middle income country.*

28. The seven *policy orientations* represent distinct areas for health system investment, focused on attaining the *policy objectives*. Each investment area requires the elaboration of a specific policy and strategic framework to guide the country on the nature, scope and rationale of the investment. In this context, the Kenya National Pharmaceutical Policy provides a guiding framework for the critical issues, requisite reforms and investments involved in attaining *Universal Access to Essential Health Products and Technologies.*



**Framework for defining Policy directions**




29. The main legislation governing the health sector is the Public Health Act (1957), plus a plethora of other laws which have evolved over time to address the myriad needs and developments in the sector. The result is a legal framework that is outdated, inadequate in scope and often with conflicting provisions. Consequently, the Health Policy mandates a review and overhaul of the health legislation in the country in order to harmonize and align it with the Constitution. Concurrently, outdated medicines-related legislation is slated for review and updating, with the aim of developing comprehensive laws governing medicines, health products and technologies.

30. Implementation of the Health Policy is through medium term (5-year) strategic plans, outlining the strategic direction and investments required to attain the overall policy imperatives. The 5-year plans are aligned to the Government Medium Term Plan (MTP), which is the implementation framework for Vision 2030. The Kenya Health Sector Strategic Plan (KHSSP III: 2012-2017) is the first medium-term plan of the Kenya Health Policy (2012-2030), and its development is guided by lessons learnt during implementation of the previous National Health Sector Strategic Plan (NHSSP II: 2005-2012).

31. The KHSSP III outlines the Kenya Essential Package for Health (KEPH) which integrates healthcare into a defined service package offered across four levels of care (Community, Primary, County and National levels)[9] and focusing on five distinct cohorts of the human life cycle[10]. The community level is the foundation for priority setting, and the devolved structure will channel funds and assign health care responsibility to hospitals, health centers and dispensaries, thereby empowering Kenyan households to take charge of their health.

### 2.4.2 Healthcare Governance and Coordination Structures

32. The country has elaborated a Sector Wide Approach (SWAp), based on three principles a set out in the Paris Declaration on Aid Effectiveness, i.e. i) *country ownership* (Government stewardship), *alignment and harmonization* (between Government and all stakeholders) and iii) *managing for results and mutual accountability* (the 'three ones': one sector plan, one implementation framework and one M&E framework).

33. Within the principles of SWAp, the health sector coordinating framework which recognizes 3 categories of health sector actors, namely:- i) *State Actors* comprising national and county Governments and state institutions providing stewardship, coordination and regulation, as well as health service provision through the devolved system; ii) *Non-State Actors* providing health services through the private, faith-based and NGO channels; and iii) *External Actors* comprising bilateral and multilateral partners,

[9] Corresponding to the four tiers of the Health System as defined in the Health Policy

[10] i) Pregnancy and the newborn ii) Childhood (29 days-59 months) iii) Children and Youth (5-19 years) iv) Adulthood (20-59 years) and v) Older persons (>59 years)



foundations and global health initiatives. Governance and coordinating structures have been defined to fit the context of national and county level coordination, namely: Joint Inter-Agency Coordinating Committee (JICC), Health Sector Coordinating Committee (HSCC), Inter-Agency Coordinating Committees (ICCs) and County Health Stakeholder Fora (CHSF). The Sector Strategic Plan and Annual Work Plans (AWPs) form the core implementation framework for the SWAp.

### 2.4.3 Health Services Structure

34. The public health care system is the major provider of health services, accounting for 53% of health facilities[11], and 59% *of* all admissions[12] in 2007, compared to 15.9% of facilities and 14% of admissions for the FBHS providers. The other partners in health care provision are the FBHS, NGOs and private providers. *Government fac*ilities account for 57% of total outpatient visits, whereas private and *FBHS facilities acco*unt for 18% and 6% respectively; and about 15% of visits are to a retail pharmacy. The number of health facilities has increased by about 20% since 2004, mainly attributable to construction of new public facilities through the CDF.

35. Utilization of health services depends to a large extent on the availability of competent and committed human resources, the state of physical facilities and the availability of essential medicines, diagnostics and equipment. Public health infrastructure is in a state of disrepair due to years of neglect, inadequate investment and mismanagement. Basic facilities like delivery rooms, maternity and laboratories are ill-equipped and those for medicines storage and dispensing are inadequate and do not meet recommended standards. The Health Policy has prioritized investment in health infrastructure to be guided by an integrated Health Infrastructure Investment Plan.

### 2.4.4 Healthcare Financing

36. Health expenditure has increased in recent years, due to increased public spending in the social sectors and international health financing, particularly for control of HIV/AIDS, TB and Malaria. However, health financing falls below regional and international benchmarks such as the Abuja Target and WHO-recommended levels. This under-funding contributes to the sector's inability to ensure an adequate level of service provision to the population, and

[11] *MOMS Facts & Figures in Health & Health Related Indicators, 2008*

[12] *Household Health Expenditure and Utilization Survey Report, 2007*

has caused sustained high levels of household and out-of-pocket expenditures on health.

37. Health sector reform is a core component of the social development pillar, and 'pro-poor spending in health' is identified as a strategy to reduce the state of inequity. Key strategies include devolution of health services management, shifting the health bill from curative to preventive care, special focus on priority public health problems and on vulnerable groups, as well as partnership with the private sector. A new constitutional dispensation will impact future health sector governance and service delivery structures.

### 2.4.5 Health Profile

38. The overall health of the population is primarily threatened by HIV/AIDS, malaria, tuberculosis; and non-communicable diseases. National HIV prevalence among adults aged 15-64 years is 7.1%, representing an estimated 1.4 million adults living with HIV. Only 35% of those in need of ART are currently accessing treatment[13]. Malaria prevalence is 14%[14], and it is the leading cause of morbidity (30%) in Kenya, followed by respiratory diseases (24.5%)[15]. Tuberculosis (TB) prevalence in Kenya is 319 per 100,000 against an MDG target of 63. Moreover, 48% of TB cases are co-infected with HIV and there is a growing threat of multi-drug/extensively resistant TB (MDR/XDR-TB)[16]. New and effective medicines, medical devices and diagnostics to manage these diseases are expensive. Ensuring their accessibility places significant demands on the entire health system. The need for qualified personnel, robust procurement and supply chain management and regulatory systems is increased.

#### 2.4.5.1 Towards Attaining Health MDGs: Access to Pharmaceuticals

39. The country is committed to attaining the MDGs, but progress is slow and uncertain especially in the health sector. MDG 4, 5 and 6 are health-related, and their attainment is dependent on access to priority essential medicines; and MDG 8 Target E (specific on access to essential medicines) calls for collaboration with the pharmaceutical industry. Substantial health sector investments by the Government and development partners have led to specific gains

[13] *Kenya AIDS Indicator Survey 2007*
[14] *Kenya Malaria Indicator Survey 2007*
[15] *Health Management Information System 2008*
[16] *WHO Global Tuberculosis Control Report 2009*



and improvements in some areas like control of malaria and HIV/AIDS. However, key health indicators related to maternal and child health have been on the decline or stagnated.

40. There are renewed global efforts towards massive reduction, and perhaps elimination of diseases like malaria and HIV/AIDS, and their success hinges on universal access to effective and safe treatment. Disease control trends are towards effective diagnosis and early treatment with newer and safer products. Resistance to current effective therapies is gradually rising and spreading globally; threatening the gains made so far. Strategies are also needed to effectively control the spread of non-communicable diseases (NCDs) and to radically reduce maternal and child mortality, while enhancing safety and efficacy of the medicines needed.

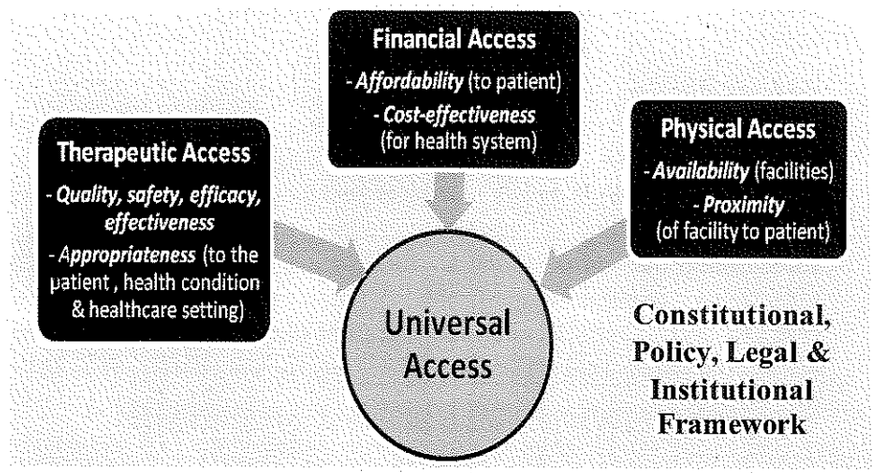
## 2.5 ENSURING ACCESS TO ESSENTIAL MEDICINES

41. This Policy seeks to facilitate attainment of MDG Target 8E: *In collaboration with the pharmaceutical industry, ensure access to affordable essential medicines in a sustainable manner*. Attainment of this target also contributes to the attainment of MDG 4, 5 and 6, i.e. improving child health, maternal health, as well as control of HIV/AIDS, TB and Malaria.

### 2.5.1 Framework for Ensuring Access to Essential Medicines

42. Access entails several dimensions, i.e. *availability* at the time of need, at a facility within *geographical* reach of the patient; *affordability*, which entails the absence of financial barriers at the point of care; *safety*, *efficacy* and *quality* of the medicine; and *appropriateness* of the medicine for the patient and the condition being treated, and for the healthcare setting. These dimensions apply equally to medicines, medical supplies and other health technologies; and similar principles apply to veterinary medicines. For Universal Access to be attained, the constitutional, policy, legal and institutional framework must be coherent and facilitative, thereby optimizing strategic actions and investments by all actors towards the stated goal.

**Framework for Enhancing Access to Essential Medicines & Health Technologies**




43. The attainment of access to medicines requires an initial definition of the priority package of essential medicines, based on the national disease patterns and health goals. The availability and affordability of this package should be ensured through appropriate financing and supply systems; and their safety, quality and efficacy ensured through an effective regulatory framework. Appropriate prescribing, dispensing and utilization by consumers, ensure that the desired health outcomes are attained. The preferential use of generic medicines is a core element, which ensures cost-effectiveness and promotes competition in the sector.

44. Development of the National Essential Medicines List and National List of Essential Medical Supplies is an integral part of the defined priority package for the delivery of health services. The Lists should be regularly updated (at least every 2 years) to maintain their relevance to national healthcare needs. Updating of the lists is a core function of Government, and it should be based on available evidence of efficacy, safety, quality and cost-effectiveness. The concept and the attendant lists should guide medicines financing, procurement, prescribing and dispensing; monitoring of pharmaceutical services as well the training of health personnel. This concept ensures cost-effectiveness in health investments, and it applies to the public as well as the faith-based and private sectors.



### 2.5.2 Performance of the Sector on Access to Essential Medicines

45. Overall, there has been some progress towards improving access to essential medicines. The availability of medicines in public health facilities has increased and coverage targets for TB, malaria and HIV are being attained. These gains are attributable to the increased allocation of government budget towards EMMS, increased donor financing of essential medicines for treating TB, malaria and HIV. Also contributing is Government policies aimed at improving the affordability of essential medicines, particularly at the lower levels of care, and for vulnerable population groups like children and pregnant women. The Government has taken steps towards restructuring and strengthening of KEMSA as a public procurement agency for EMMS. However, a comprehensive government-led focus on all dimensions affecting universal access to EMMS has been lacking, and the gains registered have been sub-optimal.

#### 2.5.2.1 Defined Package of Essential Medicines

46. The Kenya Essential Medicines List (KEML) has been adopted as the guiding tool for the procurement of essential medicines in the public, faith-based and some private providers. However, the list is not regularly updated as required, which undermines its application as a tool for healthcare. A national list of essential medical supplies has not been prepared, and this causes challenges in ensuring access to medical supplies.

#### 2.5.2.2 Availability

47. Essential medicines should be available when prescribed at a facility accessible to the individual, and in the dosages prescribed. The majority of poor Kenyans access EMMS from public health facilities. Investment by Government and partners has enabled increased availability of affordable essential medicines, including those for HIV/AIDS, TB and malaria, and medicines for children. However, frequent stock-outs of essential medicines in public sector facilities lead to low availability and thereby undermine the benefits of this primary source. Funding is also limited, hence the full package of essential medicines, health products and technologies is not guaranteed for the Kenyans who need them. The faith-based supply system offers an alternate supply of medicines, for the poor and middle-income. Affordability is often a barrier to accessing medicines from the faith-based sector.

#### 2.5.2.3 Affordability

48. Prices of medicines are generally high, and unaffordable to the majority of the population. Financing by Government and partners has resulted in reduction or elimination of user fees, making the public sector the most affordable source of essential medicines. Subsequently, the country has registered significant improvement in access to essential medicines for malaria, HIV and tuberculosis; treatment for children under-five and for most services at public and some faith-based rural health facilities. However, critical essential medicines remain unaffordable to the majority of Kenyans. These include medicines for chronic illnesses like diabetes and hypertension, essential diagnostics as well as new 2nd and 3rd line essential medicines for the treatment of some infectious diseases like malaria, HIV/AIDS and TB, especially because resistance to well established drugs is increasing. High prices of critical essential medicines in the private sector are also a barrier for many Kenyans who access healthcare through this sector.

49. A range of options exist to further improve affordability of essential medicines. These include promoting use of generics, price competition through generic procurement, prescribing and dispensing; full implementation of TRIPS flexibilities and increased public financing.

#### 2.5.2.4 Quality, Safety and Efficacy

50. Substandard and counterfeit medicines are a major public health challenge, posing major risks to patients of prolonged ill-health, drug resistance and sometimes death. Because of the international dimensions of pharmaceutical trade, there is need for stringent regulatory systems including effective cross-border control and international collaboration. A Robust QA system requires regular market surveillance to avoid wasting public resources on medicines that are ineffective, unsafe or even harmful. The two WHO-prequalified laboratories in Kenya are a key part of the national QA system, and they also provide quality control services to countries in the region.

51. The PPB is the authoritative source of information on the quality of medicines in the country. Several studies have been undertaken on the quality of pharmaceuticals, especially medicines for HIV/AIDS, malaria and TB, in collaboration with the disease control programmes. These studies, in addition to routine inspections and



quality control testing, indicate that overall, products in the market meet quality specifications with only few incidences of sub-standard medicines, suggesting that regulatory and quality assurance systems in place are effective. However, incidences of substandard quality, widespread use of ineffective treatments and counterfeit medicines are key issues that require strong market control. This underscores the need for continued investment by Government and partners, on national medicines regulatory and QA systems.

#### 2.5.2.5 Use of Generic Medicines

52. The public, faith-based and some private health services largely apply the KEML as the basis for procurement and supply of essential medicines; which are mostly generics. The local industry manufactures generic medicines and primarily those on the KEML.

## 2.6 RATIONALE FOR THIS NATIONAL PHARMACEUTICAL POLICY

53. Access to essential medicines is a core component of the Right to Health. The attainment of this goal requires strong government commitment to directing an increasingly complex pharmaceutical sector; and to realizing pharmaceuticals-related international treaties, commitments and protocols. This KNPP has been developed by Government to provide a framework for comprehensive reform and revitalization of the pharmaceutical sector, in a manner consistent with national health and development goals, as set out in Vision 2030 and its implementation strategies and plans. It defines the direction, goals, objectives and strategies for the pharmaceutical sector, touching on pharmaceutical products, human resources for the provision of pharmaceutical services and the key institutional framework and processes required to advance access to medicines for the population. Additionally, it provides a framework for coordination of pharmaceutical sector issues, encompassing the public, private and faith-based/NGO players and the regional and international aspects impacting on pharmaceuticals.

### 2.6.1 Performance of the Past National Drug Policy

54. Although implementation of the KNDP of 1994 encountered numerous challenges, the policy led to some notable achievements, namely:

a) KEMSA was established through Legal Notice No. 17 of February 2000, with the mandate to *develop and operate a*

*viable commercial service for the procurement and sale of drugs and medical supplies to public health institutions.* Through this and the revised Legal Notice No. 54 of May 2009, the institutional and legal framework for public procurement and distribution of EMMS has been strengthened.

b) The mandate of PPB was expanded at various points, and its capacity enhanced through acquisition of own premises and ongoing development of a human resource complement for pharmaceutical sector regulation.

c) Training of pharmaceutical personnel was streamlined and capacity expanded, with subsequent increase in outputs of pharmacists and pharmaceutical personnel; and expansion of postgraduate training programmes.

d) Capacity of the National Quality Control Laboratory was enhanced, and now it is WHO prequalified, serving the growing demand for quality control services locally and in the region. A quality control laboratory established by the FBHS is also WHO prequalified.

e) The local pharmaceutical industry grew in terms of production capacity, improvements in GMP compliance and regional market reach for exports.

f) Enactment of the Intellectual Property Act (2001) provided a legal framework for local production and importation of generic medicines especially for HIV/AIDS, TB and malaria, thereby increasing access to these medicines for affected Kenyans.

g) The Essential Drug Concept was widely adopted by the public, faith-based and some private sector providers, as a strategy for cost-effective medicines utilization.

55. Since the adoption of the KNDP in 1994, demands on the health system have continued to increase with the growth in population. The local pharmaceutical sector has grown in size, scope and complexity. Challenges in the health sector have persisted, including the double burden of communicable and non-communicable diseases, as well as limited human, financial and infrastructural resources.

56. Subsequently, the Government has continued to seek solutions to the challenges facing the pharmaceutical sector. In collaboration with development partners, there have been assessments, consultancies, committees and taskforces; which have highlighted different aspects of the sector challenges, with recommendations for policy and



strategic interventions. Notable among these are the WHO assessment of the pharmaceutical situation (2003 and 2008); the WHO/HAI Medicine Prices Survey (2004); World Bank supported pharmaceutical sector studies 1-5 (2005); WHO Assessment of the medicines regulatory system in Kenya (2006); PS Task Force Report on reforming the PPB; situation analysis study of FBHS vis-a-vis Government health services (2007) and the Ministerial Task Force Report on KEMSA (2009). The findings and recommendations therein have subsequently informed this policy review.

57. The policy review is occurring in the context of ongoing health sector reform, and in particular the constitutionally mandated devolution of governance structures in all sectors. Therefore its implementation will move in tandem with the evolving health sector structures, policy and legal instruments and institutional arrangements.

### 2.6.2 Constraints

58. In the implementation of the KNDP and its attendant programmes, the following constraints were encountered:

a) Inappropriate institutional structures for policy direction and governance of the pharmaceutical sector. The existing structure continuously fails to recognize and effectively address the complexities and externalities of pharmaceuticals, thereby hindering effective growth and full maturity of the sector.

b) Outdated laws that fail to address and adapt to pharmaceutical sector trends.

c) Dual roles of key government offices, defined by law, have hindered effective governance and oversight of the pharmaceutical sector. These are the offices of the Director of Medical Services (DMS) and the Chief Pharmacist.

d) Pharmaceutical policy development and implementation did not evolve with the developments elsewhere, causing stagnation and chronic underperformance.

e) Narrow conceptualization of pharmaceutical issues and scope. There is skewed focus on procurement and supply of 'commodities' and dispensing to support clinical care, leaving inherent pharmaceutical sector complexities unaddressed.

f) Lack of clear and sustainable strategies for policy implementation; weak management and programming of pharmaceutical services.

### 2.6.3 Emerging and Continuing Challenges

59. In implementing the KNDP, challenges emerged and continued to impact on the pharmaceutical sector, including:

a) Healthcare has become increasingly sophisticated, with rapid development of new drug molecules, drug combinations and other health technologies.

b) The need to align pharmaceutical policies with Vision 2030 and the MDGs.

c) Pharmaceutical trade is highly commercialized and globalized; bringing with it increasingly complex issues such as trade liberalization, intellectual property, standardization, harmonization and collaboration; and information management.

d) Rapid growth in the private pharmaceutical sector, requiring commensurate evolvement of the policy and legal framework to effectively regulate the sector.

e) The evolving role of the pharmacist as a core member of the clinical team, providing defined pharmaceutical care services.

f) The emergence of international health partnerships to finance disease control and prevention, placing pharmaceuticals in the public arena on an unprecedented scale.

g) The accelerated momentum towards regional economic, political and social integration particularly in the EAC and COMESA; calling for regional harmonization and collaboration in pharmaceutical policies, trade and regulation.

h) The unmet need for key essential medicines and for drugs to treat conditions that disproportionately affect developing countries; growing threat of antimicrobial resistance, and the need to ensure patient safety in the use of medicines.

i) Increasing use of ICT in all facets of the pharmaceutical sector.



## 2.7 FOCUS OF THIS POLICY

60. This policy re-asserts the tenets of its predecessor, the difference being that this policy:

a) Recognizes the uniqueness of the pharmaceutical sector - as a component of the health sector, yet a distinct socio-economic entity that faces significant externalities beyond healthcare and beyond the country's borders.

b) Upholds Government commitment for increased investment in the social sector including health, to spur economic development and attain health goals.

c) Delinks key policy and regulatory roles to uphold principles of corporate governance.

d) Upholds the constitutional principles of devolution, multi-stakeholder participation and transparency in national affairs.

e) Anticipates the implications on the pharmaceutical sector, of future trends in Kenya's political, economic and social development.

f) Harmonizes with regional and international commitments and obligations, in particular key targets on access to medicines and the trends in regional integration.

### 2.7.1 Health Considerations

61. In addressing the pharmaceutical sector challenges, the Policy makes the following health considerations.

a) If universal access to essential medicines is to be achieved by 2015, there is need to intensify focus on pharmaceuticals, with emphasis on policy direction, sector regulation, institutional reforms and partnership coordination.

b) Government is the primary provider of health services to the population, and it has an obligation to provide a defined package of affordable healthcare, including EMMS.

c) While medicines save lives and improve health, their inappropriate use can be harmful to the individual. Sound policies and strategies are needed to ensure medicines safety and appropriate use.

d) Some health conditions disproportionately affect specific groups, such as the poor, particular age cohorts and persons afflicted with specific conditions e.g. children and persons living with HIV. Therefore, targeted strategies are required to promote equity in access to essential medicines.

### 2.7.2 Development Considerations

62. In addressing the pharmaceutical sector challenges, the Policy makes the following development considerations.

a) Kenya has a vibrant private sector, and pharmaceutical sector enterprise development should be supported while safeguarding public health.
b) Local production of essential medicines and Medical Supplies (EMMS) has the potential to improve access to essential medicines. This can only happen if the consumer is the primary beneficiary of government incentives, e.g. lower prices.
c) Regional integration within the EAC and COMESA provides market opportunities for the local pharmaceutical sector. Exploiting this opportunity requires enhanced capacity for manufacturing and human resource development; and effective regulatory oversight to ensure quality products, personnel and services from Kenya.
d) Globalization is a key feature of the pharmaceutical sector, and it calls for harmonization of standards and reciprocity in market control and regulation.

## 2.8 CRITICAL PHARMACEUTICAL SECTOR ISSUES

63. This policy addresses the following critical issues affecting the pharmaceutical sector:

1. **Policy Direction and Governance on Pharmaceuticals:** Weak governance and lack of policy direction; low placement within the Ministry structures, leading to weak integration within the health and economic policy framework.
2. **Pharmaceutical Sector Regulation:** Weak legal framework and institutional structures for regulation; narrow scope of the pharmaceutical regulatory system.
3. **Availability of EMMS:** Uncoordinated procurement and supply, leading to irregular availability of EMMS; low adherence to established principles and standards.
4. **Local Production of Pharmaceuticals:** Lack of policies and incentives to fully utilize and promote local pharmaceutical production.
5. **Affordability of Essential Medicines:** High and unregulated prices of essential medicines, being unaffordable to the majority.



6. **Medicines Use**: Inappropriate use of medicines (human and veterinary) by health workers and consumers, leading to wastage and poor health outcomes.
7. **Pharmaceutical Research and Development:** Lack of policy direction and coordination, and inadequate funding for research on medicines.
8. **ICT Use**: Inadequate investment and utilization of ICT in all aspects of pharmaceuticals; weak policy guidance & regulation.
9. **Human Resources for the Pharmaceutical Sector**: Lack of integrated strategies for training, development, management and retention of pharmaceutical HR.
10. **Safeguarding Public Health in Pharmaceutical Trade:** Inadequate integration of pharmaceuticals in trade and economic policies and international cooperation.
11. **Enhancing Access to Veterinary Medicines:** Inadequate institutional structures, hindering development, regulation and appropriate use of veterinary medicines.
12. **Financing for Pharmaceutical Policy and Services:** Inadequate public financing for essential medicines; high burden of healthcare on poor households.
13. **Pharmaceutical Legal and Institutional Framework:** Inadequate legislation and weak institutions, hindering development of the sector and related services.

# 3 THE PHARMACEUTICAL POLICY FRAMEWORK

## 3.1 REVAMPING PHARMACEUTICAL SECTOR GOVERNANCE AND POLICY DIRECTION

### 3.1.1 Overall Policy Direction, Sector Governance and Coordination

64. The current policy direction and governance of the pharmaceutical sector is weak, constrained by outdated sector management structures. Vested in the Directorate of Medical Services (DMS), pharmaceutical sector issues are still addressed through a structure devised in the 1960s, when pharmacy was perceived primarily as a support function of medical services, dealing only with the supply and dispensing of medicines. By addressing pharmaceutical issues primarily through the lens of medical services, the complexities and externalities of the pharmaceutical sector remain poorly integrated within overall Government policy framework and the health sector strategic framework.

65. The situation is confounded by a conflict of roles for the DMS and Chief Pharmacist as policy makers and implementers on the one hand, and as regulators on the other. Consequently, there is chronic underperformance of the pharmaceutical sector, as manifested in medicine stock outs, substandard and counterfeit medicines, unregistered products and unlicensed outlets; uncontrolled sale and inappropriate use of medicines.

### 3.1.2 Management of Public Pharmaceutical Services

66. Pharmaceutical services are not delineated in the context of health services decentralization. Consequently, decentralized administration of pharmaceutical services is not provided for within the health service administrative structures. Pharmaceutical personnel are currently deployed to healthcare facilities to manage the supply and dispensing of medicines, with no defined administrative and supervisory structures. In addition, the scheme of service for pharmaceutical personnel is inadequate for the changing needs and dynamics of the health sector, and it has remained a flat structure with no defined management or specialty positions; and no modalities for career progression.

67. The inappropriate structures also lead to inadequate participation of pharmaceutical personnel in the relevant managerial, policy making and health sector reform forums; and in regional and international initiatives related to pharmaceuticals. Consequently, pharmaceutical issues are inadequately articulated; and the reform process persistently lacks appropriate orientations on pharmaceuticals policy and technical matters.

### 3.1.3 Enhancing Partnerships and Coordination on Pharmaceuticals

68. A health sector governance and coordinating framework exists through the SWAp, with the coordinating mechanisms in place through: Joint Inter-Agency Coordinating Committee (JICC), Health Sector Coordinating Committee (HSCC); Inter-Agency Coordinating Committees (ICCs); a Country Coordinating Mechanism (CCM) and District Health Stakeholders Forum (DHSF). Seventeen ICCs are in place, as the technical fora for specific health sector issues, ranging from disease control, healthcare financing to procurement.

69. However, this framework does not provide a coordinating mechanism for addressing the full scope and complexity of pharmaceutical sector issues, resulting in a policy vacuum and lack



of coherence on sector-wide strategies relating to medicines; as well as fragmentation and duplication of initiatives among sector partners.

#### 3.1.3.1 Institutional and Legal Arrangements

70. The KNDP of 1994 provided for the creation of a Directorate of Pharmaceutical Services, but this was not implemented. Therefore policy and technical direction of the pharmaceutical sector remains vested in the Directorate of Medical Services (DMS), within the Ministry of Medical Services. Under the DMS, the Department of Pharmacy, headed by the Chief Pharmacist, oversees the day to day functions of public sector pharmaceutical services. By law (Chapter 244), the DMS and Chief Pharmacist are also Chair and Registrar respectively of the Pharmacy and Poisons Board, which simultaneously regulates the pharmaceutical sector and the pharmacy profession.

71. **Key challenges related to pharmaceutical governance and policy direction are as follows:**

a) Low placement of pharmaceutical issues within Government structures, leading to weak policy direction and low prioritization in health decision making.

b) Inadequate policy scope, weak governance structures and lack of effective technical oversight of the pharmaceutical sector.

c) Lack of effective coordination leading to fragmentation, duplication, and inability to exploit synergies of partnerships and multi-sector collaboration.

d) Lack of formal decentralized structures for pharmaceutical services within the health service administrative structures.

e) Inadequate technical oversight of private, mission and NGO pharmaceutical service providers and veterinary services.

f) Unstructured and inadequate participation of Government in regional and international affairs relating to pharmaceuticals.

72. **The Government will establish structures for effective governance and policy direction of the pharmaceutical sector, and facilitate the attainment of full maturity of the sector. To facilitate the attainment of this objective, the Government will:**

1. Establish a Directorate of Pharmaceutical Services (DPS), or its equivalent, as the structure for governance of pharmaceuticals, other health products & technologies, distinct from the Directorate of Medical Services. The DPS will be mandated to:

   a) Provide overall policy direction and governance of the pharmaceutical sector, in line with Government policies and regulations.

   b) Facilitate the attainment of the goals and objectives of this Policy, in particular:
      (i) Establish the necessary institutional framework for its implementation;
      (ii) Develop and regularly review strategies to guide implementation of the Policy provisions;
      (iii) Foster collaboration between the public sector, other partners and stakeholders involved in its implementation;
      (iv) Coordinate monitoring and review of the Policy and its attendant strategies

   c) Provide pharmaceutical policy guidance to the FDA, KEMSA and NQCL through membership of the respective boards; and oversee pharmaceutical services by private, faith-based and NGO providers.

   d) Restructure and administer public pharmaceutical services in a timely, efficient and transparent manner.

2. Review schemes of service for pharmaceutical personnel to recognize specialization in handling the complexities of the pharmaceutical sector, through appropriate deployment and career progression.
3. Encourage the development of the requisite human resource capacity to address current and emerging pharmaceutical and health sector needs.
4. Restructure institutions that are envisaged to play a key role in the implementation of this Policy and its attendant strategies, in particular:
   a) Restructure the PPB to establish a Food and Drug Authority (FDA) as an autonomous national regulatory agency within



the ministry responsible for health, and delinked from the Directorate of Medical Services.
   b) Restructure KEMSA as an autonomous body corporate within the ministry responsible for health, with the full mandate to procure and distribute essential medicines and Medical Supplies.
   c) Restructure the NQCL as an autonomous body corporate within the ministry responsible for health, delinked from the drug regulatory authority.

## STRENGTHENING PHARMACEUTICAL SECTOR REGULATION

73. Pharmaceutical regulation is the totality of all measures - legal, administrative and technical - which governments take to ensure the *safety*, *efficacy* and *quality* of pharmaceutical products and to safeguard public health in their utilization. It is both a policy and technical matter; and requires a central authority with a clear mandate and scope and the requisite powers to enforce the regulatory provisions.

74. Regardless of their origin, all medicines marketed in the country must be registered by the FDA to ensure compliance with internationally acceptable standards of efficacy, quality and safety; and should be provided according to legal requirements and professional standards. The scope of pharmaceutical regulation covers the production, distribution, dispensing and sale of all medicines and pharmaceuticals for human and veterinary use; the safety and appropriate use of biological products, cosmetic and nutritional products purporting (or known) to have medical or drug-like benefits/effects; other products with the potential to cause harm to humans and animals; as well as clinical trials on human and animal subjects. Of importance is the legal provision for expansion of this scope of regulatory control, in line with trends in pharmaceutical research and development.

75. Pharmaceutical regulation has evolved into a specialized and dynamic field, adapting appropriately to the rapid globalization and sophistication of the pharmaceutical industry. The ability to regulate pharmaceuticals effectively is determined by factors such as: governance and autonomy, the state of economic development, infrastructure and prevailing health-care system. A *stringent medicines regulatory authority* is a prerequisite for quality

healthcare, growth of the local pharmaceutical industry, and access to markets for pharmaceutical exports. In the face of rapid globalization, collaboration and information sharing among countries are critical to effective pharmaceutical regulation.

#### 3.2.1.1 Institutional and Legal Arrangements

76. The Pharmacy and Poisons Board was established in 1957 under the Pharmacy and Poisons Act (Chapter 244), with the legal mandate to control the trade in medicines and poisons, and to regulate the practice of pharmacy. The structure and operations of PPB was changed fundamentally in 1993 with the amendment to section 5 of Chapter 244, making the Chief Pharmacist the de jure Registrar of PPB. In 1993, the PPB was redefined as a body corporate through an amendment of Chapter 244, with extended competence, including responsibility for the NQCL, for drug registration activities and for related functions. The PPB collaborates with law enforcement agencies like Interpol, customs and the Kenya Revenue Authority (KRA); as well as the Department of Veterinary Services, represented on the PPB to ensure effective regulation of pharmaceuticals for veterinary use.

77. The need for legal and administrative restructuring of the PPB has been recognized since publication of the first national drug policy in 1994, and despite various initiatives in this regard, the required autonomy and full realization of its regulatory role have not been achieved. The legal mandate, structure and operations of PPB have not evolved with international trends, and this is a major challenge in ensuring the health and safety of the population. In particular, the mandate of the PPB to inspect pharmaceutical establishments and to authorize the sale, handling, import and export of drugs, has been weakened through conflicting roles such as those of public health inspectors and non-technical 'drug inspectors', thus compromising public safety with respect to pharmaceuticals. An Inter-Ministerial Task Force in 2007 identified and proposed modalities for restructuring of the PPB. In the context of harmonization of regulatory requirements within the EAC, partner states have embraced the need to restructure national regulatory authorities into food and drug authorities (FDA).

78. The Pharmaceutical Society of Kenya (PSK) and Kenya Pharmaceutical Association (KPA) coordinate professional affairs of pharmacists and pharmaceutical technologists respectively. Whereas



the associations participate in the establishment, monitoring and enforcement of professional ethics and standards, PPB has the statutory mandate to regulate pharmacy practice. Institutional mandates that overlap with PPB are those of KEBS, KRA, NACADA, the Anti-counterfeit Agency and the drug inspectorates of the Ministries in health.

79. The National Quality Control Laboratory (NQCL) was established in 1992 through amendment of Chapter 244, with a mandate to examine medicines and ensure their quality. The laboratory is prequalified by WHO. The FBHS also run a WHO-prequalified QC laboratory, mainly for own use and for use by other healthcare providers. Both laboratories provide much-needed national quality control capacity, with demand for their services extending to regional and international markets.

80. **Key challenges affecting regulation of the pharmaceutical sector include:**

a) Conflict of roles of key government offices, contrary to corporate governance principles.

b) Weak central authority for pharmaceutical regulation and conflicting mandates and responsibilities between the PPB and other agencies and departments.

c) Outdated management structures and inadequate legal framework, which places the medical profession as key regulator of the pharmaceutical sector and profession.

d) Increasing globalization and sophistication of the pharmaceutical sector, including sophistication of crime such as counterfeiting and illegal trade.

e) Inadequate financial resources to cater for the full scope of pharmaceutical regulation

f) Limited human resource capacity, skills and expertise devoted to, and covering the full scope of modern pharmaceutical regulation.

g) Emerging use of traditional medicines, and the implications on patient health and safety.

h) Inadequate framework for ensuring the safety and quality of other pharmacologically relevant products, such as food supplements and nutraceuticals.

i)Inadequate framework for regulation of pharmaceutical personnel and practice.

j)Inadequate legal framework and financing for pharmaceutical quality control, hindering full development of the requisite institutional capacity to effectively exploit the opportunities in Kenya and the Region.

k) Inadequate mechanisms for effective collaboration with pharmaceutical regulators abroad and with other enforcement agencies.

l)Duplication of pharmaceutical inspectorate and engagement of inappropriately trained personnel in drug inspection.

81. **The Government will facilitate effective regulation of the pharmaceutical sector (with regard to elements affecting the product and the practice), to ensure that quality, safe and efficacious medicines are provided according to legal requirements and professional standards. To achieve this, pharmaceutical regulation will adhere to the following provisions:**

1. All products marketed in Kenya must be duly registered by the FDA. The basis for market authorization will be quality, efficacy and safety.
2. A scheduling system for medicines will be reviewed, regularly updated and enforced. The schedule will delineate appropriate levels of control for medicines prescribing, dispensing and use, based on their pharmacological and safety profile.
3. Registered products will require renewal of registration every 5 years, based on defined criteria. The FDA may de-register products that fail to conform to the set requirements.
4. Premises where medicines are stored, distributed and dispensed must be licensed
5. Only personnel registered or enrolled by the Pharmacy Council will be authorized to manage and dispense medicines. To enhance professional regulation, all pharmaceutical personnel will be required to maintain current membership of their professional association.
6. All pharmaceutical inspectorate functions will be consolidated and strengthened under the FDA. Only inspectors designated by the FDA will be authorized to inspect pharmaceutical products and premises.



7. Clinical trials and other research activities involving the administration of medicines under research to human subjects will be regulated by the FDA.
8. Cosmetics and other pharmacologically relevant chemicals and devices will be subject to regulation by the FDA.
9. All pharmaceuticals for veterinary use will be subject to regulation by the FDA.
10. The FDA will collaborate with other regulators, and law enforcement agencies; and participate in harmonization, reciprocal arrangements and other initiatives for enhancing pharmaceutical regulation and control.
11. Effective mechanisms will be established to address conflict of interest in pharmaceutical regulatory decision-making, and for the handling of complaints, disputes and disciplinary matters arising from pharmaceutical regulation and practice.

## 3.3 EXPANDING AVAILABILITY OF ESSENTIAL MEDICINES

82. Kenyans obtain medicines from the public, faith-based/NGO and private supply systems. The majority of poor patients obtain their medicines from public health facilities, whereas the faith-based services are an important source of medicines for the poor and those in remote parts of the country. The public and faith-based supply systems are virtually independent of each other, with regard to the sourcing, procurement, storage and distribution of health products. Enhanced collaboration between these supply systems has potential benefits in optimizing medicines availability, contributing to harmonization of technical requirements and enhancing generic competition. Such collaboration would involve the public, faith-based and other procurement entities, including semi-autonomous health facilities.

83. Good Pharmaceutical Procurement principles (GPP)[17] represent international best practice in pharmaceutical procurement. GPP integrates quality assurance as the core basis for rational decision-making in medicines procurement, in order to safeguard public health and safety.

### 3.3.1 Public Sector Procurement and Supply

84. The public supply system involves centralized bulk procurement of essential medicines and medical supplies, and their distribution to

[17] *Operational principles for good pharmaceutical procurement* (WHO, 1999): WHO/EDM/PAR/99.5

well over 4,000 facilities of levels II-V; and to some level II faith-based health facilities. The public procurement process through KEMSA obtains price competitiveness in relation to international reference prices, and compared to prices obtained by other procurement entities. It is funded by Government and partners, providing medicines free or at subsidized prices, and therefore offering the best affordability and a secure source of quality-assured essential medicines. Public health facilities are the primary source of medicines for the poorest households. However, irregular and inadequate supply to public sector facilities is a recurring challenge, which forces the poor to obtain essential medicines at higher prices in the private sector.

### 3.3.2 Procurement and Supply System of the Faith-Based Health Services

85. Kenya has a strong faith-based service sector, which plays a significant role in healthcare and pharmaceutical services delivery. The faith-based health services support a significant proportion of health facilities, many of them in remote, rural and marginalized parts of the country. MEDS has a WHO-prequalified quality control laboratory, as part of its quality assurance system. Availability of essential medicines is generally high in faith-based facilities, but cost-recovery charges for medicines often create a financial barrier to access.

### 3.3.3 Private Sector Supply System

86. The private sector is a major player in local pharmaceutical trade through private hospitals, clinics and retail/community pharmacies, served by about 212 importers, wholesalers and distributors; or directly by the 42 local manufacturers. There are currently about 1167 retail pharmacies registered by the PPB, and their location is heavily skewed towards urban areas, where several outlets may be found within the same locality. Authorized pharmaceutical outlets are very few in rural and remote parts of the country. Furthermore, the simultaneous operation of wholesale and retail facilities contributes to unethical practices such as price under-cutting. The private sector supplies a wider range of medicines and health supplies than the public or mission providers, and is often a source of EMMS for patients when there are stock-outs in other sectors. However, prices are generally high, and vary widely between outlets. Over-the-counter (OTC) medicines are also legally sold through general outlets (such as supermarkets and kiosks) across the country.



#### 3.3.3.1 Legal and Institutional Arrangements

87. Public sector procurement of pharmaceuticals is governed by the Public Procurement and Disposal Act (PPDA) of 2005. Kenya Medical Supplies Agency (KEMSA) is the public agency for the procurement and distribution of EMMS. It was established through Legal Notice No 17 of February 2000, with the primary objective of 'developing and operating a viable commercial service for procurement and sale of drugs and medical supplies to public health institutions'. The public supply system has in place quality assurance mechanisms which include quality control testing at the National Quality Control Laboratory (NQCL). At its inception, KEMSA was envisaged to operate as a commercial establishment, but this objective has not been met to date. Currently, KEMSA procures EMMS against funds allocated to the two ministries in health, and supplies to public facilities either using kits (push system – around 70% of lower level facilities) or through a demand driven system (pull system – around 30% of lower level facilities and all Level 4 & 5 hospitals) through drawing rights. National teaching and referral hospitals (Level 6 facilities) are semi-autonomous and source their pharmaceutical requirements independently. Currently, pharmaceutical policy direction within the Board of KEMSA is inadequate, as there is no representation from the Department of Pharmacy.

88. Some pharmaceutical supplies financed by development partners are procured separately by procurement agents contracted by the partners. This is particularly so for HIV, TB and Malaria medicines; vaccines and reproductive health products. These products are distributed to all sectors and levels of care, through the public, faith-based and selected private distribution channels.

89. MEDS procures essential medicines and supplies to the FBHSP and NGO providers and to some public facilities on a cost-recovery basis. As part of definition of roles and responsibilities within the SWAp arrangements, a MoU is in place between the Government and FBHSP, aimed at fostering a strong and effective partnership for the achievement of national health goals. The MoU provides for various categories of Government support or subsidy to FBHSP, and their increased participation in service provision and health sector governance mechanisms.

90. Some NGO providers supply medicines for relief and emergency operations locally and in neighboring countries. The Kenya Red Cross provides emergency healthcare services - including medicines - in various parts of the country. However, there are no coordinated mechanisms for the provision of emergency pharmaceutical services. Private sector supply is through wholesalers and retailers.

91. For all the supply systems, distribution of pharmaceuticals across the country is outsourced to private transporters. However, the vehicles, handling facilities and methods used are not adapted to the transportation of pharmaceutical products, and hence may not conform to standards of Good Distribution Practices (GDP).

92. In the public sector, storage infrastructure for medicines is dilapidated, and does not conform to standards of GDP, thereby compromising effective distribution and quality assurance of medicines. The health sector has identified infrastructure development as policy priority, to be guided by a comprehensive Infrastructure Development Plan. Improvement of pharmaceutical infrastructure should take into account: - capacity, design, maintenance and security. Warehousing and distribution of medicines has also failed to evolve with international trends that encompass the broader concept of logistics management, and outsourcing of non-core functions.

93. **Key issues and challenges related to increasing medicines availability are:**

a) Inadequate financial allocation and bureaucratic systems for disbursement of public funds (HSSF) for the procurement and supply of EMMS

b) Parallel procurement of public sector EMMS by numerous health sector players.

c) Lack of adherence to best practice principles, such as Good Pharmaceutical Procurement (GPP) and of Good Distribution Practices (GDP).

d) Lack of policy guidance and control mechanisms on prioritization and utilization of the public medicines budget in line with prevailing public health priorities.

e) Inadequate mechanisms for ensuring access to EMMS through non-public providers, including alternate sourcing by facilities in the event of stock-outs in KEMSA.



f) Limited HR capacity for pharmaceutical procurement and logistics; and inadequate utilization and leveraging of private sector capacity and expertise

g) Inadequate mechanisms for the procurement of medicines for emergencies.

h) Inappropriate siting of pharmaceutical outlets, with no incentives to encourage their establishment in remote and underserved areas. Lack of segregation of wholesale and retail outlets, leading to unethical practices on pricing and other supply chain functions.

i)Proliferation of unlicensed outlets for medicines, posing risks to the public of obtaining substandard, counterfeit medicines or incorrectly dispensed medicines.

j)Inadequate or unclear legal framework for KEMSA, open to misinterpretation and undermining the autonomy, governance and institutional management of KEMSA

k) Lack of coordination among procuring entities, leading to inefficiency in procurement and supply.

94. **The Government will endeavor to ensure that required essential medicines are continuously available and affordable to the population. Coherence in the procurement and supply of pharmaceuticals will be facilitated through adherence to the following principles:**

a) Centralization of core functions for public pharmaceutical procurement through KEMSA as the primary public procurement agency. Core functions comprise supplier selection and monitoring, pricing and quality assurance.

b) Adherence to the principles of Good Pharmaceutical Procurement (GPP) in all sectors and to provisions of the PPDA in the public sector.

c) Adherence to the KEML and the KEMSL. An established evidence-based process should guide any adaptation to the procurement list, in order to ensure rational selection and promote good clinical practice.

d) Optimization of the budgetary allocation for pharmaceuticals guided by appropriately developed criteria and mechanisms linked to prevailing national health priorities.

e) Other supply systems to complement the public supply system, as alternate sources in case of stock-outs or other situations of non-availability. Mechanisms will be established for ensuring

access to EMMS through non-Government actors in the context of PPP, through subsidies and other incentives.

f) Delineation of pharmaceutical wholesale from retail practices.

g) Establishment and enforcement of zoning regulations for private sector providers.

95. **To facilitate effective and efficient pharmaceutical procurement and supply, the Government will:**

1. Integrate and harmonize existing public sector parallel procurement activities to optimize procurement efficiency and effectiveness.
2. Develop an effective system for the procurement and supply of essential pharmaceuticals for disasters and emergencies.
3. Encourage specialization in pharmaceutical procurement and logistics, through relevant training, deployment and retention measures.
4. Through the FDA, establish standards for, and enforce compliance with Good Distribution Practices (GDP), including pharmaceutical logisties infrastructure at all stages of the pharmaceutical supply chain.
5. Ensure that public procurement of medicines for veterinary use follows the same principles outlined in this policy.
6. Restructure KEMSA by statute, as the centralized, autonomous, primary public procurement agency for integrated public-sector procurement and supply of medicines, medical supplies, medical devices and equipment.
7. Coordinate procurement of EMMS in the context of SWAp through the P-ICC.
8. Encourage collaboration between public and non-public procuring entities for EMMS, including pooled procurement at institutional and sub-regional levels.
9. Encourage and facilitate outsourcing or privatization of non-core functions in public pharmaceutical procurement and supply.
10. Develop and gazette zoning regulations to promote equitable access to pharmaceutical products and services in the establishment of wholesale and retail pharmaceutical outlets.



## 3.4 EXPANDING LOCAL PHARMACEUTICAL PRODUCTION

96. Kenya has enormous capacity for the manufacture of pharmaceuticals for the local and regional markets. At current production capacity of 50% and with a market size estimate of 28%, the local industry is a vibrant player in Kenya's manufacturing sector, which is a key economic growth driver towards increased industrialization and the attainment of Vision 2030. There are currently 42 local pharmaceutical manufacturers engaged in the formulation and packaging of pharmaceutical products for human and veterinary use. The local industry produces primarily generic medicines which are generally affordable.

97. A substantial and increasing proportion of generic medicines requirements in the country are supplied by local manufacturers. Through Vision 2030, the country aims to become the provider of choice for basic manufactured goods in Eastern and Central Africa. Incentives for the local industry have included exemptions from taxes and duties on raw materials, excipients and packaging materials and a 15% preference in local procurement. However, the local industry faces challenges of inadequate technology transfer, high cost required for compliance with quality standards and international accreditation of local pharmaceutical manufacturers; and lack of full implementation of TRIPS flexibilities. Incentives should be prioritized for essential medicines, with consumers as the primary beneficiaries.

98. However, high production costs undermine price competitiveness of the local industry, hampering its growth. Previously, some multi-national pharmaceutical companies had local production plants in Kenya, but over the years these have relocated to other countries, due to unfavorable business conditions such as poor infrastructure, high energy costs and taxation of production inputs. Some local firms manufacture pharmaceuticals under license for companies abroad, while at least one local company has a voluntary license for the manufacture of HIV medicines. There is virtually no local industry for active pharmaceutical ingredients (APIs), which are imported mainly from India, China, and Europe. More than 90% of other pharmaceutical inputs (excipients) and about 60% of packaging materials are imported. Importation attracts charges that contribute to the high production cost.

99. Local sourcing of generic medicines by the public and faith-based procurement agencies (KEMSA & MEDS respectively) has benefits in reducing overall transaction costs for the pharmaceutical supply chain, through short lead times, greater flexibility on deliveries, credit facilities and reduced need for large buffer stocks. Local sourcing also plays a critical role in emergency situations, where lives can be saved through speedy delivery of required supplies.

100. The local industry offers great potential for Kenya to attain self-sufficiency in essential medicines and to serve the export market, while creating much needed employment. Pharmaceutical manufacturing is governed by Good Manufacturing Practices (GMP), which require strong regulatory oversight and enforcement. A well-regulated pharmaceutical sector fosters consumer confidence in the medicines originating from and those circulating in the Kenyan market.

### 3.4.1.1 Institutional and Legal Arrangements

101. The Government is not involved in pharmaceutical manufacturing, having divested from it in the 1980's. There are 42 privately owned local pharmaceutical manufacturers, producing a wide range of generic medicines for local distribution, as well as export. Some local firms also manufacture under contract for companies either based in Kenya or elsewhere. The Federation of Kenya Pharmaceutical Manufacturers (FKPM) is the umbrella body through which local manufacturers articulate and convey their interests to relevant forums regarding policies, regulation, trade and quality. The industry is regulated by more than 10 Acts in addition to Chapter 244, and their enforcement is uncoordinated. Through the PPDA, local manufacturers are accorded an incentive of 15% preference in public procurement.

102. **Key issues in local pharmaceutical production include:**

a) Conflicting policies and legislation; and over-regulation of the industry.

b) Poor infrastructure and high costs of power and other production inputs.

c) Negative publicity on generics and on locally manufactured products.

d) Limited technology transfer for manufacture of generics.



e) High costs of GMP compliance and for international accreditation of local pharmaceutical manufacturers.

f) Lack of full implementation of TRIPS flexibilities.

g) Weak regulatory environment for GMP compliance, hindering access by the local industry to regional markets and donor-funded programmes.

h) Entry barriers (legal and administrative) to starting local manufacturing ventures.

i) Limited pool of specialized pharmaceutical personnel to meet the needs of industry (e.g. R&D, industrial pharmacy, biotechnology, quality control and assurance).

103. **The Government will promote self-sufficiency in essential medicines production and growth in pharmaceutical exports. To facilitate the attainment of this objective, the Government will:**

1. Create an enabling environment to encourage investment in local production of quality essential medicines, and compliance with established standards for cGMP.
2. Encourage technology transfer and international accreditation of local manufacturers to enhance their competitiveness.
3. Consolidate, harmonize and streamline all relevant statutes to ensure clarity and reduce bureaucratic bottlenecks to local pharmaceutical manufacturing.
4. Curb the production, distribution and sale of substandard and counterfeit medicines; and illegal sale of medicines.
5. Enhance and promote the procurement, distribution and use of quality medicines.
6. Develop incentive schemes for investment in local production of essential medicines to improve their affordability, availability and quality. Incentives may include local preference in public procurement, removal of taxes and duties, export incentives, fast-track market authorization, among others in line with national industrialization strategy.

## 3.5 IMPROVING AFFORDABILITY OF ESSENTIAL MEDICINES

### 3.5.1 Overview of Medicine Prices and Affordability in Kenya

104. Medicine prices are generally high in Kenya, and a barrier to accessing healthcare. The majority of the population cannot afford key essential medicines, which they have to pay out-of-pocket. Public and mission procurement in Kenya attains competitive prices below international reference prices (IRP)[18], but prices to patients are relatively high compared with neighboring countries and IRP. Furthermore, there are wide geographical and inter-sector variations in medicine prices as well as variations between medicines of the same therapeutic category. This suggests high and un-standardized mark-ups along the medicine supply chains. Innovator products are generally more expensive than their generic equivalents.

105. About 80% of total pharmaceutical expenditure (TPE) in Kenya is private, mostly out-of-pocket. Therefore, high medicine prices are a major burden for households, and the majority cannot afford the medicines they need[19]. Faced with catastrophic expenditures for medicines, the poor often forego treatment; procure substandard products or sub-optimal dosages, which results in worsening of the condition, spread of communicable diseases and reduced participation in economic activities.

#### 3.5.2 Medicine Pricing Approaches in Kenya

106. The Government abolished all forms of price controls since October 1994; hence medicine prices and mark-ups are not regulated. There is no policy guidance on the pricing of medicines in any sector; and competition among suppliers of essential medicines is not regulated. In the **public sector**, KEMSA issues medicines to health facilities at cost (i.e. at procurement prices), with Government providing a separate allocation for costs of distribution. The public facilities provide medicines free of charge, or at mark-ups set by the facility in the context of cost sharing. In the **faith-based health services**, MEDS sets prices to health facilities through regressive mark-ups, to cover operation costs on a non-profit basis. The facilities in turn set prices to patients independently. **Private sector** health facilities, wholesale and retail outlets set their prices independently and on a

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

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



full cost recovery basis. A common practice within the supply chain is price discounting, which is applied informally between suppliers. The price benefit of discounting may not be passed fully to the patient.

107. Some publicly procured medicines, or those financed by development partners, are provided through KEMSA and MEDS, free of charge or at a nominal fee to patients. These include ARVs, medicines for TB and malaria; immunization supplies; condoms and contraceptives, among others. The Ministry of Finance and the relevant development partner(s) usually sign an agreement for provision of donor funded medicines free of charge. Medicines for emergencies are also supplied free of charge, usually financed by Government or partners.

108. The Government does not impose pharmaceutical tariffs, recognizing that a healthy population generates economic gains that outweigh the minimal contribution to the GDP of any taxes on medicines. Furthermore, the poor would disproportionately bear the financial burden of such regressive taxes, thereby limiting access for the most vulnerable in the population. This principle extends to the EAC Customs Union, which abolished import duty on medicines in 2005. However, the lack of any regulation in the pricing of essential medicines has contributed to a high price burden, especially to the poor and disadvantaged. This approach differs from the practice in many developed countries, where pharmaceutical prices and costs are strictly regulated as a major component of public healthcare costs.

#### 3.5.2.1 Institutional and Legal Arrangements

109. There is no central authority for the pricing of essential medicines; and numerous approaches are in use by different healthcare providers. Information on import and export prices is declared on import declaration forms (IDFs) approved by PPB. The Kenya Revenue Authority (KRA) assesses the tariffs and taxes chargeable on products, and issues exemptions on pharmaceuticals as appropriate, in consultation with the PPB. The Department of Pharmacy has been monitoring prices and availability of key essential medicines, but there is no structured mechanism for corrective interventions.

110. The Restrictive Trade Practices, Monopolies and Price Control Act (Cap. 504), governs price and competition practices, through the

Monopolies and Prices Department of the Ministry of Finance. In line with recent developments at the COMESA and EAC levels, the Competition Bill 2009 is before Parliament. It seeks to strengthen the regulation and promotion of competition in the national economy. The Bill proposes the establishment of the Competition Authority as an autonomous regulatory agency; and it has provisions to protect consumers from unfair and misleading market conduct, and to align the law with Kenya's international obligations. The provisions for consumer welfare protection and empowerment provide a framework to integrate and harmonize Government efforts in ensuring the provision of affordable essential medicines to consumers.

111. **Key challenges relating to pricing of medicines are:**

a) High medicine prices to patients, being a major barrier to access.
b) Lack of systematic information on medicine prices, components and trends.
c) Inappropriate application of trade policies, without any safeguards to cushion individuals and households against the burden of high pharmaceutical prices.
d) High out-of-pocket health expenditures, with medicines taking a major proportion.
e) Large markups along the medicines supply chain, resulting in high patient prices due to cumulative price components.
f) Absence of policy guidance and regulation on the pricing of essential medicines.
g) Large disparities in patient prices geographically and across health care providers.
h) Variations in procurement prices of medicines among public and faith-based agencies.
i) Lack of transparency and inadequate consumer information on the pricing of medicines.

112. To address the challenges of high prices and low affordability of medicines the Government will monitor and negotiate prices of key essential medicines, rationalize the medicine pricing system in all sectors and promote the use of generics.



### 3.5.3 Regulation and Rationalization of Medicine Prices for Affordability

113. **The Government will endeavor to ensure that essential medicines are affordable to the population. To facilitate the attainment of this objective the Government will:**

1. Promote transparency in the pricing structure of medicines by pharmaceutical manufacturers, distributors and health service providers.
2. Establish and support a multi-disciplinary mechanism to monitor and advice on medicine prices and affordability.
3. Provide policy guidance on pricing structures for essential medicines by all categories and monitor prices and affordability of essential medicines in all sectors.
4. Institute a mechanism to monitor medicine price increases through notification to the FDA, with a view to regulating excessive increases.
5. Expand and sustain mechanisms to provide subsidized essential medicines at the primary level through the public and faith-based supply systems.
6. Establish effective exemption mechanisms to remove financial barriers that may hinder vulnerable population groups from accessing essential medicines.
7. Establish an effective mechanism for reimbursement of the cost of essential medicines through health insurance schemes for inpatient and outpatient services.
8. Waive taxes and tariffs on pharmaceutical products, including raw materials, finished goods and packaging materials.
9. Encourage and facilitate bulk procurement of pharmaceuticals, including local and regional pooled procurement where feasible.
10. Where the Government deems that specific medicines are unaffordable and that these medicines are essential to the health and well-being of a specific population group, the Government will make them available through authorized non-public health care providers at acquisition cost plus the transaction costs involved.

### 3.5.4 Promoting Use of Generics

114. The use of interchangeable multi-source pharmaceutical products, using the international non-proprietary name (INN), or generic name, is a recognized strategy to reduce medicine costs and

expenditure. It also contributes to a rational system of procurement and distribution, drug information and appropriate use in all sectors and at all levels of the healthcare system. Currently, only about one third of prescriptions in public and faith-based facilities are prescribed by generic name and the practice is even less prevalent in the private sector. Where a medicine is not prescribed by its INN, substitution of a generic equivalent at the point of dispensing (i.e. generic substitution), is a recognized safeguard to protect the patient from unnecessarily high medicine expenditures. For a few specialized medicines, patients may require to be maintained on the same product. However, strict regulation of these exemptions is required.

115. **Key issues on the use of generics in Kenya include:**

a) Absence of policy guidance on use of generic medicines and generic substitution.
b) Low prescribing by generic name in all sectors.
c) Unethical promotion of branded products, eroding the confidence of prescribers and consumers in the use of generics.
d) Lack of authoritative information on the quality of medicines in the market.
e) Information asymmetry and perverse incentives within the pharmaceutical market.
f) Conflicting legislation on counterfeits which focuses on patent protection, and creates the risk of generics being erroneously classified as counterfeits.
g) Limited public resource allocation for promoting AMU, including use of generics.

116. **The Government will promote the use of generics through implementation of incentives that favor their production, public procurement, prescribing and dispensing. To promote use of generics, the Government will:**

1. Promote generic prescribing in the public and private sectors through the formulation of an appropriate medicines use policy/strategy.
2. Create rules and regulations that allow generic substitution in the public, faith-based and private sectors. It will be incumbent upon the pharmacist, before dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that



such substitution takes place with the full understanding and consent of the patient.
3. Affirm the right of patients to make informed decisions concerning their own health, including a choice for generic medicines.
4. Through the FDA:
   (i) Gazette a limited list of products that may not be substituted.
   (ii) Enforce compliance with set quality standards for all medicines in the market
   (iii) Devise mechanisms and incentives to fast-track registration of generics

## 3.6 PROMOTING APPROPRIATE MEDICINES USE

117. In 1985 a 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 poly-pharmacy. Such practices lead to significant wastage of scarce resources for health, poor patient outcomes, and increased adverse effects. Since then, strategies have been identified globally for improving prescribing and dispensing by health workers, clinical practice of pharmaceutical personnel and the use of medicine by consumers. These include:

- evidence-based selection from the wide range of products available on the market, to standardize treatment and rationalize medicines costs
- access to objective, practical information on medicines and their proper use
- appropriate training of health workers on appropriate medicines use
- Pro-poor policies and strategies that minimize out-of-pocket expenditure on medicines by households.

118. Appropriate Medicines Use (AMU) requires that patients receive appropriate medicines in the correct dosages and within the required time frame. AMU leads to improved patient care and safety, and

prudent utilization of scarce resources for health. There is no national strategy for promoting appropriate medicines use.

### 3.6.1 Medicines Selection and Rationalization of Therapeutics

119. **Selection** of medicines is anchored to the KEML and the Standard Clinical Guidelines (SCGs). The current national clinical guidelines were developed in 2009; while the EML was developed in 2010. There is no EMSL in place and no institutionalized structures for monitoring the use of these guides or for their systematic review and revision. The use of SCG, EML and EMSL should be promoted and reinforced to standardize treatment in all sectors, and they should be regularly revised, taking into account trends in therapeutics.

#### 3.6.1.1 Institutional and Legal Arrangements

120. The National Medicines and Therapeutics Committee (NMTC), established through the KNDP (1994), is the Government advisory body responsible for broad guidance on medicines use, including selection of medicines. The NMTC requires restructuring and technical enhancement to enable it play its role effectively. Health facilities (public, private, faith-based) also establish Medicines and Therapeutic Committees (MTCs) for promoting appropriate and evidence-based use of medicines.

121. **Key issues affecting medicines selection and rationalization of therapeutics include:**

a) Lack of coordination of medicines use strategies at national and facility levels
b) Lack of implementation of AMU as a core strategy for rationalizing health resources.
c) Irregular review and updating of standard clinical guidelines (SCG) and EML
d) Low adherence by health workers to SCG and EML

122. **The Government will promote evidence-based selection of medicines to meet public health needs. To facilitate the attainment of this objective the Government will:**

1. Restructure and support the National Medicines and Therapeutic Committee (NMTC) to advise Government and stakeholders on the appropriate use of medicines.



2. Through the NMTC, collect, evaluate and disseminate systematic data on medicines utilization to monitor and act on policy adherence.
3. Review and regularly update the following standard therapeutics tools, at least every 2 years and promote their use at all levels of the health system. The Essential Medicines Concept as defined by WHO will be the basis for medicines selection.
   a) The Kenya Essential Medicines List (KEML)
   b) The Kenya Essential Medical Supplies List (KEMSL)
   c) Standard Clinical Guidelines for management of health conditions in the country.
4. Promote the Essential Medicines Concept and evidence-based selection of medicines in all sectors and in training programmes for health workers.
5. Mandate health facilities and counties to establish Medicines and Therapeutic Committees (MTCs), with membership drawn from pharmacists, physicians, nursing staff, specialists and health administrators. Each MTC will be required to:
   a) Adapt from the KEML a list of EMMS to be procured, prescribed and dispensed within the facility, based on the local disease patterns and the best available evidence on therapeutic efficacy and cost-effectiveness.
   b) Monitor therapeutic trends and other medicines use practices in the facility; and institute corrective measures to ensure rational prescribing and dispensing.
   c) Develop institutional policies, guidelines and advocacy initiatives aimed at improving use of medicines.
   d) Provide feedback to the national MTC on evidence and trends in therapeutics, to guide review of the national STG and EML.

### 3.6.2 Appropriate Medicines Information and Promotion

123. Many consumers today are knowledgeable about the diseases that affect them, the therapeutic alternatives, and their right to participate in decisions about their care. Information about medicines that is accurate, accessible, objective and practical can greatly enhance the participation of consumers in their health care decision-making and

improve medicines use. The health system also benefits from consumer feedback on medicines issues, through appropriately supported channels.

124. Medicines information to consumers and healthcare workers comes from a wide range of sources, including promotional materials and advertisements; and the media. Health workers also obtain drug information from the pharmaceutical industry through conferences, forums for continuous professional development (CPD), promotional materials and marketing representatives. The internet has also become an important source of information for both health workers and consumers.

125. However, biased information and false claims about medicines pose danger to patients and to public health. Inappropriate medicines information may emanate from various industry players, uninformed media and the internet; unlicensed outlets and unqualified personnel, all exacerbated by weak regulatory enforcement.

#### 3.6.2.1 Institutional and Legal Arrangements

126. The PPB regulates drug information, promotion and advertising, as provided for in Chapter 244. However, there is no designated poisons centre in the country, which greatly limits access to objective information on medicines and to critical information for the prevention and management of poisoning. Other organizations that may be sources of medicines information to consumers include the PSK, KPA, KMA, KMPDB, and the Nursing Council of Kenya (NCK), veterinary and nutritionists' councils/boards.

127. **Key issues affecting medicines information and promotion include:**

a) Weak regulation of sale and promotion of medicines to consumers
b) Low consumer awareness about the dangers of inappropriate medicines use
c) Increasing use of ICT for uncontrolled information to consumers on medicines
d) Inadequate mechanisms for feedback, enquiries and complaints by consumers
e) Unauthorized promotion and advertising of medicines, including TM



f) Lack of a centralized source of objective and up to date information on drugs and poisoning, including unbiased information to consumers about medicines.

128. **The Government will ensure access by health workers and consumers, to medicines and therapeutics information that is unbiased, accurate, appropriate and practical. The following actions will be taken:**

1. Strengthen and enforce legislation to control and regulate the promotion of human and veterinary medicines and other therapeutically active substances, including TM.
2. Develop mechanisms for the provision of reliable medicines information to health decision-makers at household, community and national levels, to enable them take appropriate actions.
3. Establish and support a National Medicines and Poisons Information Service.
4. Involve consumers in AMU strategies at all levels.
5. Establish an effective mechanism for consumer feedback and complaints on medicines issues, including a pharmaceutical desk within the Public Complaints Commission (Ombudsman).

### 3.6.3 Prescribing and Dispensing

129. Prescribing and dispensing should ensure the patient's best interest in terms of appropriate therapy, safety, efficacy and cost effectiveness; and promote patients' understanding of, and the appropriate use of medicines. These professional functions should be supported by monitoring and feedback mechanisms that promote adherence to standard treatment guidelines and medicine lists. STGs and the KEML are key tools for good prescribing and dispensing, and their impact is enhanced through adequate dissemination, sensitization and an effective system that monitors and enforces their use. An important consideration is ensuring that only qualified personnel prescribe and dispense medicines; and that consumers only access medicines from authorized dispensing outlets. Good prescribing and dispensing hinges on standardized tools and processes, training and an effective regulatory framework.

130. Pharmaceutical services have evolved into a comprehensive and patient-focused model of Pharmaceutical Care that ensures effective use of the most appropriate medicines; and actively involves the

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130. Pharmaceutical services have evolved into a comprehensive and patient-focused model of Pharmaceutical Care that ensures effective use of the most appropriate medicines; and actively involves the

patient in ensuring successful therapeutic outcomes. In Pharmaceutical Care, the pharmacist is a core member of the healthcare team, consulting with prescribers on appropriate drug selection and dosage, counseling patients on adherence to treatment, monitoring use of medicines and adverse drug reactions, and participating in outreach services to the community. The pharmacist's role is critical in promoting appropriate medicines use (AMU) through medicines and therapeutic committees (MTCs); evidence-based selection and other rationalization and cost containment measures.

### 3.6.3.1 Institutional and Legal Arrangements

131. Prescribing of medicines occurs in health facilities in all sectors, as well as in clinicians' private practice. It is an integral part of the practice of medicine or dentistry, as set out in the Medical Practitioners and Dentists Act. The majority of health facilities have in-house pharmacies where prescribed medicines are usually dispensed. If the medicine is not available, the patient has to obtain it from a different outlet, usually in the private sector. The PPB is responsible for developing and enforcing standards for prescribing and dispensing while the Kenya Medical Practitioners and Dentists Board (KMPDB), the Nursing Council of Kenya (NCK) and the Clinical Officers Council are responsible for regulating the practice of medical and dental practitioners, nurses and Clinical Officers respectively.

132. **Key issues affecting prescribing and dispensing of medicines include:**

a) Prescribing of medicines by unauthorized personnel
b) Dispensing of medicines though unlicensed outlets
c) High cost of health care, leading to widespread practice of self-medication
d) Lack of policy guidance on Good Prescribing Practices (GPP) and Good Dispensing Practice (GDP), including prescribing by International Non-proprietary name (INN) and lack of adherence to related legal provisions
e) Weak collaboration between regulatory and professional associations in enforcing standards of professional practice
f) Lack of enforcement of generic prescribing and substitution.
g) Increasing use of the Internet as a source of medicines



h) Lack of regular information on the quality and safety of medicines in the market.
i) Lack of policy guidance and enforcement of prescribing by level of care.

133. **The Government will promote appropriate prescribing and dispensing that optimizes therapy. To facilitate the attainment of this objective, the following principles shall apply:**

1. Only licensed outlets are allowed to dispense medicines in all sectors.
2. Only authorized personnel are allowed to prescribe medicines.
3. Only authorized personnel are allowed to dispense medicines in all sectors.
4. Prescribing is done according to legal provisions and Good Prescribing Practices.
5. Dispensing is done according to legal provisions and Good Dispensing Practices.
6. Pharmaceutical Care is institutionalized as a core strategy for patient-centered healthcare.
7. There is collaboration with:

   a) Relevant regulatory bodies and professional associations to develop mechanisms for enforcing legal provisions for levels of prescribing.

   b) Relevant ministries to ensure that veterinary prescribing conforms to this policy.

### 3.6.4 Traditional Medicines (TM)

134. TMs are an essential part of the national culture and part of primary health care. WHO estimates that 80% of people in Africa have used TMs at some point in their lives, to meet their health care needs. This significant use calls for strong policy and legislative framework to guide development and use of TM, and to safeguard public health and safety. Traditional health practitioners (THPs) are to be found throughout the country, many of them practicing within their residential localities. Other THPs come from countries such as Tanzania and China; and some Kenyans travel to these countries to obtain treatment through TM.

135. Traditional health practitioners are currently regulated as traditional and cultural practitioners through the Ministry of Culture and Social Services. However, TM use and development has implications on

health, national conservation and intellectual property, among others. The National Council for Population and Development (NCAPD) has been coordinating a multi-stakeholder process aimed at developing this policy and legal framework, and a Bill is currently before parliament.

In the context of this ongoing process, there is need to ensure that the health implications of TM practice are fully identified and comprehensively addressed, to ensure adequate protection of the health and safety of the population. The University of Nairobi and KEMRI are the main institutions that undertake research in TM. The Ministries in Health, KEMRI and the academia have critical roles in articulating and guiding TM development in the context of health, and for ensuring that commercially viable TM are appropriately developed.

137. **Key issues in TM use include:**

a) Inappropriate promotion and advertising of TM products, practitioners and practices
b) Inadequate policy, legal and institutional framework to guide TM development and utilization; and weak HR capacity to address issues of TM in the context of public health
c) Lack of comprehensive documentation on TM use, safety, efficacy and quality

138. **The Government will promote the development and appropriate utilization of safe, quality and efficacious TMs. To facilitate the attainment of this objective the Government will:**

1. Develop an appropriate policy, legal and institutional framework to facilitate and coordinate health-related TM activities, including research and development, regulation of TM products and the practitioners and consumer education.
2. Promote appropriate development and utilization of TM in such a way as to reduce the risks and maximize the benefits involved in their use.
3. Promote the local production of useful and commercially viable TM for human and veterinary use.

## 3.7 PHARMACEUTICAL RESEARCH AND DEVELOPMENT

139. Research plays a major role in industrial transformation and economic growth, as well as in healthcare delivery. Research and development (R&D) is a key feature of the global pharmaceutical



industry, with huge investments in research for new drugs and health technologies, or for improvement in the performance of existing products. Pharmaceutical R&D is driven by current developments in disease control and treatment, in particular the need for enhanced use of diagnostics; early onset of treatment and use of newer, safer, more efficacious and age-appropriate medicines. Kenyan institutions are involved in various stages of the innovation processes, such as laboratory research, drug formulation, clinical trials and bioequivalence (BE) testing. In addition, Kenya is endowed with many medicinal flora and fauna, but there is limited investment to exploit this endowment in making products for use in healthcare. In cases where research has shown the presence of pharmacological activity in plants, the research ends in only publications, but not in products. Only 0.6% of GDP is allocated by Government for all research, which is far from adequate.

140. A current gap is that R&D is virtually lacking for the neglected disease conditions that disproportionately affect poor populations. The Global Strategy and Plan of Action (GSPOA) on public health, innovation and Intellectual Property, negotiated though the World Health Assembly, provides a global framework for better investment in R&D for neglected diseases. In addition, there are initiatives to develop a global patent pool through which patent-holding drug companies would allow the development of generic versions of their drugs, including combinations with drugs of other companies. There is need for concrete national strategies to implement these initiatives for improved access to medicines, and to continue providing leadership in these endeavors in the region.

141. The potential for basic, operational and clinical research therefore exists in Kenya, particularly in formulation and product development of both conventional and herbal medicines; BE studies and research on quality of medicines. If strategically directed, pharmaceutical research can improve the health of Kenyans through addressing their priority health needs.

### 3.7.1.1 Institutional and Legal Arrangements

142. The Ministry of Higher Education, Science and Technology (MOEST) through the National Council for Science and Technology (NCST) coordinates scientific research, while KIPI administers the Intellectual Property Act. The PPB regulates clinical trials on human subjects, in collaboration with various Ethical Review Boards

(ERBs). The School of Pharmacy, University of Nairobi and the Kenya Medical Research Institute (KEMRI) have been undertaking various forms of research on medicines and treatment, including clinical trials, research on TM and in the area of product development.

143. In order to account for genetic or other differences in populations, certain drugs are required to undergo BE testing during development, to demonstrate their efficacy in the population in which they are intended to be used. BE testing is a main challenge for drugs produced and/or marketed in Kenya, because the infrastructure is lacking and the costs of conducting BE studies elsewhere is prohibitive. Kenya has the potential to develop BE testing centers to serve the domestic and regional market.

144. **Key issues in pharmaceutical R&D include:**

a) Lack of coordination of the actors involved in research on pharmaceuticals
b) Lack of harmony of research policies and legal framework
c) Lack of prioritization of pharmaceutical research, including operational research
d) Limited public investment in research, including health-related research and BE.
e) Limited local appreciation for and lack of recognition of quality research.
f) Inadequate mechanisms for dissemination and utilization of research findings
g) Limited collaboration between industry, academia and other researchers
h) Weak institutional capacities, including HR, equipment and other infrastructure
i) Limited capacity for operational research and pharmaceutical R&D.

145. **Government will promote research and innovation on medicines to address priority health issues: To facilitate the attainment of this objective, the Government will:**

1. Coordinate research primarily directed at enhancing pharmaceutical services.
2. Establish and maintain a medicines research database and facilitate the prioritization of research to address key health needs;



3. Foster collaborative mechanisms to promote and enhance pharmaceutical research.
4. Increase support for pharmaceutical research (including operational research) and utilize research findings to further develop pharmaceutical policies and practices.
5. Encourage, motivate and support health institutions and professionals to conduct R&D on medicines including TM.
6. Encourage and support the establishment of clinical and BE testing centers for pharmaceutical research.

## 3.8 INFORMATION AND COMMUNICATION TECHNOLOGY (ICT)

146. There have been numerous advances in the field of ICT, and many have been embraced in various facets of the pharmaceutical sector. ICT use in pharmaceuticals includes technological advancements in design and performance of manufacturing equipment, greater automation of processes, including production, procurement and logistics, dispensing, etc. Other areas include information management such as drug registration, including online submission and issuance of regulatory documents (application dossiers, registration certificates and licenses).

147. The country has made significant strides towards narrowing the digital divide within and between Kenya and the rest of the world, through infrastructure expansion and upgrading; and through an enabling legal and institutional framework. However, there remains a major gap in infrastructural and HR capacity for the full application of ICT in the pharmaceutical sector, and in particular, the public sector.

148. The Internet has become a growing source of pharmaceuticals for Kenyans. Many websites purport to offer brand name prescription drugs at discounted prices, and Kenyans are increasingly using this avenue as a source of affordable medicines. Online purchase of any drug poses serious health risks, especially when drugs are shipped to consumers from sources outside of the country, and without import authorization of the regulator. Counterfeit and substandard drugs are easily sold through the internet, and consumers are exposed to this risk when they order medications online.

149. **Challenges relating to ICT in the pharmaceutical sector include:**

a) The growing trend in online pharmaceuticals trade without adequate regulatory controls.

b) Inadequate investment in ICT to drive efficiency and effectiveness in service delivery.

c) Absence of a guiding policy on ICT in regulatory functions (e.g. electronic submissions and market authorizations), hindering adoption of best practices.

150. **To address the challenges of ICT use in pharmaceutical sector the Government will:**

1. Regulate online sale of medicines and implement strategies that encourage consumers to buy medications from reputable pharmaceutical outlets.
2. Invest in ICT infrastructure for effective operation of public pharmaceutical services, including procurement, distribution, regulation and quality control.

## 3.9 HUMAN RESOURCES FOR THE PHARMACEUTICAL SECTOR

### 3.9.1 Pharmaceutical Personnel and Training

151. Pharmacists and pharmaceutical technologists are the two recognized cadres of pharmaceutical personnel in Kenya. To provide adequate pharmaceutical services and compete effectively in the global economic environment, Kenya requires a highly skilled pharmaceutical human resource base with relevant aptitude and skills. The complexity of pharmaceutical issues cuts across all sectors and levels of care, requiring a broad skills mix to identify, analyze and appropriately address emerging issues. The sector is developing a critical mass of pharmaceutical technical expertise, but the numbers and skills mix are inadequate to address the diversity and complexity of health products and technologies; and this requires appropriate strategic review and planning.

### 3.9.2 Pharmaceutical Human Resource Development

152. Training capacity for pharmaceutical personnel has expanded over the years. There are two pharmacy training schools with a joint annual output of 70 and 22 accredited institutions for training pharmaceutical technologists, with an annual output of 885. These institutions also train for the sub-region, with an increasing number



of students drawn from outside Kenya. The demand for postgraduate and higher diploma training has also been growing, and various courses are currently offered by the University of Nairobi and KMTC respectively. These attract students from Kenya and the sub-region.

153. The current training content and mechanisms for deployment of pharmaceutical personnel have been identified as major constraints to their utilization. Pharmacy training is largely oriented towards clinical practice and academic knowledge, with minimal emphasis on other skills required to handle pharmaceutical sector functions, like procurement and supply, manufacturing and trade. Also lacking are mechanisms for the provision of basic pharmaceutical services at the community and primary care levels.

### 3.9.3 Pharmaceutical Human Resource Utilization

154. Currently, there are 2295 registered pharmacists and 2680 enrolled pharmaceutical technologists, i.e. one pharmaceutical personnel for every 7,698 persons or less than 1 per 10,000 persons. This ratio is very low to enable effective provision of pharmaceutical services and development of the sector. Furthermore, these personnel are inequitably distributed, the majority being in the private sector and in urban areas, where they primarily undertake trade-related activities, e.g. wholesale, retail dispensing; import and export; pharmaceutical detailing for promotion and marketing and manufacturing.

155. Recent efforts to address the critical shortage of human resources for health, has contributed to an increase in the numbers of pharmaceutical personnel in the public sector. However, the available personnel are only 25% of the current health sector norms and standards; and the mix of skills is inadequate to address the entire scope of pharmaceutical services. The low number is attributable to inappropriate scheme of service; weak policy direction and inadequate management structures in public pharmaceutical services. Consequently, only 38% of public health facilities and 31% of mission facilities have qualified pharmaceutical personnel handling medicines; a situation that greatly compromises healthcare services.

156. The faith-based health services have faced the challenge of inability to attract and retain a critical number of qualified pharmaceutical personnel. A recent policy shift has resulted in the Government

deploying health personnel to FBHS, in recognition of the complementary role that they play in healthcare delivery. However, pharmaceutical personnel are not currently deployed to FBHS under this policy.

157. Mandatory continuous professional development (CPD) is implemented for pharmaceutical personnel through the PPB and professional associations, as a way of enhancing skills for improved service delivery. However, the CPD programme is largely private sector driven, and not aligned towards the attainment of public health objectives. The country is involved in regional initiatives to develop mechanisms for mutual recognition of professional personnel which would facilitate movement and utilization of pharmaceutical personnel across the EAC and COMESA regions.

158. Implementation of this policy and its attendant strategies will require a broad skills mix and specialization in over 30 different areas to maximize the contribution of pharmaceuticals to national development. These specialties include public health, clinical pharmacy, pharmacy administration, business administration, pharmaco-economics and drug regulation. Clear policy direction is required to inform strategies that promote better utilization of pharmaceutical expertise, and thereby spur demand for rational development of pharmaceutical personnel, and their involvement and specialization in areas that are relevant to pharmaceutical and health policy.

### 3.9.3.1 Institutional and Legal Arrangements

159. Training of pharmaceutical personnel started at the Kenya Medical Training College (KMTC), established in 1927, initially training compounders, then dispensers, and later pharmacy assistants. In 1968, the Government started a 3-year diploma in pharmaceutical technology at KMTC. In the KNDP (1994), fundamental provisions were made to phase out pharmaceutical technologists' training in favor of a 2-year diploma level course for pharmacy technicians. However, the phase-out was later found to be untenable, given the high numbers of pharmaceutical technologists already in practice, the lack of modalities for their progression to degree-level training and the critical role played by this cadre in the health system. This diploma training has been expanded and streamlined through standardization of the curriculum, accreditation of additional training institutions and the establishment of a mechanism by the



PPB to enroll the qualified personnel. There are now 22 institutions accredited to offer the diploma.

160. Until 1974, there was no local institution offering degree course in pharmacy, necessitating students to study abroad. Since its inception, the School of Pharmacy of the University of Nairobi has been the only institution training pharmacists in Kenya. In 2009 and 2010, Kenyatta University and two private universities respectively, received PPB approval to mount degree courses in pharmacy.

161. **Key issues impacting on training and development of human resources for the pharmaceutical sector include:**

a) Inadequate numbers of trained personnel, and limited local training capacity to meet national and regional needs.

b) Changing role of the pharmacist in the health care setting

c) Inequitable distribution of pharmaceutical personnel across the country with the majority concentrated in the private sector and in urban areas.

d) Lack of recognition of specialties, and inappropriate deployment of expertise.

e) Unmet need for pharmaceutical training for the local and regional markets, due to limited training capacity in the region.

f) Lack of mechanisms for academic progression from diploma to degree.

g) Lack of alignment of training to the needs and trends of the pharmaceutical sector, including skills gaps in key areas pharmaceutical policy areas.

162. **The Government will direct and support appropriate training, development and management of human resources required for delivery of pharmaceutical services. To facilitate the attainment of this objective, the Government will:**

1. Develop and implement a national pharmaceutical human resource strategy.
2. Enact legislation to recognize pharmaceutical specializations
3. Review and implement pharmaceutical schemes of service to attract and retain appropriate HR for the public service.

4. Recruit and retain adequate numbers of pharmaceutical personnel in the public service in line with established health sector strategies, norms and standards.
5. Include the deployment of pharmaceutical personnel in ongoing sector strategies and initiatives for improving HR capacity in the FBHS.
6. Expand pharmaceutical training capacity and opportunities at colleges and universities and create mechanisms to enable access by trainees from other countries
7. Expand the variety and scope of postgraduate courses to meet the growing requirements for pharmacy specialists in Kenya and the sub-region.
8. Through the FDA and the Pharmacy Council:
   a) Institute mechanisms for progression from diploma to degree level.
   b) Devise and enforce a system for continuous professional development.
   c) Foster multilateral collaboration to enable mutual recognition of pharmaceutical personnel in the context of regional integration and international cooperation.
9. Define the competencies, roles and responsibilities of pharmaceutical practitioners at all levels and effectively regulate their training and practice.
10. Develop capacity and tools for the delivery of basic pharmaceutical services at the dispensary and community levels.
11. Encourage and support the review, harmonization and regulation of pharmaceutical training curricula and standards to align with defined needs of the health sector.

## 3.10 PROMOTING ACCESS AND SAFEGUARDING PUBLIC HEALTH IN PHARMACEUTICAL TRADE

163. International trade is an important instrument for promoting social and economic development, including the creation of job opportunities. Well regulated, transparent, non-discriminatory and fair multilateral trade is essential to permit developing countries to benefit from globalization.



164. Pharmaceuticals are a principle export to the EAC and COMESA sub-regions, amounting to 0.3% of the value of all exports to these destinations in 2008. In particular, Kenya is major source of medicines for Uganda, Tanzania and Southern Sudan, but the country is a net importer of pharmaceuticals, including many generic medicines that can be manufactured locally. In 2008, KSh 20.7 billion worth of pharmaceuticals were imported, a 30% increase from 2007. Pharmaceutical imports originate from over 20 countries, among them India, China, and several countries in Europe.
165. Trade policies are a major challenge for pharmaceuticals, and this is compounded by the common but erroneous misconception within the health sector, that pharmaceuticals are 'health commodities' like other inputs into healthcare services. Failure to comprehensively address pharmaceutical trade dimensions in public health is a key shortcoming of current national health policies.
166. International agreements within the World Trade Organization (WTO), in particular the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), sets minimum standards in the field of intellectual property (IP), and obliges member states to grant full patent protection (product and process) for new innovations - including pharmaceuticals - for at least 20 years. The TRIPS Agreement has built-in flexibilities for ensuring access to essential medicines, such as compulsory licensing and parallel importation. However, the role of IP issues in public health is poorly articulated and the health sector is inadequately represented in key trade and development forums.
167. Ongoing multilateral trade negotiations or Free Trade Agreements (FTAs) commonly build in stringent drug patent and marketing rules which pose a risk to access to essential medicines. They seek comprehensive agreement on liberalization of services, rules on foreign investment and IP protection, including 'TRIPS-plus' concessions that exceed the WTO standards. The Doha Round of multi-lateral trade negotiations has not been concluded since 2001; and IP is among the issues of concern for developing countries, as they impact on future access to essential medicines for HIV, TB and malaria; and other innovative health technologies.
168. There have also been initiatives to harmonize intellectual property laws across the EAC, but a key constraint is the different

manufacturing capacities and levels of development among the countries, which have different provisions under TRIPS.

### 3.10.2 Enhancing Regional and International Cooperation

169. On the regional and international levels, the current pharmaceutical management structures are inadequate to fully articulate the country's interests on pharmaceuticals. In order to reap the benefits of the multilateral trade system, there is need to enhance and support collaboration on pharmaceutical matters including participation in regional and international harmonization, to facilitate pooled procurement and reciprocity arrangements in professional practice, pharmaceutical regulation and market control.

#### 3.10.2.1 Institutional and Legal Arrangements

170. Kenya is a member of the WTO and therefore signatory to the TRIPS Agreement. Paragraph 6 of this Agreement recognizes the right of countries to use the full flexibilities in the agreement to protect public health and promote access to medicines for all. The Industrial Property Act of 2001, administered by the Kenya Industrial Property Institute (KIPI) governs implementation of the TRIPS Agreement and incorporates all the TRIPS flexibilities. The Anti-counterfeit Agency implements the Anti-counterfeit Act, which aims to prohibit trade in counterfeit goods. However, the Act gives a broad definition and interpretation of counterfeit medicines; and provides investigative and prosecutorial mechanisms that could interfere with the importation and distribution of generic medicines, thereby impeding access to life-saving medicines.

171. The Ministry of EAC Cooperation coordinates national issues concerning integration in the EAC. The country is also bound by trade policies and agreements within the common markets of the EAC and COMESA. The Ministry of Trade and Industrialization implements policies and laws relating to trade, including pharmaceutical trade. The Ministries in Health have also established offices for international relations, as well as health attaches in various embassies and high commissions.

172. **Key issues impacting on access to medicines in pharmaceutical trade include:**

a) Current health and trade policies do not capture the complexity and dynamics of pharmaceutical trade and its impact on public health.



b) Inadequate policy attention on the context of pharmaceuticals in trade negotiations and multi-sectoral international agreements.
c) Conflicting legislation that links IP protection to the growing menace of counterfeiting, and puts genuine generics at risk of being cast as 'fake' or counterfeit.
d) Ongoing regional integration processes and the requisite need to harmonize pharmaceutical policies and systems within the regional economic blocs.
e) Inadequate mechanisms for collaboration and information exchange with relevant international bodies (e.g. WHO, EU, USFDA, etc) and regional regulatory authorities, so as to benefit from mutual assessments and other regulatory experiences, including harmonization of technical and administrative requirements.

173. **The Government will place public health and access to medicines as priorities consistent with the basic tenets of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health. To facilitate the attainment of this objective, the Government will:**

1. Take all necessary precautions to safeguard all the TRIPS flexibilities, and to facilitate their full implementation in the production, procurement, importation and sale of essential medicines and essential health technologies for improved access.
2. Fully integrate pharmaceuticals in trade policy decision making, by enhancing the national capacity to effectively negotiate the multiple facets of FTAs, and to safeguard all provisions for ensuring access to essential medicines.
3. Amend the Anti-counterfeit Act to provide for a definition of counterfeit medicines that is in line with internationally agreed definitions; and to ensure that the FDA has the requisite power to identify and take action on counterfeit medicines in a manner that does not to impede access to medicines.
4. Develop a national strategy on public health, innovation and IP, in line with the GSPOA, and support its implementation.
5. Promote joint initiatives aimed at endowing negotiators at bilateral and multilateral trade fora with the necessary skills to uphold TRIPS safeguards in such negotiations.

174. **The Government will foster regional and international collaboration on matters that impact on this Policy and its attendant strategies. To facilitate the attainment of this objective the Government will:**

1. Facilitate the country's participation in regional and international initiatives to harmonize pharmaceutical policies and regulatory systems, including mechanisms for information exchange and mutual recognition of regulatory decisions.
2. Facilitate the participation of relevant state and non-state actors in regional and international initiatives for enhancing access to health products and technologies, such as national or regional pooled procurement.
3. Enhance national, regional and international collaboration effectively to address issues of drug and substance abuse.

## 3.11 ENHANCING ACCESS TO VETERINARY MEDICINES

175. The animal industry relies on medicines, medical devices and other chemicals in the prevention, control and management of animal diseases, many of which are transmissible to human beings. Use of medicines in animals is species-specific, and is guided by the OIE Aquatic and Terrestrial Animal Health Code. The safety and correct use of medicines in animals is a primary concern of the food and animal industries and the health sector. This applies to the various stages of the farm-to-fork chain, including the diagnosis, therapeutics, disease control and food processing control.

176. While human and animal therapeutics have many similarities, major differences obtain in the species range, disease-specifics, diagnostic codes, drug administration criteria and field practices. There are also clearly different technical competencies with respect to human and animal pharmaceutical management. Indeed, the two sectors have been developed fairly separately with respect to policy and legal directions. Whereas the human medicine supply system has a major public sector component, that for the animal industry is largely privatized.

### 3.11.1 Structure of Veterinary Pharmaceutical Services

177. The animal health sector has witnessed extensive liberalization in the provision of veterinary medicines and services. The strategy for provision of veterinary services changed when the Government privatized veterinary clinical services as from 1992. Veterinary



clinical services were thus largely taken over by private practitioners with the government retaining the roles of veterinary public health, extension, notifiable animal disease control and regulatory services. At the same time, ongoing integration at the regional and international level for the purpose of international trade, food safety, public health and environment, presents unique challenges and opportunities that require cross-border harmonization of policies.

178. The Director of Veterinary Services (DVS) oversees the procurement, storage and distribution of vaccines, biological products, anti-trypanosomal medicines for public use. Other veterinary clinical services have been privatized, and hence veterinary practitioners source their pharmaceutical requirements independently.

### 3.11.2 Regulation of Veterinary Pharmaceutical Products

179. Regulation of both human and veterinary medicines is done through the Pharmacy and Poisons Act (Chapter 244). Like the human medicines, effective regulation of veterinary medicines has been hampered by the inappropriate structure and legal framework for pharmaceutical regulation. Furthermore, the overlap of public health, animal health and food safety, calls for expanded roles and competencies and greater synergies in the overall regulatory framework for health products. In particular, there is need to establish well defined structures with enhanced veterinary skills within the medicines regulatory authority, for handling current and future dynamics in the use of veterinary medicines.

#### 3.11.2.1 Appropriate Use of Veterinary Pharmaceutical Products

180. The medicines use regime in veterinary practice differs significantly from that in human clinical practice. The veterinary surgeon simultaneously plays the roles of diagnosis, treatment and drug administration. Furthermore, the distribution and use of veterinary pharmaceuticals has seen the entry of many players who are often unlicensed and inappropriately regulated. These include the producers, importers, sales agents, NGOs, para-veterinarians, agro-vet shops and farmers' cooperative societies. This has resulted in unregistered products, the risk of substandard and counterfeit medicines in the animal industry and illegal sales of veterinary medicines. The consequences are rampant misuse of veterinary medicines, prevalence of antimicrobial residues in the human food

chain and development of antimicrobial resistance by animal and human pathogens.

### 3.11.2.2 Institutional and Legal Arrangements

181. Several legislations regulate veterinary services, including the Veterinary Surgeons Act (Cap 366), Animal Diseases Act (Cap 364), Meat Control Act (Cap 356) and Pest Control Products Act (Cap 346). The DVS is responsible for the procurement and management of animal vaccines and other medicines used for control of notifiable diseases. The supply of veterinary pharmaceuticals is largely through the private sector, comprising pharmaceutical wholesalers, local distributors and manufacturers or imports from other markets supplying private veterinary practitioners. The production and supply of veterinary pharmaceuticals is subject to the same regulatory principles as human pharmaceuticals (CAP 244).

182. **Key challenges affecting access to veterinary pharmaceutical products include:**

a) Lack of coherence between human and veterinary pharmaceutical policies

b) Weak pharmaceutical regulatory framework, hindering effective regulation of human and veterinary pharmaceutical products.

c) Rampant abuse and misuse of veterinary medicines

d) Prevalence of antimicrobial residues in the human food chain

e) Development of antimicrobial resistance by human and animal pathogens, with serious repercussions on animal and human health

f) Entry of many unregulated players in the distribution of veterinary medicines

g) A different medicines use regime for veterinary services, where the veterinary surgeon simultaneously undertakes diagnosis, treatment and administration of drugs.

183. **To enhance access to pharmaceutical products for veterinary use the Government will:**

1. Enhance structures and foster collaboration between pharmaceutical and veterinary services, to ensure adequate control and appropriate use of veterinary medicines.



2. Require all veterinary medicines to be registered by the FDA and enforce their compliance with O.I.E code of practice for registration of veterinary medicines.

3. Ensure that veterinary medicines are distributed only through pharmaceutical and veterinary outlets licensed by the FDA, in accordance with relevant legal provisions.

4. Through the DVS and in consultation with the DPS, establish a Veterinary Medicines and Therapeutic Committee (VMTC) to:

a) Determine the range of veterinary medicines to be marketed in the country and

b) Develop and regularly update an Essential Veterinary Medicines List (EVML).

## 3.12 FINANCING FOR ESSENTIAL PHARMACEUTICALS AND PHARMACEUTICAL SERVICES

### 3.12.1 Overall Health Care Financing

184. The attainment of health goals requires adequate Government investment in health. In recent years the Government has sought to restructure expenditure allocations across sectors to ensure the provision of basic services. In 2000, the Government adopted a three-year MTEF aimed at making spending more effective and oriented towards growth and improved social sector performance. As a result, human capital development, including education and health, has been identified as key priority areas for public spending in line with overall poverty reduction strategies. This has resulted in increased per capita public health expenditure from US$ 6 in 2002 to the current US$ 11 in 2009.

185. However, expenditure in health is still below national targets. Total health expenditure (THE) stands at about 4.8% of nominal GDP; and translates to US$ 27 per capita in 2009 compared to the WHO recommended level of US$ 34 per capita. Government Health Expenditure (GHE) accounted for about 6.4% of total Government expenditure in 2007, far short of the Abuja Declaration of 2001, where governments committed to spend at least 15% of the annual national budget on improvement of the health sector. This level of public health expenditure is about 29.3% of THE; whereas households account for 35.9% of THE. Only an estimated 25% of Kenyans are covered by any form of health insurance; and medicines insurance coverage is practically non-existent for poor

households. Health sector under-funding therefore contributes to the sector's inability to ensure an adequate level of service to the population, and has sustained high levels of out-of-pocket health expenditures.

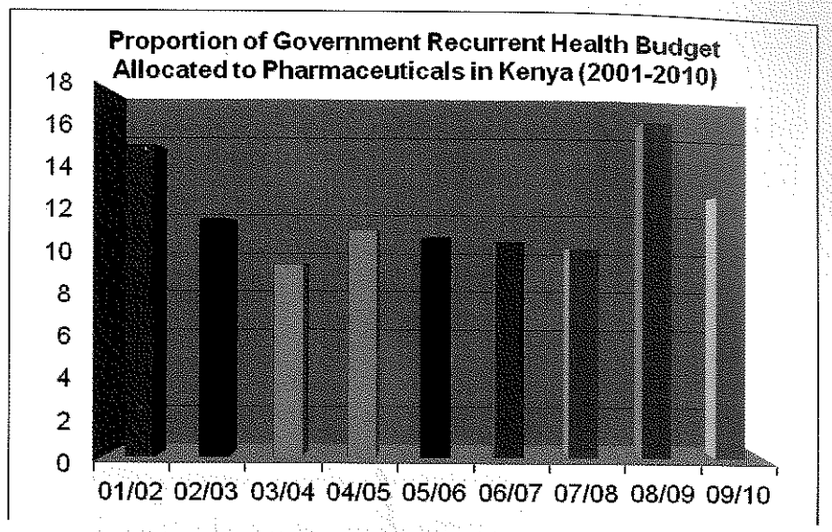
186. The health sector is in the process of rationalizing health care financing through a national Healthcare Financing Policy and Strategy, which aims to guarantee access to quality healthcare for all Kenyans, especially the poor and vulnerable. Key tenets include social protection and universal coverage with, among other actions, the removal of user fees for essential services; and a shift from out-of-pocket to tax-financing and/or social health insurance. The system is evolving with the national context and will adjust to future changes.

### 3.12.2 Specific Financing for Essential Pharmaceuticals and Services

187. Public financing for essential medicines is a key factor in attaining the MDGs. Analysis of the National Health Accounts data (1995-2006) indicates that (TPE) per capita rose from US$ 78.7 in 1995 to US$ 177.0 in 2006, representing about 20% of THE. Public pharmaceutical expenditure (PPE) has remained at about 15-20% of TPE.

188. The government allocation towards EMMS has been increasing steadily over the years, from Ksh 260 million in the financial year 1993/94 to an estimated Ksh 7.3 billion in 2009/10. However, as a proportion of the overall government recurrent allocation to health, the budgetary allocation for pharmaceuticals has decreased from 15.2% in the financial year 2000/01 to 12.9% in 2009/2010. In the Economic Recovery Strategy for Wealth and Employment Creation (2003-2007) this allocation was anticipated to increase from 12-16%, but this did not materialize. With Government spending estimated at 21.6% in 2005/06 of total public sector spending on medicines, development partners have continued to contribute the larger proportion of financing for health supplies, mostly covering medicines for HIV/AIDS, TB, malaria and reproductive health.






189. Even with increasing inputs by the Government and its partners, neither resource is sufficient to meet health sector needs. The Ministry of Medical Supplies currently estimates the EMMS requirements for 2010/11 (excluding ARVs and malaria drugs) at Ksh 11.3 billion, against a current allocation of Ksh 7.3 billion; and similar estimates for 2011/12 and 2012/13 are Ksh 11.6 and Ksh 12.2 billion respectively. Furthermore, distributive and operational inefficiencies lead to inequity and inefficient utilization. In particular, the budgetary allocation for pharmaceuticals is not ring-fenced and there is no stated policy direction on its prioritization. Consequently, the funds can be diverted to cover pending bills or to procure non-critical supplies, resulting in stock-outs of critical medicines. Further, unpredictable financing flows; inadequate quantification and lack of required budget-planning information make concrete budget projections difficult.

190. Despite its inadequacy, the public medicines budget accounts for a significant proportion of the recurrent health budget. Therefore, of critical importance to Government and partners is ensuring efficiency and transparency in the utilization of this investment, and optimizing its contribution to national health goals and targets. However, investments by Government and partners have mostly targeted the procurement of EMMS, without commensurate investment in other pharmaceutical sector functions. These comprise the systems and structures for ensuring efficient procurement,

distribution and utilization of pharmaceuticals; regulation of their quality, safety and efficacy; and M&E to ensure coherence with national health goals. This skewed investment, coupled with significant off-budget investments by partners, contribute to the gap in access to essential health products and technologies.

191. Therefore, the bulk of TPE (about 80%) is private, either through direct out-of-pocket or insurance payments, with medicines accounting for about 7% of total household expenditure. The situation is the reverse in developed countries, where a high proportion of TPE (up to 80%) is publicly financed. Cost-sharing has become an important revenue source for public health services, accounting for 7.4% of the MOH recurrent expenditures in 2005/2006[20]. The high private pharmaceutical expenditure reflects the huge financial burden to households for medicines and diverse medical products. Further, it highlights the need for cost containment measures through careful regulation of the expenditure components, particularly relating to pricing and consumption patterns. A key strategy for reducing out-of-pocket expenditures is to expand public insurance coverage for essential medicines and health technologies.

192. Therefore, whereas the public sector is the main source of affordable medicines, irregular availability in public health facilities is often a cause of catastrophic expenditure for the poor, who have to purchase the medicines at high prices in the private sector. Health sector interventions that have improved affordability of medicines include: - scrapping of the user fees/cost recovery system in 2005 for services at rural health facilities, replacing with the 10/20[21] system of nominal fixed fees; provision of free services for children under 5, maternity and reproductive health services; immunization; HIV, TB and malaria treatment - through public, faith-based and some private facilities.

193. **Key issues and challenges in medicines financing are:**

a) Inadequate government (exchequer) allocation for essential medicines

b) Lack of ring-fencing of the public medicines budget.

[20] Adopted from the *Health Sector Report 2007*
[21] KShs 10 for dispensaries and KShs 20 for health centers



c) Levying of user fees as a strategy for cost-sharing in the public and mission sectors, and without appropriate safeguards for the poor and disadvantaged.

d) High out-of pocket expenditures on medicines, of catastrophic levels for poor households.

e) Low insurance coverage and lack of policy guidance on insurance coverage for essential medicines, health products and technologies.

f) Inadequate sector investment in the full scope of pharmaceutical policy components, such as infrastructure, HR and M&E.

g) Significant off-budget financing for medicines; challenges in consolidation and coordination of DP funding flows for health overall and for pharmaceuticals.

h) Lack of policy guidance on aligning the financial allocations for medicines to optimize its contribution to national health priorities, goals and targets.

i)Inefficiencies and wastage through inappropriate practices along the supply chain.

194. **To address the challenges of financing for pharmaceuticals, the Government will:**

1. Mobilize adequate financial resources, and appropriately allocate them for effective implementation of this policy and for equitable provision of pharmaceutical services. The focus in pharmaceutical financing will be on equity and efficiency.
2. Define clear financing mechanisms for essential health products and technologies within the national health insurance benefit package and other health sector financing strategies.
3. Allocate the resources required for sustained public procurement and supply of medicines and for provision of pharmaceutical services.
4. Abolish user fees for key essential medicines in the public sector.
5. Establish mechanisms for ring fencing of Government allocations for EMMS.

6. Develop policy guidance on optimization of the public medicines budget, to ensure equity and allocative efficiency aligned with priority health needs and targets.

7. Strengthen financial management and pharmaceutical supply systems to enable effective operation and monitoring of resource utilization.

# 4 PHARMACEUTICAL LEGAL AND INSTITUTIONAL FRAMEWORK

195. Challenges in the pharmaceutical sector mainly relate to inadequate and outdated legislation and weak public pharmaceutical institutions. Therefore, effective implementation of the National Pharmaceutical Policy will hinge on rapid reform of the legislative framework and institutions that are envisaged to play a key role in the implementation of this Policy and its attendant strategies. These reforms will target the structures for pharmaceutical policy direction and governance, pharmaceutical sector regulation, quality control, as well as the procurement and supply of essential medicines.

196. Such institutional reforms will also promote the adoption of international best practices and facilitate development of centers of excellence, in order to fully exploit existing capacities and opportunities for development of the pharmaceutical sector.

## 4.1 OVERALL PHARMACEUTICAL LEGAL FRAMEWORK

197. The pharmaceutical legal framework in Kenya has been anchored on the Pharmacy and Poisons Act of 1957 (Chapter 244). Other legislation impacting on pharmaceuticals include: the *Narcotics & Psychotropic Substances Act* (1994), *Food, Drugs and Chemical Substances Act* (Chapter 254), *Use of Poisonous Substances Act* (Chapter 247), *Medical Practitioners and Dentists Act* (Chapter 253), and *Trading in Prohibited Goods Act* (Chapter 519) and the Anti-Counterfeit Act (Act no 13 of 2008).

198. The structure of Chapter 244 and associated legislation was modeled around the British law of the 1950's. However, pharmaceutical law in the United Kingdom changed fundamentally in 1960 to the Medicines Act, which has since evolved in line with developments elsewhere, to embrace the modern principles of drug regulation (built around quality, safety, efficacy and transparency). Fifty three years after enactment of the *Pharmacy and Poisons Act (1957)*, the national and global pharmaceuticals scene has changed drastically,



yet the legal framework has not evolved sufficiently in tandem with these changes. Amendments to Chapter 244 since its enactment are:

1. Amendment to Chapter 244 (1983): Introduction of rules governing the supply, distribution and dispensing of drugs.

2. Amendment to Chapter 244 (1992): Mandate to the newly established National Quality Control Laboratory to examine medicines and ensure their quality.

3. Amendment to Chapter 244 (1993): Transformation of the Drugs and Poisons Board into a Pharmacy and Poisons Board with extended competence, including responsibility for the Laboratory, Drug Registration activities and related functions.

4. Amendment to Chapter 244 (2002): Provision for the enrollment and practice of pharmaceutical technologists.

199. Regulation of medicines is not explicitly provided for in the 1957 legislation. The procedures which exist are based entirely on a general clause entitling the Minister to "make regulations" in the field of pharmacy. In 1998, a 'Workshop of Stakeholders' on the Review of Pharmaceutical Legislation proposed the replacement of the 1957 Act with a modern Medicines Act. This proposal was however not implemented. Subsequent pharmaceutical sector assessments and reviews have highlighted the shortcomings in the current pharmacy law and weaknesses of key institutions, which are a serious hindrance to development of the pharmaceutical sector and related services.

200. The Pharmacy and Poisons Board (PPB) is the main body mandated with enforcement of the Pharmacy and Poisons Act. Other institutions with mandates to enforce pharmaceuticals-related legislation are: KIPI (Industrial Property Act); Anti-Counterfeit Agency (Anti-Counterfeit Act); and the Public Procurement Oversight Authority (Public Procurement and Disposal Act). KEMSA and the NQCL are legally established with specific pharmaceutical mandates, but their legal structures are inadequate to fully realize their respective mandates.

201. **Key shortcomings of the legislative and institutional framework for pharmaceuticals are:**

a) Conflicting roles of key offices and institutions concerned with pharmaceuticals.

b) Outdated legislation, with inadequate provisions for:

(i) Regulating the broad scope of pharmaceutical regulatory issues; inadequate scope and definitions that is not in line with standard international definitions.

(ii) Adapting the regulatory scope in line with growing trends in research, development and trade in drugs, pharmaceuticals, food products, cosmetics and other pharmacologically relevant chemicals and devices.

c) Conflicting provisions in other legislative instruments, hindering enforcement.

d) Inadequate provisions for the licit use of controlled and psychotropic substances including precursors, hindering their access and appropriate use.

e) Inadequate provisions for statutory enforcement of pharmacy practice standards & ethics.

f) Inadequate legal frameworks for the PPB, KEMSA and NQCL.

202. **To ensure adequate legal and institutional framework for pharmaceutical policy, the Government will update, restructure and harmonize as required all medicines and other relevant legislation, regulations and rules, to create one modern medicines law governing the pharmaceutical sector, formulated according to well proven models.**

## 4.2 PHARMACEUTICAL SECTOR GOVERNANCE AND POLICY DIRECTION

203. The current structures for directing pharmaceutical policies and services are inadequate, and the current legal framework for pharmaceuticals is structurally and functionally outdated and incomplete. Although the KNDP of 1994 provided for the creation of a Directorate of Pharmaceutical Services, this was not implemented, and hence the pharmaceutical sector has continued to operate under the policy directorate of medical services. This structure continuously fails to recognize and effectively address the complexities and externalities of pharmaceuticals, thereby hindering effective growth and full maturity of the sector. Therefore, this Policy aims to delineate pharmaceutical sector governance structures



within the health sector, to facilitate appropriate development of the sector and effective delivery of pharmaceutical services to Kenyans.

204. **To provide clear policy direction and governance for the pharmaceutical sector, the Government will:**

1. Establish a Directorate of Pharmaceutical Services (DPS), or its equivalent, within the health ministry which will have the mandate to:

   a) Formulate, review and update policies and strategies relating to pharmaceuticals and health technologies; and monitor their implementation in order to achieve national health and economic goals.

   b) Guide the delivery of public pharmaceutical services to ensure that they are timely, efficient and transparent. To facilitate this, the DPS shall establish decentralized pharmaceutical structures within the health service structures and delegate responsibilities to the decentralized levels appropriately.

   c) Coordinate partnerships in the pharmaceutical sector for attainment of the objectives of this Policy, and in line with health sector coordinating mechanisms.

2. The DPS will sit on the respective boards of the FDA, KEMSA and NQCL, in order to provide the necessary technical guidance in line with this Policy.

3. To facilitate implementation of the provisions of this Policy and its attendant strategies, the following structures will be established within the DPS:

   a) Appropriately defined technical and administrative units to coordinate implementation of the Policy; to manage public pharmaceutical services and to oversee pharmaceutical services by the private, faith-based and NGO providers.

   b) Pharmaceutical units in relevant ministries, departments and institutions to advise on pharmaceutical issues and ensure appropriate implementation of the relevant Policy provisions. Such institutions include the Competition Authority, Anti-counterfeit Agency, NACADA, KIPI, Public Complaints Commission, Ministry of EAC Cooperation, KRA, national disease control programmes, DVS and such other institutions as determined by the needs of this Policy and its attendant strategies.

c) A Medicine Pricing and Affordability Advisory Committee within the Ministry responsible for health to monitor and advice Government on medicine prices and affordability. The committee will comprise specialists in health economics and pharmaco-economics, representatives from the Ministries of Finance, Trade and Industry, KEMSA, MEDS, FDA, pharmaceutical industry, civil society and consumer representatives. The responsibilities of the committee will be to:

   (i) Monitor prices and affordability of essential medicines in all sectors and develop a database to enable comparisons and referencing of prices.
   (ii) Encourage transparency in the pricing structure of medicines by pharmaceutical manufacturers, distributors and health service providers.
   (iii) Identify discriminatory practices in the pricing of medicines and recommend corrective measures where necessary.
   (iv) Determine reasonable pricing structures for essential medicines by all categories of healthcare providers, including a system of exemption in line with overall health sector policies.

d) An Advisory Committee on Intellectual Property and Public Health to facilitate inter-sectoral coordination for implementation of TRIPS and other IP provisions.

   This Committee will be responsible for the development and implementation of a national strategy on public health, innovation and IP, in line with the GSPOA.

e) A National Medicines and Therapeutics Committee (NMTC) to advise Government and stakeholders on the appropriate use of medicines. Membership of the NMTC will comprise clinicians, pharmacists, health administrators and the academia; and will strive to incorporate a mix of experience and specialization in the various health disciplines and in pharmaceutical supply and regulation.
f) Other specialized technical and advisory bodies as necessary to facilitate implementation of the various components of this Policy. Representation to the committees will be drawn from various stakeholders such as government departments



and ministries, the private sector, faith-based providers and NGOs.

g) A Division within the Ministry to coordinate health-related TM activities, including research and development, regulation of TM products and the practitioners and consumer education. The DPS will establish linkages with stakeholders through a Traditional Medicines Committee, involving the Ministry responsible for culture; KEMRI, the FDA, universities and representative of TM practitioners.
h) A Pharmaceutical Inter-agency Coordinating Committee (P-ICC) as the formal technical coordinating forum on pharmaceutical issues within the health sector.
   (i) The P-ICC will be chaired by the DPS, and will operate within the existing framework for health sector coordination.
   (ii) Its core function will be joint planning, coordination and monitoring of the sector investments in pharmaceuticals, health technologies and related areas, as outlined in this Policy and its attendant strategies.

## 4.3 PHARMACEUTICAL SECTOR REGULATION

205. **To ensure effective regulation of the pharmaceutical sector, the Government will:**

1. Establish by statute a national Food and Drug Authority (FDA), as an autonomous body corporate within Government. The FDA will be responsible for protecting the public health by assuring the safety, efficacy and quality of human and veterinary drugs, biological products, medical devices, cosmetics, tobacco products, food products, complementary/alternative and herbal medicines and products that emit radiation. The FDA will also be responsible for advancing the public health by helping to speed innovations that make essential health products & technologies more effective, safer and more affordable; and helping the public get the accurate, science-based information they need to improve their health. The FDA will be:
   a) A centralized authority within the national government, with appropriate decentralized structures for effective service
   b) Headed by a Director and governed through a Board of Directors and Chair – all appointed in accordance with the State Corporations Act

c) The DPS, DVS and the Directors of NQCL and KEMSA will sit on the Board
d) The Authority will:
   (i) be funded from the exchequer, and will also be authorized to levy fees on various regulatory services, and to establish such funds as may be necessary for the effective discharge of its functions
   (ii) develop and gazette rules and regulations relating to all pharmaceutical regulatory functions, as necessary for the realization of its mandate
   (iii) have specialized expert committees at national level to advise on technical and policy matters relating to pharmaceutical regulation
   (iv) endeavor to avoid conflicts of interest among those who serve on its scientific panels and advisory boards
   (v) endeavor to fulfill its regulatory scope and mandate in a timely, efficient and transparent manner. In this regard, it will establish an appropriate organizational structure and scheme of service; decentralize its services and delegate powers and responsibilities to the decentralized levels appropriately

2. Set aside, by way of annual appropriations, adequate funding for implementation of regulatory functions and enforcement of laws related to health products & technologies.
3. Build human resource capacity and expertise for pharmaceutical regulation, and institute measures to ensure appropriate recognitions and retention of this expertise.
4. Develop the necessary institutional capacity of the FDA to realize its full mandate as a stringent regulatory authority for medicines, health products and technologies.
5. Facilitate the necessary legal and institutional mechanisms for interregional collaboration and harmonization of regulatory systems.
6. Establish a National Poisons Centre within the FDA, and support it to effectively provide information and advice to healthcare workers and the public on poisoning.
7. Establish a Pharmacy Council to regulate the practice of pharmaceutical personnel, with representation from the FDA, PSK, KPA, pharmaceutical training institutions.



### 4.3.1 Pharmaceutical Quality Control

206. **To address the challenges of pharmaceutical quality control the Government will:**

1. Transform the NQCL into a state corporation and facilitate its accreditation for effective operation. The NQCL will be:
   a) A national quality control laboratory with appropriate decentralized structures mainly at the ports of entry for effective service delivery.
   b) Headed by a Chief Executive Officer and governed through a Board of Directors and Chair – all appointed in accordance with the State Corporations Act.
   c) The DPS and Director of FDA will sit on the Board.
2. Expand the mandate and capacity of the NQCL to include testing of medical devices, food products, cosmetics and other products under the regulatory scope of the FDA.
3. Provide adequate funding from exchequer in form of grants in accordance with the State Corporations Act, to enable the NQCL undertake the analytical work.
4. Enhance the capacity and collaboration in pharmaceutical quality control among national, regional and international laboratories and other relevant institutions.

### 4.3.2 Pharmaceutical Procurement and Supply

207. **To strengthen public procurement and supply of Essential Medicines, Health Products and Technologies the Government will:**

1. Transform KEMSA by statute into a state corporation, as the primary public pharmaceutical procurement agency. KEMSA will be:
   a) A centralized procurement agency with appropriate decentralized structures
   b) Headed by a Chief Executive Officer, appointed by a suitable authority in accordance with the State Corporations Act
   c) Governed through a Board of Directors, appointed in accordance with the State Corporations Act. The DPS and the Directors of FDA and NQCL will sit on the Board.

2. Integrate public-sector procurement and supply of medicines, medical supplies, medical devices and equipment under KEMSA.

3. Set aside, by way of annual appropriations, adequate funding for effective procurement and distribution of EMMS and other supplies in line with health sector investment plans.

### 4.3.3 Developing Pharmaceutical Centers of Excellence

208. This policy provides for the strengthening of key pharmaceutical institutions to facilitate their role in its implementation. In addition to their national responsibilities, Kenya's institutions have the potential to develop into centers of excellence, and to serve the growing need for quality products and services in the region and beyond. This goal is in line with the economic strategy of Vision 2030, as Kenya aims to become the provider of choice for basic manufactured goods in eastern and central Africa, before breaking into other markets. The attainment of this vision for the pharmaceutical sector requires institutions that have clear mandates and operational autonomy to enable them operate according to industry best practices and global standards. Institutional reform is a key agenda of Vision 2030, and the Ministry of Medical Services has initiated institutional reform of level 4-6 health facilities and semi-autonomous institutions.

209. Because of the strategic role of Kenya in regional and international affairs relating to pharmaceuticals, the implementation of this Policy also provides an opportunity for national pharmaceutical institutions to develop into regional centers of excellence. The potential for such centers exists in pharmaceutical procurement, manufacturing, quality control, training and bioequivalence testing among others. International standards and best practices in these areas include: - current Good Manufacturing Practices (cGMP), Good Pharmaceutical Procurement Practice (GPPP); and Good Practices for Pharmaceutical Quality Control Laboratories. Relevant accreditations include the ISO and WHO pre-qualification.

210. Two quality control laboratories in Kenya (NQCL and MEDS) have already attained WHO pre-qualification status, being the only WHO pre-qualified laboratories to date in the EAC and COMESA. Their capacity for further development into centers of excellence exists. The local industry has been involved in collaborative initiatives to enhance GMP compliance, through the Pharmaceutical Inspectorate Convention Scheme (PICS) and the WHO Prequalification programme. The attainment of such standards facilitates access to



regional and international markets, thereby contributing to the country's development agenda.

211. **Key issues in development of pharmaceutical centers of excellence are:**

a) Lack of written policy guidelines on quality systems by the regulatory levels

b) Lack of a comprehensive QA strategy for the pharmaceutical sector (manufacturing, training, product, personnel, regulation)

c) Best practices are not widely adhered to by pharmaceutical institutions.

d) Competing forces and duplication of efforts in quality systems development

e) Limited HR capacity for implementation of comprehensive QA systems

f) High cost of compliance with international quality standards

g) Lack of consumer awareness about quality of services and products

212. **To address the issues relating to pharmaceutical QA, the Government will:**

1. Enforce compliance with international standards and best practices in all sectors
2. Promote the development of quality management systems in pharmaceutical institutions, and support accreditation of such institutions to international standards.
3. Facilitate the development and implementation of a coherent national QA system for health products and technologies.

# 5 POLICY IMPLEMENTATION ARRANGEMENTS

## 5.1 INTEGRATION WITHIN EXISTING POLICY FRAMEWORK

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

1. A 5-year **Pharmaceutical Strategy** will be developed and implemented consultatively through the Pharmaceutical ICC or its equivalent.
2. The **Pharmaceutical Strategy** will align with the **Kenya Health Sector Strategic Plan (KHSSP)** and other relevant **health sector strategies**. Annual priorities in the **Pharmaceutical Strategy** will be captured in the sector's **Annual Work Plans** (AWPs), which are the main instruments guiding implementation of health policies and strategies, for Government working together with development and implementing partners.
3. Successful implementation of this Policy will hinge on:
   a) Incorporation of the relevant components of the **Pharmaceutical Strategy** into respective stakeholder **institutional development plans** and **M&E frameworks**
   b) **adequate resource** allocations by Government and partners
4. Monitoring and Evaluation of the **Pharmaceutical Strategy** will follow the framework of the KHSSP, and will comprise:
   a) **quarterly performance reports** to be shared with all actors;
   b) **annual reports** on implementation of each AOP;
   c) external **Mid-Term Review (MTR)** after 3 years of implementation and
   d) final External Evaluation after 5 years to inform subsequent review and revision
5. In order to assess the attainment of the ultimate goal of this Policy, i.e. *equitable access to essential medicines, health technologies and pharmaceutical services for the population*, standardized WHO tools and indicators[22,23] will be adapted and

[22] *Using Indicators to Measure Country Pharmaceutical Situations: Fact book on WHO Level I and level II indicators* (WHO 2006)



applied in the first year (baseline) and subsequently every 4th year of the Policy implementation period.

6. The KNPP will be reviewed within 10 years. Timing of the review will be informed by progress and lessons in implementing the successive strategies; and by the extent of changes in overall Government policy, the health sector and the pharmaceutical sector.
7. Relevant multi-stakeholder forums will be established to facilitate implementation, coordination and monitoring of the KNPP and its attendant strategies.

## 5.2 STRENGTHENING MONITORING AND EVALUATION (M&E)

214. A functional, standardized and well-resourced M&E system will be established focused on priority areas and targets (e.g. equitable medicines access for vulnerable groups), and will guide KNPP implementation and future revision. The system will link with the broader health sector M&E, to ensure coordinated and coherent health sector reporting.

215. Currently there is no structured system for monitoring and evaluation of the pharmaceutical sector. Significant data is generated through studies and assessments that are commissioned by Government or by the private sector; and supported by various development partners. However, utilization of the findings and implementation of the recommendations is uncoordinated, and hence impact of interventions is not clearly known. The main challenge remains to ensure the systematic collection, collation and analysis of pharmaceutical sector data that is relevant and up to date; and its appropriate dissemination to inform and guide policies and strategies. 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 sector and there are no mechanisms for the collection of disaggregated data on access to medicines (e.g. by gender or vulnerable groups).

[23] *Household Survey Tool to measure access to medicines* (WHO 2007)

216. **The Government will establish effective M&E mechanisms to guide policy implementation, service delivery and pharmaceutical sector development. To facilitate the attainment of this objective, the Government will undertake the following:**

1. A Pharmaceutical ICC (P-ICC), or its equivalent, will be established as the main coordinating structure for M&E of health products & technologies.
2. A Department of Pharmaceutical Policy will be established within the Directorate of Pharmaceutical Services, or its equivalent, to coordinate implementation of this policy and the activities of the P-ICC.
3. An M&E framework will be developed and implemented collaboratively by the P-ICC, incorporating the necessary tools, guidelines and performance indicators.
4. The key pharmaceutical institutions such as KEMSA, FDA, NQCL, MEDS and Schools of Pharmacy will produce annual reports as part of the AWP monitoring, and in line with their respective mandates.
5. A reliable Pharmaceutical Management Information System will be developed, implemented and sustained.
6. The P-ICC will mobilize adequate resources for pharmaceutical M&E and stakeholders will be encouraged to share routine data and research findings on pharmaceuticals.
7. Arrange for periodic external evaluation of KNPP implementation.



# ANNEXES

## Annex 1: Glossary of Terminologies

**Food** refers to any substance, whether processed, semi processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.

**Food safety** is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

**Health technologies** refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives". Essential health technologies encompass essential medicines, medical devices, biological products, diagnostics and medical laboratory technologies; transplantation of human cells, tissues or organs; and emergency, surgical and e-health technologies. Their regulatory scope encompasses human and veterinary drugs; vaccines, blood & biologics; medical devices & technologies; food products, tobacco products, cosmetics and emerging health technologies.

A **narcotic drug** is a legal term encompassing substances covered by the Single Convention on Narcotic Drugs, 1961, and the 1972 Protocol Amending that Convention, including opiates, opioids, as well as cocaine and marihuana.

A **pharmaceutical** is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms *drug*, *medicine*, and *pharmaceutical* are used interchangeably.

**Pharmacies** are premises in a health facility or community setting in which medicines are dispensed in accordance with legal provisions.

A **prescriber** is a health care professional who is legally qualified to write a prescription.

A **stringent medicines regulatory authority** is one whose operations meet the standards of the International Conference on Harmonization (ICH) of the EU, USA and Japan. Currently, no medicines regulator in Africa is considered stringent; and this limits access to international export markets.

## Annex 2: Methodology used for Policy Review and Revision

This Sessional Paper is the culmination of a policy review and revision process spanning over four years. The process evolved in tandem with political and other health sector developments, including a major general election and a major change of governance structures in the country in 2008. In the first stages of the policy development, a Technical Working Group (TWG) undertook the review, comprising representatives of various MOH departments, health institutions, the private sector, training institutions, professional associations, and civil society. The numerous studies and assessments had been undertaken on the pharmaceutical sector, and these informed the review process.

From the outset, the TWG strived not merely to update the existing Kenya National Drug Policy (1994), but to develop a coherent, comprehensive and appropriate policy responsive to the current and anticipated future situation and context. Throughout the process, policy options were selected on the basis of available evidence on the national pharmaceutical situation; taking into account national, sub-regional and global trends; and informed by normative guidance from WHO. The TWG held two consultative retreats in May and September 2006 to develop the draft document, which was enhanced through stakeholder review and technical editing facilitated by WHO experts.

An advanced draft was presented to the senior management of MOH for review and endorsement in May 2007 and the advanced draft was discussed and adopted during a national stakeholder consensus meeting in August 2007. Following the post-election events of 2008, the MOH was restructured and split into the Ministry of Medical Services (MOMS) and the Ministry of Public Health and Sanitation (MOPHS); with responsibility for pharmaceutical policy development falling under MOMS. Subsequently, the KNPP underwent further discussion and dissemination, namely a briefing to senior Ministry staff and Development Partners in December 2008, and a follow-up stakeholder consultation in April 2009.

The KNPP was formally presented to the Minister for Medical Services in January 2010. The Minister noted that the KNPP proposed vital reforms, which urgently required to be implemented in order to revitalize the pharmaceutical sector and reverse the chronic under-performance. He directed that the KNPP be re-formatted into a Sessional Paper, to facilitate the necessary cabinet approval, so as to entrench the proposed reforms



into the Government policy framework. The KNPP Task Force was subsequently expanded to include key institutions that were anticipated to play a key role in these pharmaceutical sector reforms; and it was chaired by the Permanent Secretary, with the Director of Medical Services as the Technical Chair. This new team developed the Sessional Paper with technical assistance from the WHO Country Office. The Sessional Paper was submitted to the Minister in July 2010 and subsequently endorsed and submitted to the Cabinet by the two Ministers. At the Cabinet meeting held on 19 January 2012, the Sessional Paper was approved for tabling before Parliament.

## Annex 3: Roles of Government Ministries and Institutions in Implementation of the Pharmaceutical Policy

1. **Ministry of Health:** Oversee and facilitate the implementation of all the components of this Policy. Fast-track the relevant restructuring to enable the creation of the Directorate of Pharmaceutical Services (or its equivalent), the Food and Drug Authority, KEMSA and the NQCL, in line with the provisions of this policy. Establish a Pharmaceutical Inter-agency Coordinating Committee (PICC) as the coordination forum for pharmaceutical sector issues within the health sector coordinating framework. Allocate and utilize the health budget in line with the provisions of this Policy.

2. **Ministry of Finance**: Allocate adequate financial resources for the implementation of this Policy and its attendant strategies. Enact legislation to provide for ring-fencing of the public allocation for pharmaceutical supplies, as well as its utilization in line with national health priorities.

3. **Ministry of Industrialization**: Ensure the safeguarding of TRIPS flexibilities in all trade negotiations and agreements. Establish a pharmaceutical desk to facilitate the articulation of pharmaceutical issues in local and international trade policies and initiatives. Facilitate the establishment of mechanisms to enable the regulation of medicine prices, including a pharmaceutical unit at the Competition Authority.

4. **Office of the Attorney General**: Facilitate review and harmonization of pharmaceutical legislation, to create a modern medicines act. Facilitate the necessary legal amendments to enable implementation of the policy provisions, including the restructuring of pharmaceutical institutions.

5. **Ministry of EAC Cooperation:** Facilitate ongoing initiatives aimed at harmonizing pharmaceutical policies and systems within the EAC. Establish a pharmaceutical unit to facilitate coordination of pharmaceutical issues in the EAC integration process.

6. **Ministry of Livestock Development:** Through the Director of Veterinary Services, ensure appropriate control and use of veterinary medicines. Establish a pharmaceutical unit to facilitate articulation and coordination of pharmaceutical issues in veterinary services.



## Annex 4: Key Economic & Health Indicators

| Indicator | Value (Year) |
|---|---|
| Total population | 38.6 (2009) |
| GDP per capita (current prices) (US$) | 794 (2008) |
| Life expectancy at birth (M/F) (years) | 54/59 (2006) |
| Healthy Life Expectancy at birth (M/F) years | 44/45 (2006) |
| Under 5 mortality rate per 1,000 | 92 (2006) |
| Per capita total health expenditure (THE) (US$) | 27 (2006) |
| Total health expenditure (% of nominal GDP) | 4.8% (2006) |
| Government health expenditure (GHE) as a % of total GoK expenditure (TGE) | 6.4% (2007/08) |
| Out-of-pocket health spending as a % of THE | 29.1% (2006) |
| Household health spending as a % of THE | 35.9% (2006) |
| Proportion of out-of-pocket expenditure spent on medicines | 7% (2006) |
| Proportion of MOH budget spent on medicines and medical supplies | 8.4% (2009/10) |

***Sources:*** *Kenya Economic Survey (2009); Kenya National Health Accounts (2005/06) Kenya Household Health Expenditure and Utilization Survey (2007)*

## Annex 5: Key Pharmaceutical Sector Facts & Figures

| Indicator | Value (Year) |
|---|---|
| Date of First National Drug Policy | 1994 |
| Date of National Essential Medicines List | 2010 |
| Date of Standard Treatment Guidelines | 2009 |
| Per capita pharmaceutical expenditure (US$) | 177 (2006) |
| Government expenditure on medicines (Ksh) | 7.3 billion (2010/11) |
| Per capita Government expenditure on medicines (US$) | 1.04 (2009/10) |
| Proportion of recurrent Ministries in Health budget spent on medicines | 8.4% (2009/10) |
| Number of licenced pharmaceutical manufacturers | 42 (2010) |
| Number of registered retail pharmacies | 1,167 (2010) |
| Number of registered pharmaceutical wholesalers | 212 (2010) |
| Number of registered pharmaceutical products | 12,008 (2009) |
| Number of pharmaceutical inspectors | 59 (2010) |
| Number of registered pharmacists | 2,295 (2010) |
| Number of enrolled pharmaceutical technologists | 2,680 (2010) |
| Pharmaceutical Personnel Population Ratio | 1:7,698(2010) |
| Number of pharmacists in basic training | 425 (2010) |
| Number of Pharmacists in public service | 746 (2010) |
| Number of pharm. technologists in basic training | 3,000 (2010) |
| Number of Pharm. technologists in public service | 411 (2010) |
| Number of approved pharmacy training institutions* | *26 (2010)* |
| Average annual output of pharmacists** | 70 (2009) |
| Average annual output of pharmaceutical technologists* | 885 (2009) |

**Universities (4) Diploma Colleges (22)* *** from approved local institutions*

***Sources:*** *Kenya National Health Accounts (2005/06), 39Pharmacy & Poisons Board Database (2010)*