PPB/REG/PME/POL/001

Revision No. 2

REPUBLIC OF KENYA
MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

ISO9001:2015
CERTIFIED

STRATEGIC PLAN

(2020-2025)

FEBRUARY 2020

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Prepared by Head Planning

Sign.....

Date: 4/3/2020

Checked by HQM

Sign.....

Date: 4/3/2020

Authorized by CEO

Sign.....

Date: 4/03/2020

FOREWORD

The Pharmacy and Poisons Board is established by law to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies (Pharmacy and Poisons Act of 1957, CAP 244; and, Health Act, 2017).

Since its inception, the Board has made significant progress to secure the health of Kenyans based on its mandate. It leverages modern management practices through a shared vision, mission and values that are intricately woven in robust strategies. The Strategic Plan (2020-2025) is the third in a series that builds upon past and present successes to chart the future course.

The Plan draws from the lessons learnt as well as recent developments in the pharmaceutical sector in Kenya and globally to maintain the prominence of its work. Over the years, the Board's work has expanded remarkably and notable achievements include attainment of the ISO certification, growth of the pharmaceutical workforce, automation as well as a vigorous policy framework for regulation of Health Products and Technologies.

The current Strategic Plan reaffirms the Board's commitment to assuring *the highest attainable standard of health* for all Kenyans as a right enshrined in The Constitution of Kenya, 2010. Towards this end, the Board will rely on a participatory and inclusive approach to ensure that stakeholders including manufacturers, universities, research organizations, traders, pharmacy practitioners and other healthcare professionals are proactively engaged and involved.

This will provide impetus for identifying and utilizing opportunities in training, research and technology to optimize benefits for all citizens. The emphasis is on patient centred pharmacy practice as well as service to the _difficult to reach' based on the principles of Universal Health Coverage.

The Strategic Plan (2020-2025) positions the Board to be a leader in an interconnected and highly globalized industry that links pharmaceutical research, products, trade, personnel and services intricately. It will assist the Board to curve a niche in delivering a wide spectrum of services to the highest standards within good corporate governance framework.

With this Plan, I am confident that the Board has established a strong pillar for redefining and advancing the pharmaceutical sector in the 21st Century.

Dr KIOKO Jackson K., MBS, OGW

Chairman, PPB Board of Management

PREFACE

The Pharmacy and Poisons Board is entrusted with fostering high standards of practice in the pharmaceutical sector consistent with public health principles for ensuring equitable access to Health Products and Technologies (HPTs). The Board fulfils its mandate through various directorates responsible for market authorisation; detection and mitigation of risks to quality as well as safety and efficacy of HPTs; foster integrity of the supply chain; and regulation of the pharmacy profession. The context of its work is complicated by the multiplicity of actors as well as regulatory dynamics within the sector in the country and globally.

During the previous plan period (2014-2019), the Board made significant strides in responding to the needs of Kenyans as well as evolving global practices and trends in the pharmaceutical sector. Notably, the Board is a Centre of Excellence in Pharmacovigilance on the continent and maintains cutting edge infrastructure for testing of HPTs in a bid to ensure their continued adherence to requisite standards. The Board, further, in an effort to increase visibility and improve efficiency in service delivery, commenced the process of decentralising its services and ensuring adequate linkages with stakeholders by bringing services closer to the people. In terms of pharmacy practice, there was sustained effort to diversify and increase the human capital base for pharmaceutical services through expanded training opportunities as well as Continuing Professional Development to ensure competence and fitness to practice.

Implementation of the previous plan faced some constraints owing to the evident gaps in the legal framework, inadequate human capital and conflicting responsibilities with other government agencies, among others. These hampered the full execution of regulatory functions relating to poisons, chemical substances, nutritional supplements, and complementary and alternative medicines.

The Strategic Plan (2020-2025), therefore, addresses issues of deep strategic concern to the Board while continuing to give priority to Universal Health Coverage and the right to the highest attainable standard of health by Kenyans. Implementation will leverage on the improved ICT infrastructure, embed relevant, sustainable and cost-effective programmes driven by research, innovation and emerging knowledge and technology to deliver the expanding mandate of the Board and steer the organisation towards attainment of our vision to become "**a global leader in promoting and protecting public health**".

A wide consultative and participatory approach, involving all stakeholders, was adopted in the development of this Strategic Plan. We recognise all our stakeholders, PPB Board of Directors and staff for their insights that will help to shape and expand the horizon of the Board during the next five years.

Through collective effort, the Board is charting a new strategic direction – vision, mission and values that will consolidate gains for all Kenyans in line with the Third Medium Term Plan (2018-2030) of Kenya's Vision 2030, _Big Four Agenda', the Kenya Health Policy (2014-2030) and the National Pharmaceutical Policy, 2012.

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Dr. Fred M. Siyoi
CHIEF EXECUTIVE OFFICER

EXECUTIVE SUMMARY

Vision

To be a global leader in promoting and protecting public health.

Mission

To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies

Core Values

Commitment to public health, Professionalism, Accountability and Transparency, Integrity and Respect, Quality, and Diversity and inclusion

Themes

- Use of Modern Regulatory Science
- Internationalisation
- Safety, Efficacy, Quality and Cost-effectiveness
- Stewardship
- Customer-centric service

Goals – Key Result Areas (KRAs)

Goal 1: Ensure access to safe, quality, efficacious and affordable health Products and technologies;
Goal 2: Leverage on research, innovation and technologies in the delivery of products and services;
Goal 3: Promote organisational stewardship, partnership and Accountability;
Goal 4: Promote a pharmacy practice that provides the highest attainable Standards of healthcare.

The third Strategic Plan for the Pharmacy and Poisons Board leverages opportunities in the pharmaceutical sector for optimising Universal Health Coverage as a right for all Kenyans. It focuses on broad policy interventions and initiatives for securing the health of Kenyans within its mandate as stipulated in the Pharmacy and Poisons Act, Cap 244.

Kenya's national commitments and obligations as outlined in the Kenya Vision 2030, Third Medium Term Plan; and, the Big Four Agenda are critical drivers of the choice of initiatives to be implemented during the next five years. The Strategic Plan is also aligned to Kenya Health Policy 2014-2030 and National Pharmaceutical Policy 2012. The Plan also takes cognisance of regional and international policy and legal documents, declarations and aspirations,

including the African Union Model Law on regulation of medicines and the Sustainable Development Goals, specifically SDG 3.

Current and past successes as well as the lessons learnt and emerging issues, actors, trends and practices in the health sector provided a compelling rationale for charting the new strategic direction highlighted below. The Strategic Plan is organised into a coherent sequence of five chapters summarised below.

Chapter One gives background information about the Pharmacy & Poisons Board. It highlights the mandate and functions of the Board, its governance structure, achievements, key challenges and suggested interventions. It also presents a financial assessment of the Board over the strategic period 2014-2019.

Chapter Two expounds on the policy environment and the national development agenda as outlined in the Kenya National Pharmaceutical Policy (2012), Kenya Health Policy 2014-2030 and Vision 2030 (with special reference to MTP III and the Big Four Agenda). It also presents a global overview of health with special reference to SDG 3(b), 3(c) and 3(d) and World Health Assembly Resolution 67.20 of 2014.

Chapter Three expounds on the situational and environmental analyses undertaken using the Strengths, Weaknesses, Opportunities and Threats (SWOT) and Political, Economic, Social-Cultural, Technological, Infrastructural, Environmental and Legal (PESTIEL) models. It also provides a stakeholder analysis indicating respective obligations and expectations.

Chapter Four presents the strategic direction of the Board for 2020-2025 strategic period including the Vision, Mission, Core Values, Strategic Themes, Goals, Objectives and Key Strategies.

Chapter Five highlights the implementation and coordination mechanisms and elaborates the functional responsibilities of the Board during the plan period. Risk factors, which may affect the implementation of the Strategic Plan have been identified and appropriate mitigating factors recommended. The monitoring, evaluation and learning framework is also presented.

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ACRONYMS AND ABBREVIATIONS

PPB	Pharmacy and Poisons Board
CPD	Continuing Professional Development
ISO	International Organization for Standardization
CEO	Chief Executive Officer
SDGs	Sustainable Development Goals
UHC	Universal Health Coverage
HPT's	Health Products and Technologies
EAC	East African Community
IGAD	Intergovernmental Authority on Development
HTA	Health Technology Assessment
FBHS	Faith Based Health Services
SWOT	Strengths, Weaknesses, Opportunities and Threats
P-P **ESTIEL**	Policy, Political, Economic, Technological, Informational, Environmental and Legal
QMS	Quality Management Systems
QC	Quality Control
DPER	Directorate of Product Evaluation and Registration
ICT	Information Communication Technology
MOU	Memorandum of Understanding
NQCL	National Quality Control Laboratory
MEDS	Mission for Essential Drugs and Supplies
JICA	Japan International Cooperation Agency
USAID	United States Agency for International Development
PEPFAR	President's Emergency Plan for AIDS Relief
NEMA	National Environmental Management Authority
NACADA	National Authority for the Campaign Against Alcohol
KNEC	Kenya National Examination Council
KRA	Kenya Revenue Authority
NSSF	National Social Security Fund

NHIF National Hospital Insurance Fund

RBA Retirement Benefits Authority

KEBS Kenya Bureau of Standards

WHO World Health Organization

AU African Union

ICH International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use

KEMRI Kenya Medical Research Institute

NASCOP National Aids and STI Control Programme

KUDHEIHA Kenya Union of Domestic Hotels, Education Institutions, Hospitals and Allied Workers

KMPDU Kenya Medical Practitioners Pharmacists and Dentists Union

COTU Central Organisation of Trade Unions

PUSETU Public Service Trade Unions of Kenya

CUE Commission for University Education

TVET Technical and Vocational Education and Training

KRAs Key Result Areas

CHAPTER ONE

1. INSTITUTIONAL SETTING

1.1 Background

Globalisation has made the world more interconnected and with it the benefits and challenges of the digital era. That these will become more pronounced with the Fourth Industrial Revolution and impact all aspects of the socio-economic and political context of Kenyans cannot be overstated. For the Pharmacy and Poisons Board (PPB), this marks a major turning point for working collaboratively with its stakeholders to drive and embed sustainable innovations in the practice of pharmacy as well as manufacture and trade in health products and technologies. The Board was established in 1957 to guarantee health security and well-being of all Kenyans. It is among the Government of Kenya agencies responsible for delivering the highest standards of health as a basic human right for all Kenyans. This is a key Bill of Rights provision enshrined in the Constitution of Kenya, 2010. Over the years, the Board has continually evolved to deliver on its broad functions. In the present plan period, the Board will focus on the use of modern regulatory science; internationalisation and collaboration; and effective stewardship that is customer-centric to revitalise the pharmaceutical sector and guarantee quality, safety, efficacy and cost-effectiveness of health products and technologies in a dynamic global world.

1.2 Mandate and Functions

Mandate

The mandate of the Board is articulated in the Pharmacy and Poisons Act of 1957 (CAP 244) as well as the Health Act, 2017 as: to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies.

Functions

The functions as provided for in the Health Act, 2017 include:

Part 1: Heath Products and Health Technologies Functions

1. Regulate the manufacture, import and export, storage, distribution, sale and use of health products;
2. Regulate, monitor and inspect personnel and premises that are involved in the manufacture, import and export, storage, distribution, sale, use and disposal of health products;
3. Maintain a register of health products for which marketing authorisation has been granted;

4. Regulate clinical trials of health products and health technologies;
5. Test health products regulated under this law;
6. Conduct post-marketing surveillance of safety and quality of health products;
7. Regulate the promotion, advertising and marketing of health products;
8. Regulate the use of unregistered health products for trial purposes or for compassionate use;
9. Disseminate information on the quality and safety of health products to health professionals and the public;
10. Disseminate information on health products to health professionals and to the public in order to promote their responsible use; and
11. Collaborate with other national, regional and international institutions on health products regulation.

Part 2: Pharmacy Practice Functions

1. Regulate the training, continuing professional development (CPD) and practice of pharmacy;
2. Regulate, monitor and inspect personnel and premises that are involved in training, CPD and pharmacy practice;
3. Maintain a register of pharmacy practitioners for which licensure or authorisation has been granted;
4. Disseminate information on pharmacy practice to health professionals and to the public in order to promote Good Pharmacy Practice; and
5. Collaborate with other national, regional and international institutions on regulation of the pharmacy profession.

Part 3: Common Functions

1. Advise the Cabinet Secretary of Health on all matters relating to administration and implementation of the Act;
2. Levy, collect and utilise fees for services rendered; and
3. Perform such functions as may be assigned by the Board of Directors.

1.3 Achievements

In the previous Strategic Plan 2014-2019, the Board set out to accomplish the five goals. A review of the major achievements, challenges encountered and lessons learned was undertaken and the findings are summarised in this section.

Substantial progress was made in delivering on the Board's mandate based on the five goals pursued in the previous plan period:

1. Establish good governance and management of the Board;

2. Regulate and promote the development of local pharmaceutical industry;
3. Regulate the manufacture, trade and use of medicines, medical devices, herbal, nutraceuticals, health technologies and cosmetics in Kenya;
4. Establish PPB quality control laboratory for pharmacovigilance and post-market surveillance; and
5. Regulate and promote pharmacy training and ensure pharmaceutical practitioners are competent and fit to practise

A key highlight was the mark of excellence evidenced by attainment of the ISO certification (ISO 9001:2015) in 2018. Structures and systems for entrenching robust corporate governance were established and this will be critical in the present plan period as the Board moves towards establishing itself as an independent and sustainable organisation.

A roadmap and instruments for Good Manufacturing Practices were developed and are being used to promote growth of the pharmaceutical industry in Kenya. This is expected to strengthen the linkage between industry and trade in health products and technologies and to diversify and enhance the practice of pharmacy.

The Board is recognised by the African Union as a Centre of Excellence in Pharmacovigilance. It has put in place modern infrastructure and mechanisms for detecting and mitigating risks to quality, safety and efficacy of health products and technologies.

Physical-chemical laboratory infrastructure was established in preparation for testing of medicines. It will expedite testing of medicines and enhance timeliness in service delivery.

The Board also sustained effort to develop a competent pharmacy workforce for the pharmacy sector by expanding access to pharmacy training programmes in universities and diploma training colleges. The Board has also spearheaded curriculum reforms consistent with global trends and practices. Partnerships with relevant organisations have expanded opportunities for Continuing Professional Development that enables practitioners to enhance their capacities consistent with the evolving demands of the profession.

Substantive progress was also made in the automation of services. The Pharmacy and Poisons Board is the first national drug regulatory authority in Africa to automate the clinical trials registry. Further, the Short Messaging Service (SMS) platform for confirmation of registered premises and pharmacy practitioners' is particularly popular.

Testing of Health Products and Technologies (HPTs) was decentralised to the regions and has improved access to quality HPTs for the marginalised. This was also enhanced by a robust process of recalling poor-quality products from the market.

Key achievements on each goal are summarised in the table below.

Table 1.1: Goals and Key Achievements

Goal 1: To Establish Good Corporate Governance Practices			
	Objective	**Target**	**Achievement**
1	To strengthen internal operational policies	To develop or review 34 operational policies, guidelines and manuals	31 operational policies, guidelines and manuals developed
2	To automate an integrated process	Develop and implement quality management system	ISO certification (ISO 9001:2015) was attained and maintained
3	Establish adequate infrastructure to support the organisational structure and operations	Acquire and operationalise 6 PPB regional offices	4 offices were acquired (Nyeri, Eldoret, Mombasa and Machakos), but are not yet in operation
		Acquire 3 PPB vehicles	4 vehicles acquired
4	Redesign the organisational structure	Revise the organisational structure, right placement and employee welfare	Revised organisational structure, staff placed on permanent and pensionable terms, medical insurance provided
Goal 2: To Control, Regulate and Promote the Development of Pharmaceutical Industry in Kenya			
1	Develop regulation of nutraceuticals cosmetic, and health technologies Framework (Draft bill amending CAP 244 to include nutraceutical and health technologies regulation)	Review CAP 244 to include the functions of regulating nutraceuticals, cosmetics and health technologies	CAP 244 was revised
2	Promote good manufacturing practices	Develop Good Manufacturing Practices Programmes	Roadmap was developed and being implemented
Goal 3: To Regulate the Manufacture, Trade and Use of Medicinal Products, Nutraceuticals, Health Technologies and Cosmetics in Kenya			
1	Strengthen regulation, quality, safety & efficacious use of medicine in Kenyan market	Develop initiative to Strengthen the PPB Pharmacovigilance centre of excellence	Centre of excellence established and put into operation
2	Strengthen regulation, quality, safety & efficacious use of medicine in the Kenyan market	Develop programme on regulation of clinical trial by (incorporating clinical trials in CAP 244 and Perform regular quality audits for clinical trials sites)	Amendment Bill passed by Parliament

Goal 4: To Establish a Quality Laboratory for Post-market Surveillance and Pharmacovigilance			
	Objective	**Target**	**Achievement**
1	To strengthen the quality of pharmaceutical products in Kenya	Establish PPB quality Control Laboratory	Physical-Chemical infrastructure is in place but not yet in operation
Goal 5: To Optimise Mechanisms to Ensure Pharmaceutical Practitioners Are Competent and Fit to Practise			
	Objective	**Target**	**Achievement**
1	To strengthen Continual Professional development	Establish Continual Professional Development (CPD) Framework (legal aspects, guidelines and capacity building)	Continuing Professional Development framework developed
		Develop Pharmacy Curriculum Improvement Framework (Aligning the pharmacy training programmes to be accredited to meet current and new pharmacy practice, researching, M&E and benchmarking	Development of Curriculum improvement framework is ongoing

1.3 Key Challenges and Interventions

During the 2014-2019 Strategic Plan period, PPB faced a number of challenges. The table below outlines key challenges faced and their respective interventions, which have been planned for in the 2020-2024 Strategic Plan period:

Table 1.2 Challenges and Interventions

	Challenges	**Interventions**
1	The goals and objectives in the 2014-2019 strategic were describing the mandate and not providing actionable and measurable activities	Link goals to the vision and mission of the Board
		Develop actionable and measurable objectives with clear indicators
2	The 2014-2019 strategy implementation plan was not linked with performance management	Link implementation plan with performance management
3	Inadequate provisions in the current law, CAP 244, to provide for the adequate regulation of medicines, health products, health technologies and the profession of pharmacy	Initiate revision of the legislation
4	Challenges in executing some regulatory functions, including; poisons and chemical substances, nutritional supplements, complementary and alternative medicines, radio pharmaceuticals and tobacco products; scheduling of medical products and health technologies; and support for local manufacturing of pharmaceuticals	Revise and harmonise the regulatory framework
5	Inadequate human capacity (both technical and non-technical)	Enhance human capacity

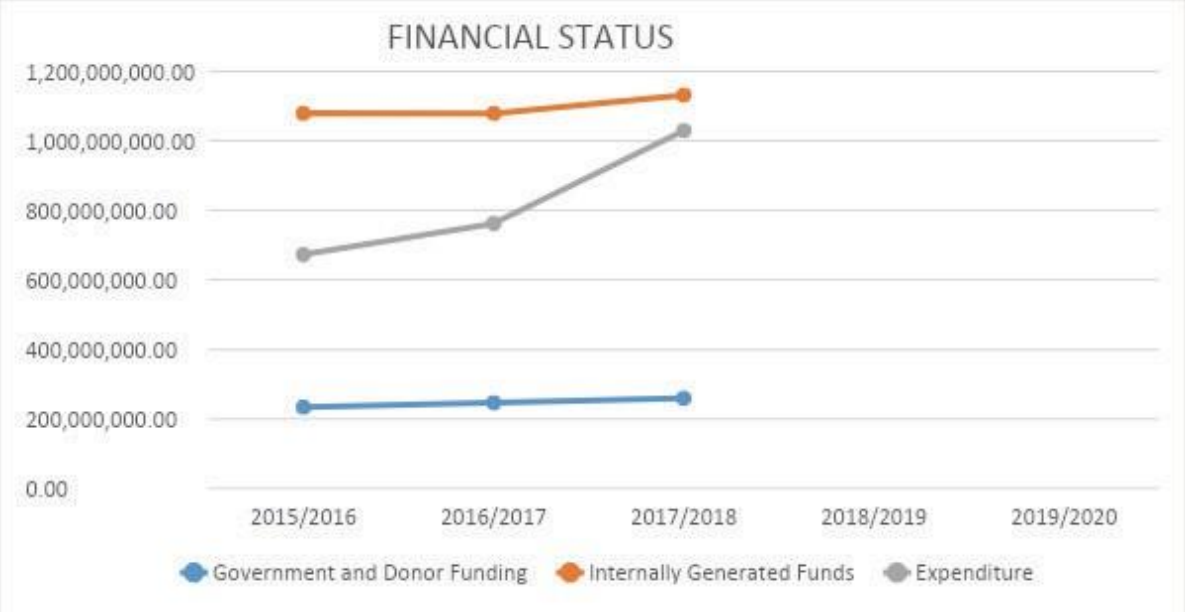
	Challenges	Interventions
7	Inadequate standards and guidelines to operationalise regulatory functions	Review regulations and develop and implement relevant standards and guidelines
8	Low public awareness on the PPB mandate	Enhance public awareness
		Strengthen stakeholder engagement
9	Practice of pharmacy is not adequately being regulated	Establish levels of practice
		Recognise pharmacy specialties
		Conduct continuing professional development and enforcing standards of internship and pharmacy practice
10	Inadequate capital investment funding	Expand and streamline revenue streams
		Lobby for funding
11	Overlapping/or conflicting responsibilities between the Board and other government agencies	Revise the law to provide clear responsibilities between the Board and other government agencies
12	Directive on removal of the Board functions from the ports of entry	Lobby for the recognition of the need of the Board in the ports of entry
		Conduct inspection at the bonded warehouses
13	Dependency on development partners to fund, develop and implement capital projects	Diversify sources of funding
14	Inadequate offices and storage space in nine regions	Acquire four and lease five offices in the regions
15	No scientific advisory committee for medical devices and diagnostics, nutritional supplements and complementary and herbal medicines	Establish and operationalise scientific advisory committee
16	Delayed post-market surveillance analysis of samples and reports	Speed up operationalisation of the physical-chemical lab for testing of samples
		Establish and operationalise two satellite laboratories
17	Lack of resource and poisons centre	Establish and operationalise a resource centre
18	Universities Act 2012 – amendments removing the role of PPB in approval of Bachelor of Pharmacy degree	Revise and harmonise the regulatory framework
19	Unclear role of county governments in pharmacy practice	Enhance partnership and collaboration with county governments
20	Uninformed decision making due to failure to conduct data and trend analysis through research	Develop capacity in research
21	Poor financial planning	Establish and operationalise a Finance and Administration Directorate
22	Lack of effective and efficient management systems and culture	Enforce adherence to management procedures
		Institute a culture of performance evaluation, rewards and sanctions

1.5 Financial Status

There is a general understanding that the Board should delink from the parent ministry. Plans are underway to delink and allow autonomy in execution of the Board's mandate. However, in the past, questions have been raised as to why the Board cannot be self-sustaining. The 2014-2019 Strategic Plan, did not include any objective or strategy on optimising revenue collection and cost containment. It is also worth noting that surplus is an important measure of sustainability and especially when accrued from internally generated funds.

PPB surplus declined from 461 million to 102 million over a three-year period from 2015/2016 to 2017/2018. At the same time, PPB revenue grew by 4.85% between 2016/2017 and 2017/2018 while total expenses grew by 35%. It is evident that costs were increasing at a faster rate than the revenue generated, which led to a decline in financial sustainability. While effort to generate additional revenues cannot be understated, management of costs is more critical.

Figure 1.1: Growth in PPB Revenue and Expenses, 2015/2016 – 2017/2018



Further analysis shows that the expenses mentioned above do not include the cost of technical staff amounting to Kshs 259 million in 2017/2018 (PPB has two cadres of staff; technical staff are pharmacists and employees of the Ministry of Health, while non-technical staff are employed by the Board to provide business support services). Had this cost component been included in the analysis, assuming that it was not borne by the Government; the financial status would have been on the declining trend described below:

- Financial Year 2016 - a surplus of Kshs 227 million;
- Financial Year 2017 - a surplus of Kshs 70 million; and,
- Financial Year 2018 - a loss of Kshs 157 million.

Therefore, while in previous years PPB could have met its obligations without government support, the sustainability of PPB in 2017/2018 was dependent on grants from the government.

A scrutiny of the accounts shows that in the three years, 2015/2016 to 2017/2018, major expenses that experienced significant growth were: travel and accommodation (from 110 million to 130 million); depreciation (from 27 million to 198 million); and IT expenses (from 15 million to 77 million). The top four contributors to revenue generation in 2017/2018 were drug registration fees (39%); import permit and import declaration forms (30%); pharmacy practice (14.6%); and GMP inspection (13%).

To attain financial sustainability, the Board will need to:

- Raise internally-generated revenue;
- Contain the growing costs; and
- Mobilise donor funds.

The present Strategic Plan (2020-2025) will focus on strategies that enhance revenue generation and hold revenue generation centres responsible for raising desirable targets. In addition, a culture of cost management will be instituted through all levels of management in PPB. The Board of Directors' performance management will also include revenue and cost containment measures to ensure the financial sustainability of the organisation.

1.6 Organisational Structure and Coordination Framework

1.6.1 Membership of the Board of Directors

According to the Pharmacy and Poison's Act, Amendments effective May, 2019; the Board of Directors' shall be constituted as follows:

(a) A chairperson who shall be appointed by the President and who shall
   i) be a registered pharmacist of good standing with a degree in pharmacy; and
   ii) have at least ten years' experience in the pharmaceutical sector;

(b) The Director of Pharmaceutical Services;

(c) The Principal Secretary in the ministry for the time being responsible for matters relating to finance or his or her representative;

(d) Two persons representing the pharmacy training institutions of which one shall be a pharmacist and the other one a pharmaceutical technologist;

(e) Three other persons appointed by the Cabinet Secretary, of whom:
   i) One person shall be a pharmacist representing institutions of higher learning;

ii) One person shall be a pharmaceutical technologist representing mid-level colleges; and
iii) One person shall be an enrolled pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association.

(f) The Chief Executive Officer, who shall be an *ex officio* member; and,

(g) One medical practitioner nominated by the Kenya Medical Association and appointed by the Cabinet Secretary.

It is further stated that:

- Members of the Board of Directors shall be appointed by the Cabinet Secretary from among members nominated by their relevant professional associations, each of which shall nominate two candidates in each category taking into consideration gender, ethnicity and regional balance.

- A person shall not qualify for appointment as a member of the Board unless such person is the holder of a minimum of a diploma in the relevant field from an institution recognised in Kenya and has at least five years managerial experience.

1.6.2 Functions of the Board of Directors

The Board of Directors is the top decision-making organ and is mandated to carry out the following functions:

1. Advise the Cabinet Secretary of Health on all matters relating to administration and implementation of the law on health products, health technologies and the profession of pharmacy;

2. Provide strategic guidance to the Board in the discharge of its functions;

3. Approve the strategic and annual work plan and budget;

4. Review the quarterly and annual reports;

5. Monitor and evaluate the activities of the Board ;

6. Establish such committees, as it deems necessary for the functioning of the Board;

7. Approve the appointment or removal of senior management officers;

8. Provide the Cabinet Secretary for Health with an annual report to be tabled in Parliament; and

9. Perform such functions as may be assigned by the Cabinet Secretary for Health.

1.6.3 Committees of the Board

The Board executes its functions through specialist committees. The committees examine and determine specific issues and advise the Board on the actions to be taken. These committees engage the services of resource persons where necessary.

1.6.4 Duties and Responsibilities of the Chief Executive Officer

The Chief Executive Officer is accountable to the Board of Directors in carrying out the following functions:

(i) Develop or review policy, rules, regulations and corporate strategies under the law governing the activities of the Board;

(ii) Develop or review guidelines, standards, infrastructure, tools, and processes for all the activities of the Board;

(iii) Management of the business and affairs of the Board;

(iv) Implementation of the law governing the activities of the Board;

(v) Execution of the decisions and directives of the Board of Directors;

(vi) Develop and coordinate implementation of a quality management system and benefit-risk strategies in regulatory decision-making with regard to regulation of health products, health technologies and the pharmacy profession;

(vii) Provide strategic leadership to all functional areas of the organisation;

(viii) Review and approve strategic, business, and annual work plans and budgets of the directorates;

(ix) Review and approve the quarterly and annual reports presented by the directorates;

(x) Monitor and evaluate activities and appraise Directors and Heads of Units;

(xi) Make periodic reports to the Board of Directors;

(xii) Make periodic reports to the appointing authority through the Board of Directors;

(xiii) Analyse trends affecting the Board's mandate and resource requirements in order to facilitate the achievement of its vision; and

(xiv) Foster partnerships with key stakeholders in the pharmaceutical industry.

1.6.5 Directorates of the Board

The Board is currently organised into the following five (5) technical directorates and one (1) non-technical directorate:

(a) Product Evaluation and Registration;

(b) Medicine Information;

(c) Professional Affairs and Standards;

(d) Inspectorate and Enforcement;

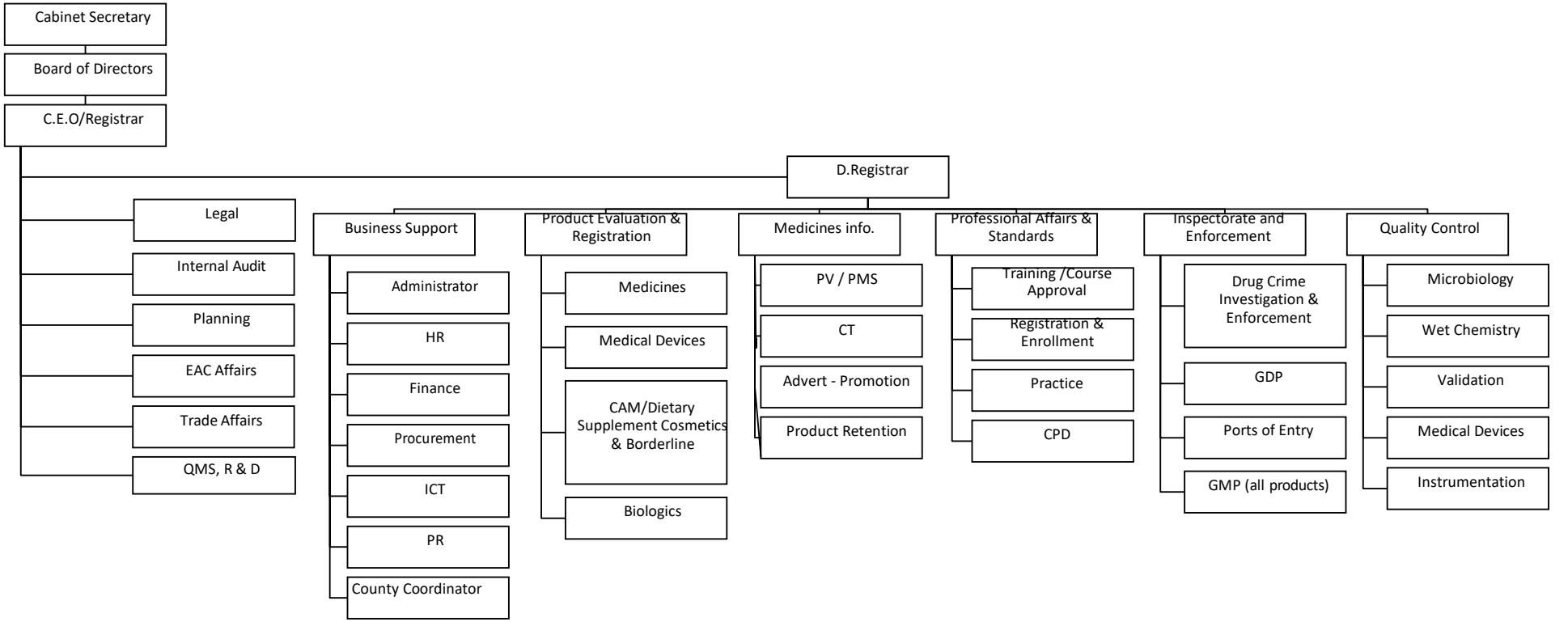
(e) Quality Control; and

(f) Business Support and Administration.

1.6.6 The Secretariat

The Secretariat consists of competitively recruited professionals with experience in pharmacy, research and other relevant fields. Under the leadership of the Chief Executive Officer (CEO), the Secretariat facilitates and coordinates all the work to enable the Board deliver on its mission. The CEO works closely with technical officers deployed from the Ministry of Health to manage the five (5) technical Directorates. The current staff establishment is 636 with 180 staff in post. The organogram of the PPB is illustrated in Figure 1 below.

Figure 1: The Structure of the Pharmacy and Poisons' Board



1.6.7 Analysis of the Current Organizational Structure

Before the year 2009, the Board had been operating as a department under the Ministry of Health without an independent fully-fledged Secretariat. The technical staff working for the Board are deployed from the Ministry of Health. This prompted the Ministry to appoint an Inter-Ministerial Task Force to make recommendations for reorganization and staffing of the PPB. The task force completed its work in the year 2009 and its report provided a basis for reorganizing Board operations and staffing.

The current Strategic Plan (2020-2025) recommends further restructuring to enable the Board to transform its operations consistent with global trends and practices as well as the Board's elaborate mandate. The proposed organizational structure is provided in Annex 2.

CHAPTER TWO

2. POLICY ENVIRONMENT AND NATIONAL DEVELOPMENT AGENDA

2.1 Kenya Pharmaceutical Sector Overview

The pharmaceutical sector in Kenya is part of a specialized and highly globalized industry with unique national and regional elements. The sector is characterized by pharmaceutical research, products, trade, personnel and services that are intrinsically linked in a complex and dynamic matrix of health, economics and political issues. The sector's multi-dimensional nature encompasses numerous externalities that often conflict with public health principles for ensuring equitable access to essential medicines.

Within this context, the Government of Kenya is increasingly focusing on institutional and regulatory strengthening. The Kenya National Pharmaceutical Policy-Session Paper No.4 of 2012 seeks to streamline pharmaceutical service delivery to ensure harmony with other health and development policies. Overall, the policy focuses on:

- Strengthening the management and delivery of pharmaceutical services through relevant legislative and institutional reforms;
- Strengthening national institutions for procurement of medicines, supply, regulation and quality control;
- Developing and appropriately managing pharmaceutical human resources; and
- Enhancing collaboration with other sectors and partners.

The PPB is a key Government agency responsible for realising the Kenya National Pharmaceutical Policy. It is the mandate of the PPB (Pharmacy and Poisons Act of 1957, CAP 244; Health Act, 2017) to regulate health Products and Health Technologies; foster high standards of Pharmacy Practice; and advice the Cabinet Secretary of Health on all matters relating to administration and implementation of the Pharmacy and Poisons Act, CAP 244.

Health Products and Technologies (HPT) encompass a wide range of items that are a vital component of healthcare. The PPB scope of interventions in HPTs) is described below.

- Regulation: ensuring that HPTs meet established standards of quality, safety and efficacy, efficiency and performance;

- Assessment of HPTs**:** assessment of clinical effectiveness, cost-effectiveness and appropriateness in the context of the national healthcare system, including cultural and ethical considerations. Health Technology Assessment (HTA) provides evidence-based guidance (guidelines, protocols, lists, etc.) on appropriate HPT for specific levels of care and clinical settings;

- Management of HPTs**:** including budgeting and planning for appropriate prescribing, dispensing and professional administration and or use of the products in accordance with established guidelines and protocols; commissioning, user training and corrective and preventive maintenance of medical devices; disposal of HPT; monitoring and educating consumers on appropriate use and storage.

The work of the Board is enabled by appropriate legislation and regulations. However, some limitations in the regulatory framework have constrained the range of HPTs available in the country and increased exposure to health risks. For instance, treatment for emerging conditions like coronavirus, Ebola, Mad Cow disease and dengue fever require medications that are yet to be domesticated based on gaps in the regulatory framework. Similarly, there is no provision for regulation of locally derived natural products and cosmetics within the healthcare system.

The country is under pressure to meet a growing demand for national pharmaceutical human resources and services. This is against a backdrop of declining enrolments in pharmacy programmes at all levels—a matter of great concern. Therefore, the need to diversify and enhance quality of training as well as other capacity building initiatives that guarantee the availability of diverse, quality and equitably distributed specialised technical skills within the sector cannot be overemphasised. It is the responsibility of the Board to develop human capital for the pharmacy sector and to foster a robust pharmacy practice.

Similarly, there is a wide scope for research, innovation and commercialisation of HPTs and especially locally from derived natural products. Partnerships with universities and research organisations have the potential to catalyse research in this regard but are largely underused. Other opportunities for innovation can lead to enhanced operational efficiency and effectiveness in service delivery across the spectrum, from training to promotion of local production to streamlining trade and distribution of HPTs as well as pharmacy practice. Collaboration with the relevant sectors as well as a broad range of stakeholders in the pharmaceutical sector can also provide impetus for innovation. These overarching issues underscore the need to revitalise the pharmacy profession and practice and this will be the focus of Strategic Plan (2020-2024).

2.2 Kenya Health Policy and Development Agenda

The opportunities highlighted above should be seen in the realm of the Kenya national development agenda. Specifically, the country's overall development framework for the health sector is guided by Kenya's Vision 2030 and the "Big Four Agenda". Priority areas of focus in Vision 2030 include: manufacture of HPTs; provision of a robust health infrastructure network countrywide, enhanced quality of health service delivery, promotion of partnerships with the private sector, and broadening access for the marginalised. The national development agenda for health has been revitalised by the focus on health and manufacturing in the "Big Four Agenda".

The Constitution of Kenya, 2010, Bill of Rights 43. (1) (a) stipulates: the Government of Kenya is committed to securing the health of its citizens as a basic human right to *the highest attainable standard of health.* It states that "*very person has the righ to the highest attainable standard of health, which includes the right to healthcare services, including reproductive healthcare*" .
Under the fourth schedule of the constitution 2010, the National government, through Ministry of Health is mandated to set health policy; run national referral health facilities; capacity building; technical assistance to counties and develop norms and standards for staffing

The Ministry of Health has developed the Kenya Health Policy 2014-2030 to help achieve health outcomes as outlined in the Constitution and other national policy documents. Further, Medium Term Development goals are articulated in Sector Strategic Plans such as the Second Kenya Health Sector Strategic and Investment Plan 2013-2018.

Further, the devolution of health services to county governments necessitated the enactment of the Health Act 2017. The Act established a unified health system in which the inter-relationship between the national and county government health systems is well defined. The two levels of government carry distinct responsibilities in the provision of healthcare services with the Pharmacy and Poisons Board mandated to regulate pharmacy practice as well as manufacture, trade and distribution of health products and health technologies.

Provisions in the Constitution and other policy documents provide opportunities for the health sector in general and the pharmaceutical sector in particular to secure the health of 52.2 million Kenyans. However, limited resources, infrastructural and human capital capacity constraints have conspired to undermine progress towards establishing a comprehensive healthcare system that assures *the highest attainable standard of health* for all Kenyans.

2.3 Global Pharmaceutical Sector

The pharmaceutical sector is a distinct economic entity with multi-dimensional aspects that affect international trade and cooperation. The sector is also at the centre of global initiatives on control and elimination of diseases. These factors shape the direction of pharmaceutical investments, human resource development as well as access to health products and technologies. Kenya is part of this complex regional and international ecosystem and, therefore, international trends and advancements in the pharmaceutical industry have a continuous impact on the health and safety of its population. Similarly, the growth of the local pharmaceutical industry contributes to the growth of the national economy.

The pharmaceutical sector shares responsibility for SDG 3:

3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

3.c Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in the Least Developed Countries and Small Island developing States.

3.d Strengthen the capacity of all countries, in particular the developing countries, for early warning, risk reduction and management of national and global health risks.

The World Health Assembly (WHA) Resolution 67.20 of 2014 tasks Member States to undertake regulatory system strengthening for medical products including medical devices and in-vitro diagnostics. The resolution encourages Member States to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of health products and technologies and, where appropriate, to participate in international harmonization.

International harmonization has been embraced at continental and regional levels where a treaty to set up the African Medicine Agency has been approved by African states. Similarly, Kenya is participating in the Medicines Harmonization Programmes that are being implemented within the East African Community (EAC) and the Inter-Governmental Authority (IGAD) regions.

The global pharmaceutical industry has developed tremendously, becoming increasingly globalized and technologically advanced. Broad 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);
- Monitoring drug efficacy, safety and quality; drug and poison information;
- Training and development of pharmaceutical personnel in colleges and universities;

- Institutionalise HTA (Health Technology Assessment) to guide evidence-based use of health products and technologies;
- Definition of specifications for all health products and technologies;
- Management and promotion of rational use of health products and technologies;
- Pharmaceutical research and development, including clinical trials;
- Ensuring availability of and access to affordable good quality health products and technologies; and
- Establishing stewardship for management of health products and technologies.

Inherent in the pharmaceutical sector functions are critical and highly complex issues that affect the nature and quality of healthcare. Such factors as intellectual property rights, counterfeit medicines, taxes and tariffs, registration, licensing and inspection, pricing and affordability, and unbiased consumer information determine access to appropriate health products and technologies.

2.4 Global Health Situation

The global context has an impact on local realities; increased cross-border movement of goods, services and people as well as international regulations have greatly influenced national health risks and priorities. Diseases like malaria, tuberculosis, Ebola, bird flu and mad cow disease move across borders effortlessly. International trade as well as multilateral and bilateral partnerships have facilitated global access to medicines, health technologies, cutting-edge research in medicine, medical information, training opportunities and specialised health sector expertise.

In 2015, world leaders and decision makers agreed upon a set of 17 Sustainable Development Goals (SDGs) to end poverty, protect the planet and improve the lives and prospects of everyone, everywhere by 2030. Overall, action to meet the Goals is not advancing at the speed or scale required and 2020 has been declared a decade of ambitious action to deliver on the Goals. SDG 3 is dedicated to health: to *''Ensure healthy lives and promote wellbeing for all at all ages''*. The aim is to substantially reduce maternal mortality, deaths of newborns and children under five years, epidemics such as AIDS, tuberculosis, malaria, and premature mortality, among other health risks. To respond to these challenges, a number of regional and global initiatives focusing on health have been undertaken and Universal Health Care (UHC) is considered a key instrument: *Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.*

Health is a priority area of concern for the donor community, but spending varies dramatically. Emerging global efforts and commitments are aimed at achieving Universal Health Coverage (UHC). A number of international declarations (Rome 2003, Paris 2005, Accra 2008, and Busan 2011) on Aid Effectiveness focus on aligning donor support to country policies, strategies

and priorities and using country systems in implementation for purposes of ownership. Subsequent commitments and milestones provide the platform for sector planning and development at national levels and also serve as the international yardstick for assessing progress.

Within this context, the African Union (AU) in its Agenda 2063 aspires for an Africa that is an influential global player and partner. The African Union also aspires for prosperity for all Africans based on inclusive growth and sustainable development and emphasizes health and nutrition in Goal Three of Agenda 2063. In April 2001, the AU countries met and pledged to set a target of allocating at least 15 per cent of their annual budget to improve the health sector and urged donor countries to scale up support.

While health funding has increased in some African countries since 2001, it has not yet reached the level agreed in the Abuja Declaration, although some success has been recorded. For instance between 2001 and 2013, health budgets in AU Member States increased from 9 per cent to 11 per cent of public expenditure. Six AU Member States (Liberia, Madagascar, Malawi, Rwanda, Togo and Zambia) achieved the Abuja target. Djibouti, Ethiopia, Lesotho and Swaziland are within reach of the target, while 11 countries had reduced their budgetary allocations to health. There was no clear trend for others.

Closer home, the East African Community has developed several frameworks and instruments to respond to identified regional health challenges and priority interventions. Kenya has made several commitments in health consistent with international and regional aspirations, declarations, treaties and protocols. The Constitution of Kenya guarantees conformity with internationally ratified obligations.

A review of 100 global core health indicators shows that Kenya is lagging relatively behind in the SDGs and in securing the health of its citizens. This is despite the fact that Kenya is a signatory to several global declarations, international commitments, protocols as well as national development targets on health. For instance, with an average life expectancy of 66.7 years, Kenya is placed at position 132 out of 195 countries in the world. Similarly, the infant mortality rate is 39 per 1000 live births and will be expected to be as low as 12 in 2030; death among under-five-year-olds is 52 per 1000 live births and should reduce to 25 by 2030, and maternal mortality, which stands at 362 per 1000,000, should reduce to less than 70 by 2030. Other pandemics include malaria, tuberculosis (TB), HIV/AIDS and non-communicable diseases (NCDs) such as cancer, diabetes and hypertension. The situation is exacerbated by an increased risk of communicable diseases by refugees from neighbouring fragile states.

These challenges as well as the national and global regulatory frameworks provide a wide spectrum of opportunities for intervention in the Kenya Pharmaceutical Sector. The Pharmacy and Poisons' Board will, therefore, use the present Strategic Plan (2020-2025) to refocus its attention on these issues

so as to consolidate gains from the health sector for the public and other stakeholders.

CHAPTER THREE

3. SITUATION ANALYSIS

3.1 Overview

The internal and external environment influences the operations of the Board and determines the extent to which it delivers on its mandate. As part of the strategic planning process, therefore, three tools were used to analyse key factors within the Board ecosystem: Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis; Policy, Political, Economic, Technological, Informational, Environmental and Legal (P-PESTIEL) analysis; and Stakeholder Analysis. The findings described below illustrate various factors that will either support or impede the process of implementing the PPB Strategic Plan 2020- 2024. They also provide a basis for identifying potential risks and formulating robust risk management strategies.

3.2 PESTIEL Analysis

A broad Policy, Political, Economic, Social, Technological, Informational, Environmental and Legal (P-PESTIEL) scan was undertaken with a view to examining the external environment under which the Board operates. Results of the policy analysis were reported in Chapter Two, and the subsequent outcome is presented below.

3.2.1 Political Factors

Governance and associated political power dynamics, interests, motives and actions have the potential to impact on the Board's operations. The political imperatives summarised in Table 3.1 can influence the extent to which the Board achieves its strategic objectives in the next five years.

Table 3.1 Political factors

	Factor	Positive Strategic Implications	Negative strategic implication
1	Transition in government	• None	• Disrupts momentum of activities as well as expected impact • Frequent change of policies
2	Corruption	• None	• Provokes inflation and higher prices of HPTs
4	Standards of practice	• Quality HPTs promote better health outcomes	• May exclude marginalised groups
5	Delinking PPB from the Ministry of Health	• Independence in decision making • Employee motivation, satisfaction and greater productivity • Greater sense of team and organisational	• Expensive to maintain and run • Focus on sustainability as opposed to health related goals could constrain service delivery

	Factor	Positive Strategic Implications	Negative strategic implication
		culture	
6	Government budgetary allocation	• Increased scope of the services	• Limited scope and coverage of services
7	Government subsidies	• Lowers price and increases accessibility to affordable healthcare and health products	• Promotes dependency
8	Political goodwill	• Creation of conducive legal framework • Improved local and international funding	• Skewed service delivery
9	Political interferences	• Some communities will benefit from enhanced service delivery	• Skewed service delivery that excludes some communities • Discourages investments in health

3.2.2 Economic factors

Structural factors within the economy determine the level of economic activity including investments, trade, incomes and access to pharmaceutical sector services as well as HPTs. The strategic implications of these factors are illustrated in Table 3.2.

Table 3.2 Economic factors

	Factor	Positive Strategic Implications	Negative Strategic Implications
1	Inflation	• Stimulates economic growth, increased incomes hence improved health standards in the long run	• Low purchasing power • High cost of HPTs thus reduces access to health services in the short run
2	Currency fluctuations	• A weaker currency stimulates exports of locally manufactured HPTs • Growth in local production of HPTs • Increased income from trade in pharmaceuticals • Increase in revenue • Kenya is a net importer of HPTs hence a stronger currency will increase access to HPTs	• Hampers local production because of increased imports
3	Level of disposable income	• High level of disposable income improves affordability of HPTs	• Low levels of disposable income reduces access to HPTs
4	Interest rate	• Low interest rate leads to business growth within the pharmaceutical sector, hence increased revenue • Increased disposable income hence greater access to HPTs	• High interest rates lower investments in the Pharmaceutical sector hence less revenue • Less disposable limits access to HPTs

	Factor	Positive Strategic Implications	Negative Strategic Implications
5	Taxation	• Tax exemptions facilitate trade and enhanced access to HPTs • May lead to increased budgetary allocation to health in the long run	• Higher taxes reduce volume of trade in HPTs • Higher taxes leads to higher prices and lower disposable income, which compromises affordability of HPTs
7	Government subsidies	• Enhances local manufacture of HPTs • Reduces prices of HPTs hence greater access	• Promotes dependency
6	Unemployment trend	• Pool of cheap labour for pharmaceutical industry which lowers cost of production and possibly price of HPTs	• Lack of income, which excludes access to quality healthcare • Promotes illegal pharmacy practice
7	Bilateral economic agreement	• Elimination of trade barriers e.g. tariffs, export restraints • Encourages trade and investments • Enhanced standards of HPTs • Encourages competition which lowers prices of HPTs and increases access to quality healthcare	• Inhibits local production of HPTs • Facilitates access to unwarranted HPTs through porous borders
8	Donor funding	• Improved scope and quality of services • Enhanced partnership and collaboration	• Lack of creativity • Dependency • Delay in donor funding affects momentum of service delivery

3.2.3 Social factors

Social factors are important in explaining the behaviour of the public and the choices they make on a range of pharmaceutical services, health products and technologies. These choices are shaped by the individual's personality, attitudes, lifestyles, experiences, access to information and capacity to interact with others. Such factors will ultimately affect the operations as illustrated in Table 3.3 below.

Table 3.3 Social factors

	Factor	Positive Strategic Implications	Negative Strategic Implications
1	Beliefs, values, attitudes, norms	• Positive beliefs, values, attitudes regarding pharmaceutical sector services and HPTs builds customer satisfaction and raises the profile of the Board	• Negative beliefs, values, attitudes regarding pharmaceutical sector services and HPTs erode public confidence and provoke search for alternative services • Promotes illegal trade in HPTs

	Factor	Positive Strategic Implications	Negative Strategic Implications
2	Disease burden	• Triggers research and innovations • Broadens regulatory framework	• Delayed interventions • High cost of service delivery as well as HPTs • Stigma
3	Ethics	• Accountability and responsibility • Professionalism • Improved performance • Increased customer satisfaction • Improved image	• Corruption • Drug and substance abuse • Illegal practice • Litigation
4	Family instability and gender violence	• Inclusivity goals and values to address the vulnerable	• Reduced disposable income and increased cost of healthcare • Increased dependence on healthcare services • Abuse of substances
5	Demographic factors e.g. population size, age distribution, gender and growth rate	• Pharmaceutical human capital development • Disability mainstreaming • Gender mainstreaming • Universal Health Coverage	• Pressure on existent pharmaceutical services • Illegal trade in pharmaceuticals • Exclusion of marginalised groups from healthcare services
6	Immigration and emigration	• Increased workforce • Blend of skills • Collaboration and partnership	• Pressure on existent pharmaceutical services • Exposure to new diseases • Illegal practice
7	Lifestyles and wealth distribution	• Skewed access to HPTs in favour of the wealthy and urban areas • Universal Health Coverage	• Skewed access to HPTs excluding marginalized groups

3.2.4 Technological factors

Technological advancements in the digital era have impacted on all aspects of life; from education to transport and communication, trade and health. The technological factors outlined in Table 3.4 provide impetus for improved service delivery.

Table 3.4 Technological factors

	Factor	Positive Strategic Implications	Negative Strategic Implications
1	Communication infrastructure	• Automation to achieve efficiency and effectiveness • Enhanced accuracy • Centralised information sharing • National single window • Eases decentralisation of services	• Infrastructural deficiencies can lead to breakdown in communication • Loss of data and information • Loss of revenue • Litigation

	Factor	Positive Strategic Implications	Negative Strategic Implications
2	Rapid technological advancement	• Increased productivity of operations • Opportunity for human resource development	• Obsoleteness • Cost of depreciation • Cost of training on new technologies • Cost of system disruption
3	Media	• Increased publicity and awareness through social media, mainstream and alternative media • Real time communication of health risks	• Ethical issues in media coverage • Biased media focus • Abuse of social media
4	Data analytics	• Informed decision making • Enhanced responsiveness	• Lack of technical skills for advanced data analysis
5	Research, innovation and development	• Informs best practice • Informed decision making • Improved service delivery and efficiency	• High cost of research and innovation • Limited technical research skills
6	Cybercrime/security	• Creative solutions • Legislation to mitigate abuse of digital technology	• Loss of data • Breach of confidentiality • Litigation • Loss of revenue and resources
7	E-commerce	• Increased volume of trade and access to HPTs • Reduction of turn-around-time	• Difficult for the Board to regulate online practice and optimize revenue generation

3.2.5 Environmental Factors

The condition of the natural world and its ecosystem of water, soil, climate and living things is often exacerbated by human activity. The result is adverse weather conditions and environmental hazards that predispose people to health risks and increase the burden of disease. Table 3.5 below summarises key environmental factors that affect operations.

Table 3.5 Environmental factors

	Factor	Positive Strategic Implications	Negative Strategic Implications
1	Global Warming	• Demand for diverse pharmaceutical products • Increased investment in pharmaceutical industry to combat increased disease outbreaks	• Increased disease outbreaks
2	Environmental degradation (air and water pollution and deforestation)	• Stimulates research and innovation • Increased demand for HPTs • Local commitment to SDGs	• Increased disease burdens • Reduced potential for alternative and herbal medicines

	Factor	Positive Strategic Implications	Negative Strategic Implications
3	Waste management ● Domestic waste ● Toxic chemical waste ● Radio Nuclear Waste ● Electronic waste ● Pharmaceutical waste	● Increased demand for HPTs ● Stimulates research in appropriate technologies ● Enhanced opportunity for legislation and regulation of waste management ● Local commitment to SDGs	● Increased cost of waste management ● Increased disease burden ● Lack of clear pharmaceutical waste management and environmental policies
4	Natural disasters	● Increased demand of pharmaceutical products ● Capacity building in preparedness for disaster management	● Increased disease burden ● Infrastructural and skills deficiencies for natural disaster responses
5	Availability of natural resources	● Potential for investment in locally derived natural products	● Limited research in locally derived natural products ● Restricted regulatory framework for locally derived natural products ● High cost of pharmaceutical production
6	Anti-microbial resistance	● Potential for relevant research capacity building ● Development of clinical pharmacy	● Resistance to drugs ● Pressure on innovation of new drugs ● High cost of drugs
7	Lack of awareness towards green products and renewable energy	● Potential for relevant research capacity building ● Local commitment to SDGs	● Poor attitude towards green products and renewable energy ● Limited research in locally derived natural products ● Delays in domesticating international and regional health aspirations, declarations and commitments
8	Health risk factors from cross-border conditions, like Ebola	● Potential for relevant research capacity building ● International and regional health commitments	● Delays in domesticating international and regional health aspirations, declarations and commitments ● Limited funding for relevant research

3.2.6 Legal Factors

Laws concerning the production, trade, distribution and use of HPTs can either hamper or facilitate access to essential services and thus influence health outcomes either positively or negatively. The laws determine among others, the diversity and availability of opportunities for training, standards of pharmacy practice as well as ease of production and doing business in the pharmaceutical sector. Legal factors are influenced by the actions of a number of unique actors such as government, Parliament, Judiciary, trade, industry and health. Some of the legal factors are captured in Table 3.6 below.

Table 3.6: Legal factors

	Factor	Positive Strategic Implications	Negative Strategic Implications
1	Weak legal framework	• Innovation and stakeholder involvement to secure broad based support	• Slow response to health risks • Gaps in distribution and manufacturing systems for HPTs • Lag in domestication of global and regional health aspirations
2	High litigation • Medico-legal • General	• Lessons drawn for streamlining services	• High legal costs • Delay in service delivery
3	Unfavourable labour laws	• Increased job creation • Increased disposable income and access to pharmaceutical services and HPTs	• Increased cost of pharmaceutical products • Increased industrial action • Demotivated staff
4	Poor contract management system	• Skills enhancement and diversification • Mechanisms for strengthening service delivery	• Poor service delivery • Increased litigation • Increased costs of project implementation
5	Regulatory framework • NEMA • OHSE • Statutory requirements	• Quality standards for service delivery and HPTs	• Increased litigation • Increased cost of compliance • Increased cost of pharmaceutical products • Increased cost of investment in local manufacturers

3.3 Strengths, Weaknesses, Opportunities, Threats (SWOT) Analysis

An analysis of the Strengths, Weaknesses, Opportunities and Threats provides additional insights on the peculiar features of the Board and their implications for a new strategic direction. The internal environment indicates aspects that are controllable and changeable through planning and management processes while the external environment indicates uncontrollable factors.

3.3.1 Internal Environment Analysis

The internal environment is associated with the human resource, the organisational culture as well as organisation of resources to undertake work in accordance with the mission of the Board. Important aspects include human resources, organisational culture, organisational structure, management styles, assets and access to financial resources. The discussion below highlights relative strengths, weaknesses and implications for the present strategy.

Strengths

The factors described in the table below have placed the Board in a unique position to fulfil its mandate.

Table 3.7: Strengths

	Strengths	Strategic Implication
1	Qualified staff	• Optimal performance • Efficient and effective service delivery
2	Automated processes	• Improved efficiency in service delivery
3	Effective Quality Management System	• Quality products and services • Efficiency in service delivery
4	Ability to generate income internally and from external sources	• Operational effectiveness • Broad scope of services
5	Regulated profession and medical products	• High profile • International recognition
6	Training and continuous professional development opportunities	• Diverse and specialised skills • Less expenditure on external expertise
7	International recognition of Pharmacovigilance as a Centre for Excellence	• Improved surveillance • Improved capacity for real time responses to medical emergencies
8	Effective public relations	• High profile • Enhanced public awareness of services
9	Active stakeholder's engagement	• Improved collaboration and partnership • Trust
10	Established quality PMS laboratory	• Improved quality of HPTs • Enhanced surveillance

Weaknesses

The SWOT analysis also revealed a number of issues that will need to be addressed to enable the Board create the desired impact in the health sector. These are captured in the Table below.

Table 3.8: Weaknesses

	Weaknesses	Strategic Implication
1	Insufficient human resource	• Work overload constrains efficiency
2	Role conflicts and vested interests	• Skewed service delivery
3	Negative staff attitude and culture	• Less-than-optimal performance • Poor corporate image
4	Lack of performance measurement and monitoring	• Lack of accountability and responsibility for service delivery
5	Poor compensation (Remuneration, incentives/rewards and sanctions)	• Low staff motivation and less-than-optimal performance

	Weaknesses	Strategic Implication
6	Lack of teamwork (silo mentality)	• Bureaucratic bottlenecks to service delivery
7	Poor communication mechanisms	• Low customer satisfaction • Misunderstanding of the Board's mission
8	Lack of active operational research	• Limited innovation in services
9	Lack of capacity to carry out data analysis	• Limited evidence for decision making
10	Failure to hold regular management review and departmental meetings	• Difficulty to track progress towards achievement of strategic objectives • Lack of accountability and responsibility
11	Process oriented rather than service delivery to customers	• Above average customer satisfaction
12	Inadequate resources	• Limited scope of service delivery • Centralised services
13	Poor coordination of post-market surveillance	• Time lag in response to medical emergencies
14	Conflict between oversight and operational management	• Leadership capacity development
15	Weak interface between different levels of management	• Poor coordination of service delivery

3.3.2 External Environment Analysis

While the external environment is not within the Board's control, its leadership has some measure of control as to how the organisation reacts to these changes. Such factors as changes to law or difficult economic conditions can be mitigated to minimise a potentially negative impact so as to maximise the positive effects. A review of the external environment revealed several opportunities as well as threats to the Board's operations which are described below.

Opportunities

The opportunities outlined below would be drivers of sustainable transformation in the work and impact of the Board, if adequately exploited.

Table 3.9: Opportunities

	Opportunities	Strategic Implication
1	Support from partners and donors	• Improved service delivery • Increased uptake of projects
2	Rollout of the UHC programme	• Goodwill and Government support
3	Reviewed legal framework (Amendments in CAP 244 and Health Act bill) - legal	• Expanded mandate • Autonomy of the Board
4	Regulation of blood and blood products	• Increased revenue
5	Diversified communication media channels	• Improved awareness creation

	Opportunities	Strategic Implication
6	Technology advancement for digitisation of services	• Increased operational efficiency due to innovation
7	Devolvement of functions to the County Governments	• Efficiency and effectiveness in service delivery
8	Collaborations and partnership	• Increased scope and access to PPB services
9	Continuous professional development services	• Improved standards of healthcare
10	Accreditation by certifying bodies e.g. QMS, QC, ICT	• International recognition • High profile • Quality products and services
11	Increased scope of testing HPTs	• Improved access to quality and safety of health products and technologies • Increased revenue • Better surveillance • Reduced analysis turn-around time

Threats

The presence, scope and magnitude of the following risks can constrain operations. A comprehensive risk management strategy will help mitigate the threats identified below.

Table 3.10: Threats

	Threats	Strategic Implication
1	Negative publicity	• Poor image and diminishing stakeholder confidence
2	Conflicting and inadequate laws for some of the regulatory functions	• Conflict in execution of Board's mandate • Litigation
3	Devolution of health function (proposal by county governments to buy their own medical products without passing through the regulatory agency)	• Quality of HPTs cannot be guaranteed
4	Unscrupulous traders engaging in SSFC through porous borders	• Substandard, spurious, falsely labelled and counterfeit) products in the market • Poor image of the Board
5	Unqualified persons trading in HPTs (quacks)	• Compromises the quality of products and safety of the public • Lowers the standards of healthcare
6	Public perception that the medical products in the market are neither safe nor quality	• Poor image and diminishing stakeholder confidence
7	Fast-changing technology leading to obsoleteness of the technology in use	• High cost of upgrading/replacing technology
8	Unfavourable government policy changes	• Unpredictable momentum and progress towards strategic objectives
9	Lack of prosecuting powers	• Delays in determination of pharmacy related cases
10	Political interference	• Skewed service delivery • Corruption • Compromises execution of Board's mandate

	Threats	Strategic Implication
11	Corruption	• Increases cost and scope of service delivery
12	Unemployment	• Illegal pharmacy practice • Exclusion from quality healthcare
13	Changing global economic trends	• Decreased external funding • Limited potential for partnerships • Increased cost of production hence prices of HPTs
14	Change in disease patterns and re-emerging diseases	• Opportunity for research and partnerships • Slow rate of domestication of health aspirations, declarations and commitments
15	Increased drug and substance abuse	• Low productivity • High dependency on healthcare services
16	High population growth rate	• Increased pressure on existent healthcare services
17	High poverty levels	• Increased use of unregulated and alternative healthcare products such as herbal products

3.4 Stakeholder Analysis

As the Board seeks to diversify and enhance its operational capacities to deliver effectively on its broad mandate, the number and nature of its stakeholders gain more prominence. A stakeholder analysis established the interests, power, expectations as well as the mutual responsibilities and obligations of a variety of stakeholders. The results provided in Table 3.11 below illustrate the functional relationship of various actors within the socio-economic and political context of Board.

Table 3.11: Stakeholders Analysis

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
Internal Stakeholders			
1	Board of Directors	• Development and oversight for strategic plan implementation • Strategic direction • Policy formulation • Performance review • Robust corporate governance • Lobbying on behalf of the Board	• Implementation of strategic plan and policies • Resource mobilisation • Safeguarding image • Favourable terms and conditions of service • Shared vision • Realisation of the mission
2	PPB staff	• Competitive terms of service • Good work environment • Equal opportunities for career growth • Effective leadership • Mentorship • Timely payment of salaries and remuneration • Effective communication • Adequate staff establishment • Succession planning • Teamwork • Flexibility in working hours • Participatory decision making	• Satisfactory performance • Commitment • Professionalism • Loyalty • Discipline • Integrity • Teamwork • Timeliness • Efficient and effective use of resources • Compliance to policies, laws and regulations • Accountability • Responsibility

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
		• Fair performance appraisals	• Realisation of the mission
External Stakeholders			
3	Public	• Availability of quality, safe, efficacious and affordable HPTs • Adequate surveillance and monitoring to ensure quality, safety and efficacy at all times • Professionalism • Integrity in service delivery • Accountability • Accurate and timely information • Efficiency in service delivery • Policy formulation and implementation • Decentralisation of services • Collaboration and partnership with other agencies • Responsiveness • Effective communication and feedback • Awareness and sensitisation on Board's mandate	• Compliance with the Board's regulations • Prompt feedback • Participate in initiatives • Cooperation and responsiveness • Maintain integrity in dealing with the Board and its staff • Partnership and mutual responsibility • Goodwill
4	Pharmacy practitioners	• Well managed profession • Efficient and effective registration processes • Appropriate professional development programmes • Timely service delivery • Effective communication and feedback • Diversification of specialisations • Coordinate and harmonisation of continuous professional development • Fair levies	• Compliance with laws, regulations and policies • Maintenance of professional standards • Cooperation with • Discipline • Professionalism • Prompt feedback • Integrity • Accountability and responsibility • Collaboration
5	Students	• Well-coordinated internship • Efficiently administered examinations • Efficient and effective registration processes • Effective communication and feedback • Diversified specializations • Good career prospects	• Compliance to rules, regulations and policies • Cooperation with the Board • Discipline • Prompt feedback • Integrity • Accountability and responsibility
6	Licensed laboratories such as the Drugs Analysis Research Unit of the University of Nairobi, National Quality Control	• Memorandum of Understanding (MOU) • Cooperation • Timeliness in testing services • Prompt payment for services	• Memorandum of Understanding (MOU) • Quality and uncompromised testing services • Cooperation • Integrity and commitment

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
	Laboratory (NQCL), MEDS etc.		
7	Ministry of Health	• Prudent resource management • Professionalism • Integrity • Development and implementation of strategic plan • Generation of revenue • Development and enforcement of national health and pharmaceutical policies	• Robust legal framework • Adequate funding • Relevant policy guidelines • Sensitivity to needs • Support the implementation of national pharmaceutical policies • Lobbying
8	Government of Kenya	• Accomplishment of Board's mandate • Good corporate governance • Revenue generation • Compliance with government policies and circulars • Prudent resource utilisation	• Adequate budgetary allocation • Autonomy • Promote bi-lateral and multilateral donor support • Political stability • Goodwill and support • Strategic leadership • Good governance • Appropriate legislation
9	Development partners such as JICA, World Bank, USAID, Global Fund, United Nations Organizations, PEPFAR, among others	• Good corporate governance • Timely feedback and reporting • Membership and participation in relevant international conventions • Effective project implementation • Efficient resource utilisation • Compliance with MOUs • Compliance with laws, policies and regulations • Transparency and Accountability • Effective communication	• Appropriate responses to Kenya national healthcare needs • Goodwill • Timely funding and other technical support • Continuous sensitisation • Effective communication • Compliance with MOUs and regulation
10	Suppliers	• Compliance with Procurement and Disposal Act of 2005 • Fair competition • Prompt payment • Planned procurement • Effective communication and feedback • Integrity • Customer care	• Compliance with contractual obligations • Integrity • Customer care • Competitive pricing • Effective communication and feedback
11	County Governments	• Compliance with laws policies and regulations • Payment of levies • Collaboration in resources management • Decentralised services	• Develop relevant county facilities and infrastructure • Observe Board's policies and protocols • Partnership in enforcement of Board's policies

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
12	Statutory bodies like NEMA, NACADA, KNEC, KRA, NSSF, NHIF, RBA, KEBS,	• Compliance with regulations • Partnership and collaboration in the execution of health mandate • Effective communication and feedback	• Compliance with appropriate regulations • Partnership and collaboration in the execution of health mandate • Effective communication and feedback
13	International and regional organisations (WHO, AU, EAC, IGAD, ICH, SWISS MEDIC, other regulatory agencies	• Sharing of health information • Partnership in relevant training and research • Domesticate best practice • Mutual recognition of health aspirations • Compliance with agreed protocols	• Sharing of international and regional health information • Support for relevant training and research • Domesticate best practice • Mutual recognition of health aspirations
14	Collaborating institutions like National Public Health Laboratories, KEMRI, NASCOP, National Radiation Protection Board, etc.	• Utilize available facilities for training, testing and research • Domesticate best practice • Sharing of information • Mutual recognition	• Provide facilities for training, testing and research • Sharing of information • Share best practices • Mutual recognition of outputs
15	CPD Providers and professional bodies	• Streamlining continuous professional development in the pharmacy sector (levels of practice, levels of training and internship) • Timeliness • Effective communication • Partnership and collaboration on regulation of the sector	• Enforce discipline among professionals • Implement continuous professional development guidelines • Effective communication and feedback • Partnership and collaboration • Timeliness
16	Media	• Share timely, adequate and accurate information	• Create awareness • Balanced and fair reporting
17	Police	• Information sharing and partnership • Cooperation in crime investigation • Accurate and timely documentation • Professional advice	• Provision of security • Maintenance of law and order • Cooperation in crime investigation and prosecution • Professional advice
18	Judiciary	• Compliance with legal requirements • Partnership and collaboration • Accurate and timely documentation • Professional advice	• Partnership and collaboration • Appropriate judicial services • Professional advice

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
19	Trade Unions (KUDHEIHA, KMPDU, COTU,	• Good labour relations • Implementation of collective bargaining agreements	• Robust labour relations • Fair negotiation of Collective Bargaining

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
	PUSETU)	• Staff welfare and good working conditions	Agreements • Professional advice • Enforce professionalism and ethical standards
20	Politicians	• Effective delivery of services • Prudent resource utilisation	• No political interference • Robust legal framework
21	Inspectorate of State Corporations	• Adherence to State Corporations Act • Robust corporate governance • Effective service delivery • Information sharing and timely feedback	• Information sharing • Timely and objective feedback • Professional advice
22	Financial institutions	• Credit worthiness • Good corporate governance	• Responsive • Professionalism and high integrity
23	Ministry responsible for higher education, Training Institutions like Universities and colleges and education regulatory agencies (CUE, TVET)	• Partnership and collaboration in training and research • Develop and implement guidelines on training and career development • Timely assessment and approval of pharmacy programmes • Private- public- university-industry-government linkages	• Partnership and collaboration in training and research • Compliance with laws, policies and guidelines • Appropriate and transformative human resources development • Quality graduates
24	Pharmacy outlets, distributors and hospitals	• Fair and objective enforcement of rules, regulations and standards • Elimination of quacks from the practice • Timely information and feedback • Efficient and effective service delivery • Interactive and effective communication • Responsiveness • Integrity • Partnership and collaboration • Accountability for HPTs	• Compliance with rules and regulations • High standards of practice and service • Partnership and collaboration • Timely information and feedback • Maintain integrity • Professionalism in service delivery
25	Pharmaceutical manufacturers	• Fair and objective enforcement of rules, regulations and standards • Lobby government for incentives (ease of doing business) • Timely information and feedback	• Compliance with rules and regulations • High standards of practice and service • Partnership and collaboration • Timely information and feedback • Maintain integrity
26	Foreign countries/ Embassies	• Efficient and effective service delivery	• Professionalism in service delivery

	Stakeholder	Stakeholder Expectations	Stakeholder Obligations
		• Interactive and effective communication • Responsiveness • Integrity • Partnership and collaboration • Quality standards on all cross-border products • Enforcement of regulatory decisions • Partnership and collaboration • Information sharing and timely feedback • Domesticate international and regional health aspirations, declarations and protocols	• Competitive pricing • Consistent and adequate supply of essential HPTs • Accountability for HPTs • Partnership and collaboration • Expedite provision of consular services • Timely information and feedback • Facilitate trade in HPTs • Support for international and regional health aspirations, declarations and protocols • Mutual recognition of regulatory decisions

CHAPTER FOUR

4. STRATEGIC DIRECTION

4.1 A New Strategic Direction

Pharmaceutical services have increased exponentially in the past decade and devolved governance has provided pathways for enhancing access for the most marginalised communities in Kenya. To ensure access to quality, safe, efficacious and affordable health products and technologies, the Board bears a daunting responsibility. It is expected to foster pharmaceutical innovations, promote cutting edge research, integrate technological advancements, and, facilitate curriculum transformation as well as best practice in the manufacture, trade and distribution of HPTs in tandem with global trends. Consistent with these dynamics, the mandate of the Board has broadened, but it remains at a crossroads. Its workforce is considerably small and approach to work is largely classical--from regulation of HPTs to pharmacy training and practice. Careers in pharmacy, the very pillar of pharmacy practice, are declining and enrolments in pharmaceutical programmes at all tertiary levels are dwindling.

This Strategic Plan provides a new strategic direction for renewed growth in the Kenyan pharmaceutical sector in pursuit of global competitiveness in an intricate and complex pharma industry.

4.1.1 Vision

To be a global leader in promoting and protecting public health.

4.1.2 Mission

To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies.

4.1.3 Values

The Board will seek to cultivate a conducive and responsive organisational culture for both internal and external stakeholders and enhance service delivery by embracing the following core values:

1. Commitment to public health
2. Professionalism
3. Accountability and transparency
4. Integrity and respect
5. Quality
6. Diversity and inclusion

The core values are elaborated in Table 4.1 below while the "*Dos*" and "*Don'ts*" associated with respective values are provided in a separate document.

Table 4.1: Core Values

Commitment to public health	We demonstrate our commitment to safeguarding the public health in our actions
Professionalism	We shall maintain high standards while discharging our duties by abiding by professional considerations on the methods, standards, procedures and timeliness in our work
Accountability and transparency	We take personal responsibility for meeting individual, team and organisational commitments
Integrity and respect	We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions
Quality	We set high standards of excellence for our work and take the necessary action to continuously improve
Diversity and inclusion	We implement national values and principles of governance including diversity, inclusivity, human rights, equality, non-discrimination and human dignity

4.2 Strategic Themes

Strategic themes are the main, high-level business strategies that form the basis for the organisation's business model and operationalise the mission into key areas. They guide in the development of goals and objectives and form the "pillars of excellence". In the 2020-2025 Strategic Plan, the Board has set the following five strategic themes:

1. Use of Modern Regulatory Science
2. Internationalisation
3. Safety, Efficacy, Quality and Cost-effectiveness
4. Stewardship
5. Customer-centric service

4.2.1 Use of Modern Regulatory Science

The Board shall use modern regulatory science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and cost-effectiveness of health products and technologies. Modern regulatory science is fundamental to its core mission of promoting and protecting the health of the public. The Board must be a science-based agency and, therefore, it is critical to access the best available scientific data to inform regulatory decision-making and thus improve access to health products and technologies. The Board's regulatory mandate will use modern science to ensure that regulation is not reactionary, but proactive. Modern regulatory science will require it to be a research-based and led institutions, not only learning from lessons, but also proactively supporting cutting edge research that will develop innovation in regulation of health products and technologies. The Board will also partner with institutions locally and abroad that have the modern science of regulating healthcare products and technologies. Such knowledge will be used to inform PPB decisions as well as guide local manufacturers to improve the quality and variety of healthcare products and technologies. In so doing, the Board will aim at being the "Best health products and technologies regulatory body in the region".

4.2.2 Internationalisation

Kenya is not self-sufficient in production of pharmaceutical products and other Board-regulated products. Indeed, over 70 per cent of pharmaceutical and regulated products used in Kenya are imported. Internationalisation requires that the Board think, act, and engage globally. The Board will engage with other government regulatory counterparts, as well as with industry, regional and international organisations, to encourage the implementation of science- based standards that ensure the safety, efficacy, quality and affordability of healthcare products and technologies before they reach Kenya. It will endeavour to do the same with export of healthcare products and technologies. The strategic result of internationalisation shall be "Best health products and technologies supplier in the region".

4.2.3 Safety, Efficacy, Quality and Cost Effectiveness

The mission of the Board clearly stipulates that safety, efficacy and quality are integral to promoting and protecting public health. Safety, efficacy and quality include:

(a) Good Manufacturing Practices, for making the best and most affordable health care products and technologies
(b) Good Distribution Practices used to deliver healthcare products and technologies to their users that ensure product integrity and cost effectiveness
(c) Protecting the public through such measures as control of clinical trials, post-market surveillance and pharmacovigilance systems as well as promoting rational use of health products and technologies.

It is paramount that industries producing and delivering healthcare products and technologies provide products that promote and protect the health of the public. This will require that the Board ensures that all health products and technologies delivered by industries have product faithfulness (that is, they are what they say they are), product efficiency (that is, they do what they say they will do), and are distributed through a system that ensures their safety, efficacy, quality and cost-effectiveness. The strategic result of this theme is "quality, safe, efficacious and cost-effective healthcare products and technologies".

4.2.4 Stewardship

The realisation of the goals set by the board is dependent upon the stewardship executed by the management and the Board. Sound management and governance practices will ensure effective decision making and implementation. It is the intention of the Board to maximise public health value from each shilling available so as to keep up with the dramatic technological and market- based changes affecting how healthcare products and technologies are produced.
The Board will effectively and efficiently use limited resources to increase productivity while maintaining regulatory integrity. It will also mobilise

resources to augment those provided by the national and county governments. It will further employ efficient operational procedures supported by an effective organisational structure. The organisation and its units shall endeavour to plan for the efficient use of resources and achievement of her mandate. The Board and individual staff shall take responsibility for their choices and actions. The strategic result of the stewardship theme is "Best run health regulatory body in the region".

4.2.5 Customer-centric Service

The Board shall carry its mandate in a way that provides a positive customer experience before and after the services. It shall endeavour to ensure that the health of the public comes first in all regulatory decisions and actions. The public forms the main customers and as such shall be consulted and kept informed of all regulatory decisions and actions including the effect on their health resulting from its actions. Internal customers shall be appreciated and treated with respect so as to deliver a world-class service. The Board will use modern technology, including data analytics, to understand customer behaviour, interests and engagement so as to identify opportunities to best serve them. The strategic result of Customer-centric Service is to be the "Best customer/stakeholder rated health regulatory body in the region".

4.3 Goals and Objectives

The five strategic themes will be translated into action through four thematic goals. Each goal will be achieved through relevant objectives. Goals form the broad, long-range attributes that the Board seeks to accomplish over the entire five-year Strategic Plan 2020-2024. The strategic themes as well as goals and objectives provide an integrated framework for fulfilling the Board's mission. The goals and objectives are necessarily interconnected because they address the overarching mission of the Board. The realisation of one goal or objective can easily affect the success of others and, therefore, they must be pursued with unity of purpose. The four goals that the Board will pursue in this Strategic Plan are:

Goal 1: Ensure access to safe, quality, efficacious and affordable health products and technologies;
Goal 2: Leverage on research, innovation and technologies in the delivery of products and services;
Goal 3: Promote organisational stewardship, partnership and accountability; and
Goal 4: Promote a pharmacy practice that provides the highest attainable standards of healthcare.

The rationale of each goal, the corresponding objectives and major activities are presented below.

Goal 1: Ensure access to safe, quality, efficacious and affordable health products and technologies

The Board aims at achieving *equitable, affordable and quality health and related services at the highest attainable standards to all Kenyans* as envisioned in the Kenya health policy. Therefore, in pursuing the requirements of Vision 2030, and agenda 4 on Universal health coverage, the Board will *ensure access to safe, quality, efficacious and affordable health products and technologies.* **Access** implies putting strategies to work with other governmental agencies and the private sector to enhance availability of health products and technologies that are ***safe, of quality, efficacious and affordable*** to the public. Access also entails provision of information that enables patients to make safe use of health products and technologies, manufacturers, distributors, pharmacy practitioners and healthcare workforce to make sound decisions and other government agencies to make sound health policies. Kenyans must be assured of having the right quality and number of pharmacy practitioners both at the community and clinical levels. Nevertheless, rules and regulations relating to practice must take into consideration social, political environmental challenges and especially those of marginalised areas.

The Board shall endeavour to protect the safety of patients through detection and intervention strategies. Such strategies will include control of clinical studies, good manufacturing practices and good distribution practices, pharmacovigilance and active post-market surveillance. Such strategies will ensure that unsafe products, manufacturing and distribution conditions are discovered, and regulatory actions taken before they can do harm to the public.

To ensure access to safe, quality, efficacious and affordable health products and technologies, the Board will pursue the seven (7) key strategic objectives outlined in the Table in Section 4.4.

Goal 2: Leverage on research, innovation and technologies in the delivery of products and services

Research and technological innovation is crucial to the Board's core mission of protecting and promoting the health of the public. The Board acknowledges the need to develop research and technological innovations that provide the opportunity to translate new technologies and research discoveries into real-world solutions for diagnostics, treatments, and cures. It also acknowledges the value of research and technological innovation in the potential oversight of how health products and technologies are produced, stored and transported. Research and innovation will, in addition, improve pharmacovigilance and post-market surveillance to better account for the movement of health products and technologies and to better detect and validate safety and respond to toxicity signals.

To leverage on research, innovation and technologies in the delivery of products and services in the present plan period, the Board will pursue the four (4) key strategic objectives outlined in the Table in Section 4.4.

Goal 3: Promote organisational stewardship, partnership and accountability

The Board has a wide mandate to oversee the safety**,** quality, efficacy and affordability of health products and technologies as well as the pharmacy practice while operating with limited resources. To fulfil that mandate, the Board needs to efficiently and effectively carry out its operations.

There is a need to be a good steward of resources, both government grants and internally generated revenues. That calls for organisational excellence and accountability to the Kenyan government, the public, donors and other stakeholders. Excellence requires raising sufficient revenues, cost management and continuous development of the workforce, systems, and infrastructure. The mandate of promoting and protecting the health of the public cannot be achieved by one agency. As a result, the Board will work with other public and private sector organisations to share knowledge and resources as well as develop and implement nationwide improvements, systems and infrastructure. The Board commits to fostering an effective corporate governance, evolving robust and transparent management systems, investing in people, creating positive work environments and investing in infrastructure that will help realise the mission of promoting and protecting the health of the public.

To promote organisational stewardship, partnership and accountability over the next five years, the Board will pursue the six (6) strategic objectives outlined in the Table in Section 4.4.

Goal 4: Promote a pharmacy practice that provides the highest attainable standards of healthcare.

The Board will ensure that the pharmacy profession protects, promotes and maintains the health, safety and wellbeing of the public. In particular, the Board will ensure that pharmacy practitioners adhere to such standards as the board considers necessary for the safe and effective practice of pharmacy. It will pursue strategies that support and improve the delivery of safe and effective pharmaceutical care and uphold trust in the pharmacy profession. In so doing, the Board will ensure that pharmacists have the necessary knowledge, attitudes and behaviours to deliver pharmaceutical services. It will also ensure that registered pharmacies deliver safe, effective care and services. In addition, the critical importance of diversification, specifically to develop clinical pharmacists cannot be overstated. Evidence has shown that non- dispensing clinical roles are feasible and add value to patient care. As a result, the Board will pursue strategies that support patient-centred pharmacist systems while maintaining the traditional product centred pharmacy in tandem with global trends and practices.

To promote a pharmacy practice that provides the highest attainable standards of healthcare in the present plan period, the Board will pursue the two (2) strategic objectives outlined in the Table in Section 4.4.

4.4 Goals, Strategic Objectives and Key Strategies

Strategic Objectives	Key Strategies	Primary Responsibility
Goal 1: Ensure access to safe, quality, efficacious and affordable health products and technologies		
Strategic Objective 1.1 Increase regulatory science capacity to effectively evaluate health products and technologies	1) Create or customise regulatory science innovations for product evaluation and registration	DPER
	2) Collaboration with scientific community, industry, regional and international agencies e.g. WHO to advance regulatory science	
	3) Support public-private partnerships to advance regulatory science	
	4) Improve the effectiveness of evaluations for dietary supplements borderline and cosmetics with regard to safety (toxicity evaluations)	
	5) Modernise bioinformatics infrastructure to apply the most recent data in product evaluation and registration	
	6) Strengthen an infrastructure that supports high quality scientific investigations/ evaluation and registration for all HPTs	
Strategic Objective 1.2 Foster integrity of the supply chain of health products and technologies	1) Establish and implement national HPTs accountability system	DISE
	2) Monitor and enforce compliance with good distribution practices	
	3) Investigate and gather intelligence on pharma-crime	
	4) Monitor and enforce compliance with good manufacturing practices	

Strategic Objectives	Key Strategies	Primary Responsibility
Strategic Objective 1.3: Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs	1) Review and improve surveillance systems for HPTs	MIPV
	2) Develop partnerships to implement PPB PV-RCORE functions	
	3) Review and improve market surveillance systems for HPTs	
	4) Partner with laboratories for testing of HPTs	
	5) Strengthen and enforce control of clinical trials	
	6) Review and improve medicines information system for HPTs	
Strategic Objective 1.4 Strengthen response to risks to quality, safety and efficacy of health products and technologies	1) Enhance the effectiveness of response system to unsafe health products and technologies	
	2) Enhance ability to prevent and respond to shortages in HPTs arising from regulatory hiccups	
Strategic Objective 1.5 Enhance cost effectiveness in access to HPTs	3) Periodically determine the reimbursable cost for every treatment package	Head Trade
	4) Exploit TRIPS provisions and safeguards to avail HPTs at affordable cost	
Strategic Objective 1.6 Promote local production of HPTs in line with UHC	1) Expedite time taken for registration of locally produced HPTs	DPER
	2) Lobbying and partnerships to spur local pharmaceutical growth	
	3) Capacity building for local manufacturing	
	4) Establish a regulatory framework for locally derived natural health products	
Strategic Objective 1.7 Decentralise PPB services	1) Fully operationalise regional offices	Regional Coordination
2) Goal 2: Leverage on research, innovation and technologies in the delivery of products and services		

Strategic Objectives	Key Strategies	Primary Responsibility
Strategic Objective 2.1: Enhance capacity of the laboratory to test HPTs	1) Operationalise the physico-chemical laboratory	Director QC
	2) Establish and operationalize a microbiology laboratory	
Strategic Objective 2.2 Produce high quality research and development outputs in health products, technologies and practice	1) Review and improve research infrastructure for effective coordination of all research projects	Head Research
	2) Foster research outputs to patenting	
	3) Establish and operationalise regional microbiology laboratory	
Strategic Objective 2.3 Utilise research innovation and technology in the delivery of services and products	1) Apply research outputs in regulation of HPTs and Pharmacy Practice	Head Research, DPER, DISE, MIPV
	2) Promote research into appropriate products (including locally derived natural health products) and facilitate their subsequent development and incorporation into the health system	
Objective 2.4: Enhance organisational excellence through research and innovation	1) Develop and implement research and innovations to enhance directorate's/department's excellence	All Directors
2) Goal 3: Promote organisational stewardship, partnership and accountability		
Strategic Objective 3.1: Improve the overall operational efficiency and effectiveness	1) Enhance organisational strategic management	Planning/All directors
	2) Foster good corporate governance	Corporate/Legal
	3) Promote public awareness	PR
	4) Minimise losses resulting from legal issues	Legal
	5) Build strategic partnerships	All Directors
Strategic Objective 3.2: Invest in infrastructure to enhance productivity	1) Create a work environment and ergonomics design that promote excellence	Finance/Admin
	2) Automate and integrate processes	ICT

Strategic Objectives	Key Strategies	Primary Responsibility
Strategic Objective 3.3: Recruit, develop, retain, motivate and strategically manage a world-class workforce	1 Improve overall staff productivity 2 Hire and retain a diverse highly qualified and talented workforce 3 Promote a competitive reward and remuneration package 4 Cultivate an organisational culture that promotes continuous improvement and work life balance	HRM
Strategic Objective 3.4: Enhance financial resources and probity for sustainability in service delivery	1) Enhance effective budget management	Finance
	2) Enhance resource mobilisation	
	3) Cost rationalisation and management	
	4) Enhance stewardship, accountability and value for money in procurement	Procurement
Strategic Objective 3.5: Improve accountability and risk management	1) Assess the adequacy of good stewardship of both financial, personnel and other resources	Audit
2) Goal 4: Promote a pharmacy practice that provides the highest attainable standards of healthcare		
Strategic Objective 4.1: Enhance the competence and capacity of pharmacy workforce	1) Implement relevant continuing professional development (CPD) programmes	Pharmacy practice
	2) Review and reorient pharmacy practice consistent with UHC and overall health needs of the country	
	3) Diversification of career tracks in pharmacy (including clinical, industrial, public health, supply chain management and research)	
Strategic Objective 4.2: Enhance and refocus the role of pharmacy practice in national healthcare	1) Enhance pharmacy practice regulatory environment	
	2) Increase access to pharmacy services at primary level healthcare centres offered by appropriate pharmacy personnel	
	3) Increase access to medication therapy management at community pharmacy level	
	4) Foster ethical practice and professionalism	

4.5 Strategic Themes and Goals

The Table below presents the relationship between the strategic themes and goals

Strategic Focus/Themes/Thrust	**Goal 1: Ensure access to safe, quality and efficacious health products and technologies**	**Goal 2: Leverage on research, innovation and technologies in the delivery of products and services**	**Goal 3: Promote organisational stewardship, partnership and accountability**	**Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare**
Modern Regulatory Science	1.1 Increase regulatory science capacity to effectively evaluate health products and technologies 1.2 Foster integrity of the supply chain of HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.5 Enhance cost effectiveness in access to HPTs	1.1 Increase regulatory science capacity to effectively evaluate health products and technologies 1.2 Foster integrity of the supply chain of HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs	3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.3 Recruit, develop, retain, motivate and strategically manage a world-class workforce 3.4 Enhance financial resources and probity for sustainability in service delivery	4.1 Enhance the competence and capacity of pharmacy workforce 4.2 Enhance and refocus the role of pharmacy practice in national healthcare

Strategic Focus/Themes/Thrust	Goal 1: Ensure access to safe, quality and efficacious health products and technologies (HPTs)	Goal 2: Leverage on research, innovation and technologies in the delivery of products and services	Goal 3: Promote organisational stewardship, partnership and accountability	Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare
Modern Regulatory Science		1.7 Decentralise PPB services 2.1 Enhance capacity of the laboratory to test HPTs 2.2 Produce high quality research and development outputs in health products, technologies and practice 2.3 Utilise research innovation and technology in delivery of services and products 2.4 Enhance organisational excellence through research and innovation 3.1 Improve the overall operational efficiency and effectiveness of PPB		

Strategic Focus/Themes/Thrust	Goal 1: Ensure access to safe, quality and efficacious health products and technologies (HPTs)	Goal 2: Leverage on research, innovation and technologies in the delivery of products and services	Goal 3: Promote organisational stewardship, partnership and accountability	Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare
Internationalisation	1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.7 Decentralise PPB services	1.1 Increase regulatory science capacity to effectively evaluate HPTs 2.1 Enhance capacity of the laboratory to test HPTs 2.2 Produce high quality research and development outputs in health products, technologies and practice 2.3 Utilise research innovation and technology in delivery of services and products 2.4 Enhance organisational excellence through research and innovation	2.3 Utilise research innovation and technology in delivery of services and products 3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.3 Recruit, develop, retain, motivate and strategically manage a world-class workforce	4.1 Enhance the competence and capacity of pharmacy workforce 4.2 Enhance and refocus the role of pharmacy practice in national healthcare
Safety, Efficacy and Quality	1.2 Foster integrity of the supply chain of HPTs	1.1 Increase regulatory science capacity to effectively evaluate HPTs	2.4 Enhance organisational excellence through research and innovation	4.1 Enhance the competence and capacity of pharmacy workforce

Strategic Focus/Themes/Thrust	**Goal 1: Ensure access to safe, quality and efficacious health products and technologies (HPTs)**	**Goal 2: Leverage on research, innovation and technologies in the delivery of products and services**	**Goal 3: Promote organisational stewardship, partnership and accountability**	**Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare**
Safety, Efficacy and Quality	1.2 Foster integrity of the supply chain of HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs 1.7 Decentralize PPB services 2.2 Produce high quality research and development outputs in health products, technologies and practice	1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs 2.1 Enhance capacity of the laboratory to test HPTs 2.2 Produce high quality research and development outputs in health products, technologies and practice 2.3 Utilize research, innovation and technology in delivery of services and products	3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.3 Recruit, develop, retain, motivate and strategically manage a world-class workforce	4.2 Enhance and refocus the role of pharmacy practice in national healthcare

Strategic Focus/Themes/Thrust	Goal 1: Ensure access to safe, quality and efficacious health products and technologies (HPTs)	Goal 2: Leverage on research, innovation and technologies in the delivery of products and services	Goal 3: Promote organisational stewardship, partnership and accountability	Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare
Stewardship	1.2 Foster integrity of the supply chain of HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of health products and technologies. 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs 1.7 Decentralise PPB services	2.2 Utilise research, innovation and technology in delivery of services and products 3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.5 Improve accountability and risk management	1.7 Decentralise PPB services 2.3 Develop innovations to enhance organisation excellence 3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.3 Recruit, develop, retain, motivate and strategically manage a world-class workforce 3.4 Enhance financial resources and probity for sustainability in service delivery 3.5 Improve accountability and risk management	1.7 Decentralise PPB services 4.1 Enhance the competence and capacity of pharmacy workforce 4.2 Enhance and refocus the role of pharmacy practice in national healthcare

Strategic Focus/Themes/Thrust	**Goal 1: Ensure access to safe, quality and efficacious health products and technologies (HPTs)**	**Goal 2: Leverage on research, innovation and technologies in the delivery of products and services**	**Goal 3: Promote organisational stewardship, partnership and accountability**	**Goal 4: Guarantee a pharmacy practice that provides the highest attainable standards of healthcare**
Customer Focus	1.2 Foster integrity of the supply chain of HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs 1.7 Decentralise PPB services	1.1 Increase regulatory science capacity to effectively evaluate HPTs 1.3 Strengthen detection and surveillance of risks to quality, safety and efficacy of HPTs 1.4 Strengthen response to risks to quality, safety and efficacy of HPTs 2.2 Produce high quality research and development outputs in HPTs 2.3 Utilise research, innovation and technology in delivery of services and products	2.4 Enhance organisational excellence through research and innovation 3.1 Improve the overall operational efficiency and effectiveness 3.2 Invest in infrastructure to enhance productivity 3.3 Recruit, develop, retain, motivate and strategically manage a world-class workforce 3.4 Enhance financial resources and probity for sustainability in service delivery 3.5 Improve accountability and risk management	1.7 Decentralise PPB services 4.1 Enhance the competence and capacity of pharmacy workforce 4.2 Enhance and refocus the role of pharmacy practice in national healthcare

CHAPTER FIVE

5. IMPLEMENTATION STRATEGY

5.1 Introduction

Implementation of the 2020-2025 Strategic Plan will be based on a matrix of goals, strategic objectives, key strategies as well as corresponding outputs and indicators (Annex 1). The matrix incorporates baselines, yearly milestones and targets for a strategic plan period of five years. Responsibility has been distributed for various components of the KRAs and respective costs projected. The matrix will inform annual work plans to actualise implementation of planned activities.

The strategic plan implementation matrix is a critical and important management tool for:

- Mobilising, allocating and utilising resources for implementation of the Strategic Plan;
- Efficient and effective management and coordination of implementation of the Strategic Plan;
- Soliciting collaboration and support from partners and stakeholders in health and other relevant sectors;
- Monitoring and evaluation of the plan implementation;
- Facilitating mid-term and end of term reviews and evaluations.

5.2 Responsibility for Strategic Plan Implementation

PPB has put in place a hierarchical planning framework to enable achievement of strategic priorities. At the top is the PPB Board of Directors, which provides strategic leadership within a robust corporate governance system. The Board of Directors has overall responsibility for development of the Strategic Plan to articulate its vision and strategic direction for PPB. Further, the Board receives, discusses and approves progress reports while providing strategic guidance and thought leadership for sustainable implementation of the Strategic Plan to achieve the expected impact. The Board works closely with PPB senior leadership (Directors) led by the Chief Executive Officer (CEO).

To facilitate implementation, the Directorates will integrate respective strategic themes in the annual budget and formulate processes for achieving target milestones. Each directorate and standalone units will implement programme-specific activities based on annual work plans, monitor key metrics and report on progress towards achieving the strategic objectives and strategies. Progress will be monitored by aligning annual executive and employee performance contracting and metrics with long-term objectives and strategies. Strategic performance will be reviewed regularly through monthly, quarterly and annual meetings of management as well as meetings of the Board of Directors.

The supervisory role in each Directorate will be critical for achievement of the set targets. A member of staff with the right competencies will therefore be

designated to support the Monitoring, Evaluation and Learning process required for effective implementation of the Strategic Plan. The Planning directorate coordinates the MEL function and reports progress periodically based on progress achieved through implementation of the work plans. The Planning Directorate will, therefore, work closely with all PPB directorates responsible for delivering on various components of the KRAs. To facilitate in- depth understanding, secure support for the shared vision and successful implementation of the Strategic Plan by the Secretariat; the Strategic Plan will be cascaded accordingly and appropriate capacity building undertaken where necessary.

5.3 Monitoring Evaluation and Learning

Baseline data is being collected to provide adequate benchmarks against which the outputs, outcomes and impact of PPB will be measured at the end of the SP period. Subsequently, data on established indicators will be collected, analysed and reported periodically. Data sources as well as the intervals of data collection will be determined and elaborated in the Monitoring Evaluation and Learning operational plan. Intervals of data collection will be determined by the nature of strategic objectives and key strategies. For instance data on curriculum reforms may be collected annually while data on the more routine procedures will be collected on a quarterly basis. Monitoring will also include other intentional and unintentional positive results beyond the somewhat narrow focus of the indicators in the Strategic Plan framework. Factors in the external environment, which may confound or facilitate attainment of milestones will, therefore, be identified and monitored closely. For example, such aspects as changes in legislation or national commitments and declarations on health or health emergencies. Important lessons will be harnessed from the progress made and used to enhance progress towards the goals of the Strategic Plan. Progress will be monitored by aligning annual executive and employee performance contracting and metrics (e.g., annual performance measures) with long-term objectives and strategies. Strategic performance will be reviewed regularly through monthly, quarterly and annual meeting at board, senior management and middle management levels. Performance-based rewards will be instituted to encourage desired behaviour, but sanctions will be applied when performances fall short of expectation.

5.4 Risk Management Strategy

The PPB maintains a risk register. This will be updated to capture any potential new risks associated with the present Strategic Plan. The risks will be analysed, rated, and appropriate mitigation strategies developed. Distinct responsibilities and mutual obligations for proactively managing risks will be distributed across the PPB directorates. Risk owners will monitor and assess the presence, magnitude and scope of risks as well as responsiveness to predetermined mitigation strategies and modify the risk register periodically. The outcome will be reported to PPB management as part of internal review process. Through frequent reviews, redesign of mitigation strategies and updating of the risk register, the PPB management will maximise opportunities

for minimising and controlling risks so as to optimise achievement of strategic objectives. Any alarming risks will be escalated to the Board of Directors.

ANNEXURE 1: STRATEGIC PLAN 2020-2024 IMPLEMENTATION FRAMEWORK

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
Goal 1: Ensure access to safe, quality, efficacious and affordable health products and technologies													
Objective 1.1 Increase regulatory science capacity to effectively evaluate health products and technologies (HPTs)			% increase in regulatory science capacity to evaluate HPTs/% implementation of adopted regulatory science		100% compliance	100% compliance	100% compliance	100% compliance	100% compliance	100% compliance	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Create or customise regulatory science innovations for product evaluation and registration		% annual increase in number innovations created or customized	0	10%	0%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and Implement guidelines on duplicate licensing	% compliance with guidelines on duplicate licensing for locally manufactured products	0	100%	10%	20%	20%	25%	25%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Adoption of the EAC approved APIMF and manufacturing sites	% PPB approved API sites using EAC APIMF centralised procedure	0	100%	0%	0%	20%	20%	60%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement National guidelines on bioequivalence through partnerships	% compliance with Bioequivalence guideline through partnerships	0	100%	10%	20%	20%	25%	25%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement Blood and Blood Products standards	% compliance to standards	0	100%	10%	10%	20%	30%	30%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Coordinate regulatory framework for haemovigilance, GDP and GMP for Blood establishments	% implementation of other regulatory functions for blood and blood products	0	100%	5%	15%	20%	30%	30%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Coordinate regulatory framework for pre-market, on-market and post market for medical devices	% implementation of other regulatory functions for medical devices and IVDs	10	100%	10%	20%	20%	25%	25%	Director, Products Evaluation & Registration	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	Collaboration with scientific community, industry, regional and international agencies e.g. WHO to advance regulatory science		% annual increase in number innovations advanced through collaborations	0	10%	0%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	452
		Review and implement National Drug registration guideline to incorporate a reliance model as a regulatory practice	% implementation of the reliance model	50%	100%	0%	25%	25%			Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement of abridged procedures	% compliance with the abridged procedures	0%	50%	10%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		To undertake capacity building through collaboration with WHO, USP, EAC, SWISS MEDIC, among others	Number of staff trained	7	17	2	2	2	2	2	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Support public-private partnerships (PPPs) to advance regulatory science;		% annual increase in number of PPPs in Innovations		10%	0%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		To undertake stakeholder consultative, knowledge sharing and sensitisation meetings	Number of meetings	2	10	2	2	2	2	2	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement guidelines for Technology transfer of Registration of New and High Technology Medicines,	% compliance with guidelines on technology transfer of Registration of New and High Technology medicines,	0	100%	0%	20%	20%	20%	40%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Improve the effectiveness of evaluations for dietary supplements, borderline and cosmetics with regard to safety (toxicity evaluations);		% of dietary supplements and cosmetics in the market evaluated	0	70%	10%	20%	30%	50%	70%	Director, Products Evaluation & Registration	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement Guidelines for Food supplements (Nutritional formulations)	% implementation of the Food Supplements Guidelines	0	100%	0%	40%	30%	20%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement guideline for Borderline products	% implementation of the Borderline Guidelines	0	100%	0%	10%	40%	20%	30%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement guideline for cosmetics	% implementation of the Cosmetics Guidelines	0%	100%	0%	80%	20%			Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Capacity Building in assessment of scientific data on food supplements, cosmetics and borderline products	Number of people trained	0	13			5	5	3	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Modernize bio-informatics infrastructure to apply the most recent data in product evaluation and registration;		% annual increase in products evaluated using bio-informatics	0	10%	0%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		ERP upgrades to link registration, variation and retention modules and databases	% of upgrades achieved	50%	100%	10%	10%	10%	10%	10%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Database standardization, system reconfiguration and adoption for track and trace set of technologies	% of approved products meeting the new database requirements	0	100%	5%	10%	20%	35%	30%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Upgrades of the screening and eCTD user interfaces to improve on user uptake and acceptance	% increase of products screened (issued with eCTD numbers) using upgraded system	0%	60%	5%	10%	10%	15%	20%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Strengthen an infrastructure that supports high quality scientific investigations/evaluation and registration for all HPTs		% of HPTs scientifically evaluated and registered	0	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		To implement first and second evaluator in Dossier Assessment	% of registered products which complied with the procedure	0	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement Quality Assurance tool	% of products meeting quality assessment	0	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Strengthen QMS, Risk Management and CAPA implementation	% of CAPA completed	0	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
Objective 1.2: Foster integrity of the supply chain of health products and technologies			Compliance with good distribution practices	To be determined	100% compliance	100% compliance	100% compliance	100% compliance	100% compliance	100% compliance	Director, Inspectorate and Enforcement	Deputy CEO, HPT	1400
	Establish and implement national health products and technologies accountability system		Percentage of HTP accounted for from source to use	To be determined	100%	50%	70%	80%	90%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Update the product registration databases	% update of database	0%	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Update the HPT database	% completion and standardized database	30%	100%	50%	75%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Utilization of track and trace platforms	% of development, adoption and implementation of track and trace set of technologies	0	100%	0%	50%	100%	100%	100	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Monitor and enforce compliance with good distribution practices		% of HPT safely distributed		100%	100%	100%	100%	100%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Conduct compliance inspections of the licensed pharmacies in Kenya to deter and reduce the incidence of violations of the law	% Compliance with Good Distribution Practices	To be determined	100%	100%	100%	100%	100%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Develop and implement a roadmap for stepwise quality improvement to achieve compliance with Good Distribution	% increase of premises complying with the roadmap	0	100%	20%	40%	60%	80%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Practices											
		Develop and implement mechanisms to eliminate illegal trade in health products and technologies;	% of illegal outlets	30%	0%	0%	0%	0%	0%	0%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		To continuously monitor and enhance good distribution practices within HTPs distribution chain	Percentage of Premises audited	50%	100%	60%	70%	80%	90%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Verification of all imported health products and technologies at all gazetted ports of entry;	Percentage of imported HPT that are approved by PPB	100%	100%	100%	100%	100%	100%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Coordinate safe disposal of pharmaceutical waste;	Percentage of pharmaceutical waste safely disposed	50%	100%	60%	70%	80%	90%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
	To investigate and gather intelligence on Pharma crime		Percentage reduction in pharma crime	10%	0	10%	7%	4%	2%	0%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Investigate all Pharma crime cases received, reported or detected	Number of Pharma-crime cases received/recorded and number of Regions visited for Routine investigations	0	240	48	48	48	48	48	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Undertake periodic intelligence gathering surveillance and awareness programs	Number of surveillance / intelligence and awareness exercises carried out at identified POE's and regions.	15	60	12	12	12	12	12	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Collaborate with other agencies and stakeholders to detect and control pharma crime nationally and internationally	Number of Joint operations and meetings held.	20	40	8	8	8	8	8	Director, Inspectorate and Enforcement	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	Monitor and enforce compliance with good manufacturing practices		% compliance with good manufacturing practices	100%	100%	100%	100%	100%	100%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Implement mechanisms to enhance compliance to Good Manufacturing Practices by local manufacturers	% of local manufacturer complying to GMP	0	95%	95%	95%	95%	95%	95%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		To continuously inspect and enhance good manufacturing practices for all marketing authorization holders	% of local market authorization holders complying to GMP	0	95%	95%	95%	95%	95%	95%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Achieve and maintain PICS certification	Number of major non conformities	4	0	0	0	0	0	0	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
	Capacity building for the officers to effectively monitor and enforce compliance with regulatory requirements		Percentage of officers with appropriate competencies	0	100%	100%	100%	100%	100%	100%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Identify the relevant trainings(modules)	Number of training modules identified	0	5 modules per year	5 module	5 module	5 module	5 module	5 modules per year	Director, Inspectorate and	Deputy CEO, HPT	
		Conduct training needs assessment	% completion	0	100%	100%	100%	100%	100%	100%	Director, Inspectorate and	Deputy CEO, HPT	
		Liaise with Human Resource to project and implement the trainings	Percentage implementation of the trainings	0	100%	20%	40%	60%	80%	100%	Director, Inspectorate and Enforcement	Human Resource	
	Partner and Collaborate with relevant government agencies and stakeholders in enforcing regulations of HPTs and Pharmacy practice		% increase in number of compliance initiatives advanced through partnership and collaborations	0	50%	10%	10%	10%	10%	10%	Director, Inspectorate and Enforcement	Deputy CEO, HPT	
		Develop and implement a collaboration framework	% compliance to the framework	0	100%	100%	100%	100%	100%	100%	Director, Inspectorate and	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Create awareness to sensitize stakeholders on the collaboration framework	% of stakeholders sensitized		100%	20%	40%	60%	80%	100%	Director, Inspectorate and Enforcement	Public Relations	
Objective 1.3: Strengthen detection and surveillance of risks to quality, safety and efficacy of health products and technologies			Percent of registered products meeting quality standards	89%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	700
	Review and improve pharmacovigilance surveillance systems for HPTs		% increase in number of incidents reported and evaluated	0	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To conduct Pharmacovigilance inspections	% of sites and studies inspected that complies with legal and regulatory requirements for Pharmacovigilance in Kenya	0	50%		10%	12%	14%	14%	Director, MIPV	Deputy CEO, HPT	
		To develop and implement guidelines on evaluation of quality and safety reports for regulatory decision making	% compliance with guidelines	0	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To establish and operationalize regional PV and PMS sites	No. of sites operationalized	0	4		1	1	1	1	Director, MIPV	Deputy CEO, HPT	
		To conduct active Pharmacovigilance surveillance on selected HPTs	No. of surveillance reports disseminated to stakeholders	0	2		1		1		Director, MIPV	Deputy CEO, HPT	
		To conduct targeted spontaneous reporting(TSR) for Selected HPT	No. of TSR reports disseminated to stakeholders	0	2	1		1			Director, MIPV	Deputy CEO, HPT	
		Upgrade IT PvERS systems	%Completion and maintenance of Data base	25%	100%	45%	65%	75%	85%	100%	Director, MIPV	Deputy CEO, HPT	
	Develop partnerships to implement PPB PV-RCORE functions		Number of activities implemented with partners	0	5	1	1	1	1	1	Director, MIPV	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement a training curriculum for QPPV	% compliance with curriculum for QPPV	0%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		Provide capacity-building to PV centres within the region	Number of trainings	0	4	0	1	1	1	1	Director MIPV	Deputy CEO, HPT	
	Review and improve post marketing surveillance systems for HPTs		% increase of HPTs complying with specifications	89%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To conduct risk based post market surveys on selected HPT	No. of Surveys reports disseminated to stakeholders	2per year	10	2	2	2	2	2	Director, MIPV	Deputy CEO, HPT	
		initiate appropriate regulatory actions	% implementation of regulatory actions	80%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To conduct investigations of quality complaints on HPTs	% of complaints successfully investigated and regulatory actions implemented	50%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To develop and maintain a database on quality complaints management system for HPTs	(% of complaints and regulatory actions captured in the system)	0	100%	20%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To develop and implement a reliance and convergence mechanism for regulation of HPTs	% implementation of the reliance mechanism	0	100%	20%	30%	30%	20%	100%	Deputy CEO, HPT	CEO	
	Partner with laboratories for testing of HPTs		% Increase in the number of partnerships for laboratory testing of HPTs	0	100%	30%	30%	30%	10%	100%	Director, MIPV	Deputy CEO, HPT	
		Develop and implement a service level agreement with PPB Laboratory for testing of applicable HPTs	% of HPTs tested internally	0	100%	50%	50%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		Develop and implement MOU with external testing laboratories for testing HPTs	% of HPTs tested externally	0	100%	20%	30%	30%	20%	100%	Director, MIPV	Deputy CEO, HPT	
		Develop and implement a	% of HPTs tested externally	0	100%	20%	30%	30%	20%	100%	Director, MIPV	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		collaborative arrangement with other regulatory agencies for testing of HPTs											
	Strengthen and enforce control of clinical trials		% of clinical trials registered and monitored	60%	100%	65%	70%	80%	90%	100%	Director, MIPV	Deputy CEO, HPT	
		To review and implement CT legal regulations and guidelines based on WHO GBT requirements	% of compliance with CT guidelines	50%	100%	60%	75%	90%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To conduct clinical trials and clinical site inspections	% of sites inspected that comply	50	100%	60%	70%	80%	90%		Director, MIPV	Deputy CEO, HPT	
		Upgrade CT IT systems	% System development completion and maintenance of Data base	25%	100%	50%	60%	70%	85%	100%	Director, MIPV	Deputy CEO, HPT	
	Review and improve medicines information systems for HPTs		Number of scientific and factual information on HPTs provided and services offered	0	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To review and implement the guidelines for the advertisement and promotion of health products and technologies;	% of compliance to guidelines	100%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To develop and implement guidelines for scheduling and rescheduling of all HPTs	% of compliance to guidelines	0	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To establish and operationalize an information Resource Centre	% annual increase in number of documented queries received and responded to	0	50%	10%	10%	10%	10%	10%	Director, MIPV	Deputy CEO, HPT	
		To evaluate all advertisements and promotions of HPTs	% of advertisements and promotions complying with guidelines	100%	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		To automate applications on advertisements and promotional	%Completion and Implementation	0%	100%	50%	60%	70%	85%	100%	Director, MIPV	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		materials											
Objective 1.4 Strengthen response to risks to quality, safety and efficacy of health products and technologies			Timeliness and completeness of response	0	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
	Enhance the effectiveness of response system to unsafe health products and technologies;		Quality of response system as per external audit.	To be determined	100%	100%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
		Conduct trainings and sensitizations of the healthcare workers on PV and PMS reporting- (from a representative sample)	No. of HWC trained and sensitized on PV and PMS reporting	To be determined	3600	720	720	720	720	720	Director, MIPV	Deputy CEO, HPT	
		Conduct sensitizations of healthcare workers, media and general public on clinical trials	No. of stakeholders sensitized on clinical trials	0	500	100	100	100	100	100	Director, MIPV	Deputy CEO, HPT	
		Carry out awareness campaigns on safety, quality, efficacy and rational use of HPTs	Level of awareness	0	80%	16%	16%	16%	16%	16%	Director, MIPV	Deputy CEO, HPT	
		Develop and implement a guideline on risk communication and response- develop a tool for measuring response	% compliance to risk communication and response guideline	0	100%	0%	100%	100%	100%	100%	Director, MIPV	Deputy CEO, HPT	
	Enhance ability to prevent and respond to shortages in health products and technologies arising from regulatory hiccups;		% of drug shortages in country/% availability of products of public health importance	To be determined	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Compliance with service charter timelines for Registration of HPTs	...% of applications reviewed within the set timeline	30%	40%	30%	30%	40%	40%	40%	Director, Products Evaluation & Registration	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Implement communication mechanism on cessation or revocation of medicines from the market to stakeholders	number of regulatory actions disseminated	0%	100%	20%	20%	20%	20%	20%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Implement expedited review of certain products of public health importance including orphaned drugs	Number of products registered through expedited reviews	20%	100%	10%	10%	20%	20%	20%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
Objective 1.5 Enhance cost effectiveness in access to health products and health technologies			Percent of health products and health technologies within regional average price	0	95%	60%	75%	85%	90%	95%	Head, Trade	Deputy CEO, HPT	111
	Periodically determine the reimbursable cost for every treatment package		% of updated reimbursable cost for existing treatment packages is available	0	100%	20%	40%	60%	80%	100%	Head, Trade	Deputy CEO, HPT	
		Establish and operationalize department of Health Technology Assessment (HTA)	% of health products and technologies assessed by the department	0	95%	60%	75%	85%	95%	95%	Head, Trade	Deputy CEO, HPT	
		Conduct Pharmaco-economic surveys to inform average prices of health products and health technologies	% of health products and technologies with known average price	0	95%	60%	75%	85%	90%	95%	Head, Trade	Deputy CEO, HPT	
		Use schedules of health products and technologies and promote generic prescribing	% health products and technologies under dynamic and active schedule process	0	95%	60%	75%	85%	90%	95%	Head, Trade	Deputy CEO, HPT	
		Collaborate with other healthcare provider to develop and implement prescription format	% compliance with prescription format	0	100%	100%	100%	100%	100%	100%	Head, Trade	Deputy CEO, HPT	
	Exploit TRIPS (Trade Related Aspects of Intellectual Property Rights) provisions and safeguards to		% of products accessed through exploitation of TRIPS provisions	0	10%	10%	10%	10%	10%	95%	Head, Trade	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	avail HPTs at affordable cost												
		Establish and implement a mechanism for making available products under parallel importation program	% of parallel imported products complying with the system	0	100%	100%	100%	100%	100%	100%	Head, Trade	Deputy CEO, HPT	
		Identify and undertake joint initiatives to exploit TRIPS provisions and safeguards	Number of joint initiatives in the exploitation of TRIPS	1	20	4	4	4	4	4	Head, Trade	Deputy CEO, HPT	
Objective 1.6 Promote local production of health products & technologies in line with UHC			% local production in HPT	30%	50%	30%	35%	40%	45%	50%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Expedite time taken for registration of locally produced HPTs;		Local products registered within the service charter timelines for locally manufactured products	30%	70%	30%	50%	60%	70%	70%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and Implement Fast track Guidelines	% compliance with fast track guidelines	0	100%	50%	50%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Improve the quality of dossiers for locally manufactured products	% of local manufacturers complying with registration process	50%	100%	50%	60%	70%	90%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Lobby and undertake partnerships to spur Local Pharmaceutical growth		% increase in partnerships and Collaboration with development partners and MDA's	0	10%	10%	10%	10%	10%	10%	Head, Trade	Deputy CEO, HPT	
		Lobby for government support e.g. tax and licenses;	% Level of legislative costs (tax, licenses) reduction for health products and technologies	0	50%	20%	30%	40%	50%	50%	Head, Trade	Deputy CEO, HPT	
		Control importation through ring-fencing mechanisms;	% No. of local products protected through tariffs or Non-tariff barriers	0	50%	20%	30%	40%	50%	50%	Head, Trade	Deputy CEO, HPT	
		Partner and collaborate with development partners locally and internationally, and	% increase in partnerships and Collaboration with development partners and MDA's	0	10%	10%	10%	10%	10%	10%	Head, Trade	Deputy CEO, HPT	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		with MDA's											
	Capacity building for local manufacturing		% compliance with guidelines on technology transfer of Registration of New and High Technology medicines	0%	100%	0%	20%	20%	20%	40%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Develop and implement guidelines for Technology transfer of Registration of New and High Technology Medicines	% compliance with guidelines on technology transfer of Registration of New and High Technology medicines	0%	100%	0%	20%	20%	20%	40%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
	Establish a regulatory framework for locally derived natural health products		% compliance with the regulatory framework	0%	100%	20%	40%	60%	80%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Review and implement guidelines for complementary and alternative medicines registration of locally derived natural health products	% compliance with the guidelines	0	100%	100%	100%	100%	100%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Undertake stakeholder engagement of herbalists	% of stakeholder engaged	0	100%	20%	40%	60%	80%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
		Capacity building for herbalists	% of herbalist with competency to prepare quality applications	0	100%	20%	40%	60%	80%	100%	Director, Products Evaluation & Registration	Deputy CEO, HPT	
Objective 1.7 Decentralize PPB services			% implementation of decentralized services		100%						Director, Regional Coordination	CEO and All Directors	
	Fully operationalize regional offices		Proportion of fully operational decentralized regional offices.	30%	100%	40%	60%	80%	90%	100%	Director, Regional Coordination	CEO and All Directors	460
		Develop and implement a strategy for decentralization of PPB services	% of services offered in regional offices	0	100%	100%	100%	100%	100%	2	Director, Regional Coordination	CEO and All Directors	
		Coordinate procurement of contract services for design and construction/partiti	Number of offices build/partitioned	0	14	2	4	4	2	2	Director, Regional Coordination	CEO and All Directors	

		oning of regional offices											
Goal/Objective	**Key Strategies**	**Activities**	**Indicator for Key Strategies and Activities**	**Baseline**	**Target**	**2020**	**2021**	**2022**	**2023**	**2024**	**Primary Responsibility**	**Secondary Responsibility**	**Budget (KSH. Million)**
		Coordinate equipping of the offices	Number of offices equipped	0	14	2	4	4	2	2	Director, Regional Coordination	CEO and All Directors	
		Staffing and capacity building of the offices	Number of staff deployed to the offices	35	70	7	7	7	7	7	HR	CEO and All Directors	
		Undertake the decentralized services	% of decentralized services undertaken	30%	100%	40%	60%	80%	90%	100%	Director, Regional Coordination	CEO and All Directors	
Goal 2: Leverage on research, innovation and technologies in the delivery of products and services													
Objective 2.1: Enhance capacity of the Laboratory to test			Percentage of samples tested in the laboratory	0	100%	50%	60%	70%	80%	100%	Director, Quality Control	Deputy CEO, HPT	980
	Operationalize the Physico-chemical Laboratory		Percentage of samples tested in the laboratory	0	100%	100%	100%	100%	100%	100%	Director, Quality Control	Deputy CEO, HPT	
		Finalize equipping the Lab	No. of new testing equipment acquired and installed	10	10	2	2	2	2	2	Director, Quality Control	Procurement	
		Undertake timely HPT testing on all applicable samples	Percentage testing of all products submitted within expected timelines (%)	100	100%	100	100	100	100	100	Director, Quality Control	Director, Inspectorate, Director, MIPV and	
		Digitalize the lab services and implement appropriate quality management systems	% compliance with quality management system standard	0	100%	100%	100%	100%	100%	100%	Quality Control Inspectorate	IT Department	
		Enhance human resource capacity	% of staff with required competence		100%		100%	100%	100%	100%	Director, Quality Control	HRM	
	Establish and operationalize a microbiology laboratory		Percentage of samples tested in the laboratory	0	100%	100%	100%	100%	100%	100%	Director, Quality Control	Deputy CEO, HPT	
		Procure, in consultation with the Procurement Department, services of a consultant to design the laboratory	percent completion of laboratory design	0	100%	0	100%	0	0	0	Director, Quality Control	Procurement	
		Procure, in consultation with the Procurement Department, services of a contractor to build the laboratory	percent completion of laboratory structure	0	100%	0	0	100%	0	0	Director, Quality Control	Procurement	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Equip the laboratory	Percentage of testing equipment acquired and installed	0	100%	0	0	0	50%	100%	Director, Quality Control	Procurement	311
		Enhance human resource capacity	% of staff with required competence	0	100%	100%	100%	100%	100%	100%	Quality Control Inspectorate	HRM	
		Undertake microbiology testing of HPTs	Percentage testing of all products submitted within expected timelines (%)	0	100%	0	0	0	0	100%	Director, Quality Control	CEO and all Directors	
Objective 2.2: Produce high quality research and development outputs in health products, technologies and practice			Number of research outputs produced		15	3	3	3	3	3	Head, Research and Innovation	CEO and all Directors	
	Review and improve research infrastructure for effective coordination of all research projects		Number of research projects carried out in a year	2	5	1	1	1	1	1	Head, Research and Innovation	CEO and all Directors	
		Appoint and operationalize a research advisory committee	% operationalization of Research advisory committee	0	100%	100%	100%	100%	100%	100%	Head, Research and Innovation	CEO and all Directors	
		Create a research culture through incentives, conferences, networking and collaboration	Number of research projects carried out in a year	2	5	1	1	1	1	1	Head, Research and Innovation	CEO and all Directors	
		Actively review, approve and register research projects in health products, technologies and pharmacy practice;	Number of research projects reviewed and approved in a year	0	10	2	2	2	2	2	Head, Research and Innovation	CEO and all Directors	
		Monitor and evaluate research programmes and outputs;	Number of research outputs evaluated in a year	0	5	1	1	1	1	1	Head, Research and Innovation	CEO and all Directors	
		Disseminate research outputs through publications, public reports and conferences;	Number of research outputs disseminated	0	5	1	1	1	1	1	Head, Research and Innovation	CEO and all Directors	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Enhance co-operation and collaboration in research with universities and research organizations;	Number of active collaborations in research	2	15	3	3	3	3	3	Head, Research and Innovation	CEO and all Directors	
		Mobilize resources for research	% increase in level of research funding generated from external sources	12M	50% annually	50% annually	50% annually	50% annually	50% annually	50% annually	Head, Research and Innovation	CEO and all Directors	
	Foster research output patenting		Percentage of research output patented	0	100%	100%	100%	100%	100%	100%	Research and Development/PER/ INSPECTORATE/M IPV	ALL Directors	
		Develop and implement a policy on patenting	Percentage implementation of the policy	0	100%	100%	100%	100%	100%	100%	Head, Research and Innovation	ALL Directors	
		Review and implement research policy to include the patenting policy	Percentage implementation of the policy	0	100%	100%	100%	100%	100%	100%	Head, Research and Innovation	ALL Directors	
Objective 2.3 Utilize research, innovation and technology in delivery of services and products			Number of research outputs produced and utilized	0	10	0	2	2	3	3	Research and Development/PER/ INSPECTORATE/M IPV	ALL Directors	
	Apply research output in regulation of HTPs and pharmacy practice		Number of research output applied in regulation of HTPs pharmacy practice	0	5	0	1	1	1	2	Research and Development/PER/ INSPECTORATE/M IPV	ALL Directors	
		Conceptualization, verification, validation and application of the research outputs	Number of research output applied in regulation of HTPs and pharmacy practice	0	5	0	1	1	1	2	Head, Research and Innovation	ALL Directors	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	Promote research into appropriate products (including locally derived natural health products) and facilitate their subsequent Development and incorporation into the health system		Number products researched on in the country and incorporated into healthcare system	0	5	0	1	1	1	2	Research and Development/PER/ INSPECTORATE/M IPV	ALL Directors	
		Review and implement standards for regulation of products including(locally derived natural health products)	Percentage compliance with the standards	baseline to be determined	100%	100%	100%	100%	100%	100%	Director, PER	ALL Directors	
		Review and implement policies on regulation of products including(locally derived natural health products)	Percentage compliance with the policies	baseline to be determined	100%	100%	100%	100%	100%	100%	Director, PER	ALL Directors	
		Collaborate and partner with research organizations and universities to support research in products including(locally derived natural	Number of research organizations and universities in partnership	2	5	1	1	1	1	1	Head, Research and Innovation	ALL Directors	
Objective 2.4 Enhance organization excellence through research and innovation			Number of innovations developed and utilized	0	5	0	1	1	1	2	All Directors	Head, Research and Innovation	
	Develop and implement research and innovations to enhance directorate's/department's excellence		Number of research and innovation developed and implemented	baseline to be determined	15	3	3	3	3	3	All Directors	Head, Research and Innovation	
		Identify research gaps in Directorates /Departments	Number of researchable gaps identified	0	15	3	3	3	3	3	All Directors	Head, Research and Innovation	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Conceptualization research themes, proposals and protocols	Number of researchable proposals drawn	0	15	3	3	3	3	3	All Directors	Head, Research and Innovation	
		Undertake research on approved proposals	Number of management research carried out	0	10	2	2	2	2	2	All Directors	Head, Research and Innovation	
		Establish and apply innovations in Directorate's/Departments operations	Number of research output applied in management	0	5	0	1	1	1	2	All Directors	Head, Research and Innovation	
Goal 3: Promote organizational stewardship, partnership and accountability.													
Objective 3.1: Improve the overall operational efficiency and effectiveness			%of key performance targets met	30%	95%	30%	50%	70%	80%	95%	Planning/All Directors	Corporate Services	111
	Enhance organizational strategic management		Average achievement of the strategic goals and strategies	30%	95%	30%	50%	70%	80%	95%	Planning/All Directors	Corporate Services	
		Finalize operationalization of PPB as a state corporation (Delinking)	Percent completion	75%	100%	100%					Human Resource	Corporate Services	
		Develop and implement tool for measuring organizational effectiveness and efficiency	% compliance with the tool	0	100%	100%	100%	100%	100%	100%	Planning/All Directors	Corporate Services	
		Coordinate unpacking and implementation of the strategic goals and objectives into annual activity based work plans	% implementation and achievement of the annual work plans	70%	95%	95%	95%	95%	95%	95%	Planning/All Directors	Corporate Services	
		Develop, review and implement effective organizational structure and performance management;	Average staff performance score	50%	80%	70%	75%	80%	80%	80%	Human Resource/	Corporate Services	
		Develop, review, implement, monitor and take corrective actions on operational procedures and quality management	Number of major non-conformities with QMS external Audit	2	0	0	0	0	0	0	QMS	All directors	117

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Review and address non-conformities from internal and external audits	Number of major non-conformities with internal and external Audit	3	0	0	0	0	0	0	QMS	All directors	
		Continuous engagement of external customers (stakeholders) to address their needs and expectations	Customer/stakeholder satisfaction	58%	70%	60%	65%	70%	70%	70%	Communication	Corporate Services	
		Assessing the adequacy of good stewardship by conducting objective assessments of management processes, risks, systems and internal controls.	% Number of major risk and internal controls weaknesses resolved in 6 months	None	95%	95%	95%	95%	95%	95%	Internal Audit/ Finance	CEO	
	Foster Good Corporate Governance		% compliance with governance requirements	To be determined	95%	95%	95%	95%	95%	95%	Corporation secretary/ Legal Services	CEO	
		Ensure compliance with "Mwongozo" and other good corporate governance practices	% compliance with governance requirements	To be determined	95%	95%	95%	95%	95%	95%	Corporation secretary/ Legal Services	CEO	
		Coordinate objective assessments of governance processes, risks, systems and internal controls	Number of major governance risk and control weaknesses dealt with in 6 months	To be determined	90%	90%	90%	90%	90%	90%	Corporation secretary/ Legal Services	CEO	
		Monitor and report on progress in implementation of Board recommendations	% implementation of Board's recommendations	To be determined	100%	100%	100%	100%	100%	100%	Corporation secretary/ Legal Services	CEO	
		Cause the board to undertake self evaluation committee charter compliance audits	% of weakness in Board effectively addressed within 6 months	To be determined	100%	100%	100%	100%	100%	100%	Corporation secretary/ Legal Services	CEO	
	Promote public awareness		Stakeholders Level of awareness	40%	80%	40%	50%	60%	70%	80%	Head, Public Relations	Corporate Services	392
		Review and implement the communication and PR strategy	% implementation of communication and PR strategy	60%	100%	100%	100%	100%	100%	100%	Head, Public Relations	Corporate Services	
		Strengthen media relationships	% increase in positive media reporting	To be determined	25%	5%	5%	5%	5%	5%	Head, Public Relations	Corporate Services	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Plan and execute corporate social responsibility activities(CSR)	No. of CSR activities	2	one	one	one	one	one	one	Head, Public Relations	Corporate Services	
		Use and monitor social media	%Increase in engagement/interaction on social media	To be determined	25%	5%	5%	5%	5%	5%	Head, Public Relations	Corporate Services	
		Disseminate product information	Level of awareness of products	58%	83%	5%	5%	5%	5%	5%	Head, Public Relations	Corporate Services	
		Monitor and report on implementation of Communication and PR strategy to the Board	% implementation of communication and PR strategy	To be determined	100%	100%	100%	100%	100%	100%	Head, Public Relations	Corporate Services	
	Minimize losses resulting from legal issues		Percentage of cases successful settled.	To be determined	90%	90%	90%	90%	90%	90%	Legal Services	CEO	303
		Identify and address legal risks	% reduction in legal risks	To be determined	90%	90%	90%	90%	90%	90%	Legal Services	CEO	
		Develop and implement a framework for reduction of legal costs	% compliance to the framework	0	100%	100%	100%	100%	100%	100%	Legal Services	CEO	
		Identify issues and initiate review of relevant acts or regulations to minimize legal risks	No. of issues identified for which the acts or regulations are reviewed	1	5	1	1	1	1	1	Legal Services	CEO	
		Monitor and report on progress in implementation of framework to the Board	% implementation of the framework on reduction of legal costs	0	100%	100%	100%	100%	100%	100%	Legal Services	CEO	
	Build strategic partnerships		No. of active strategic partnerships	0	10	2	2	2	2	2	Director, Corporate Services	CEO	
		Develop and implement an institutional framework for partnerships	% compliance with framework	0	100%	70%	80%	90%	100%	100%	Director, Corporate Services	CEO	
		Identify and implement initiatives with partners	% of active partnerships	0	70%	30%	40%	50%	60%	70%	Respective Directors	CEO	
Objective 3.2: Invest in infrastructure that will enhance			% Implementation of master plan	0	90%	60%	65%	75%	80%	90%	Director, Corporate Services	CEO and all Directors	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
productivity													
	Optimize return on assets		% Return on Assets		20%	20%	20%	20%	20%	20%	Admin/Finance	Finance and Admin	
	Create a work environment and ergonomics design that promotes excellence		% Employee satisfaction with work environment	62%	85%	85%	85%	85%	85%	85%	Admin/HR	Finance and Admin	1200
		Develop and implement an organization master plan	% Implementation of master plan	0	90%	60%	65%	75%	80%	90%	Director, Corporate Services	CEO and all Directors	
		Optimize the efficient use of PPB assets	Assets-turnover ratio	0	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	Director, Corporate Services	CEO and all Directors	
		Promote Health, Safety Environmental (SHE) standards	SHE audit score	0	95%	95%	95%	95%	95%	95%	Admin	Finance and Admin	
	Automate and integrate processes		Systems maturity level	3	4	3	3.5	3.5	3.5	4	ICT	All Directors	540
		Map out the processes	% of processes mapped	40%	100%	50%	65%	75%	85%	100%	ICT	All Directors	
		Review, update and integrate the current automated processes	Percentage of automated and integrate processes	15%	100%	35%	55%	75%	90%	100%	ICT	All Directors	
Objective 3.3: Recruit, develop, retain, motivate and strategically manage a world-class workforce			Number of staff as a percentage of establishment required per strategy	28%	78%	38%	48%	58%	68%	78%	Human Resource	Corporate Services	4400
	Diversify PPB skill sets		% level of requisite skill sets available at PPB	0	95%	60%	70%	80%	90%	95%	Human Resource	Corporate Services	
		Develop and implement PPB skills set	% implementation	0	100%	60%	70%	80%	90%	100%	Human Resource	Corporate Services	
	Improve overall staff productivity		Percentage average staff performance	0	80%	80%	80%	80%	80%	80%	Human Resource	Corporate Services	
		Review and coordinate implementation of the performance appraisal system	% Implementation	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
		Develop and implement a reward and sanction mechanism	% Implementation	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	Hire and retain a diverse highly qualified and talented workforce;		Number of staff as a percentage of establishment required per strategy	28%	78%	38%	48%	58%	68%	78%	Human Resource	Corporate Services	
		Develop and implement HR plan	% Implementation	0	100%	50%	70%	80%	90%	100%	Human Resource	Corporate Services	
	Develop and advance staff capacity and execute the development plan		Percentage skills gap addressed by training		95%	60%	70%	80%	90%	95%			
		Develop and review training needs assessment and annual training projections	% completion of training need assessment	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
		Coordinate implementation of training projection	% implementation of training projection	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
	Promote a competitive reward and remuneration package		% level of employee satisfaction	62%	85%	67%	72%	77%	82%	85%	Human Resource	Corporate Services	
		Coordinate review of remuneration package by relevant state agencies and other stake holders	% completion of the review of remuneration packages	100%	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
		Implement approved remuneration packages	% implementation of approved remuneration	To be determined	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
	Cultivate an organizational culture that promotes continuous improvement and work–life balance		Percentage staff satisfaction based on cultural assessment	0	90%	60%	70%	80%	90%	90%	Human Resource	Corporate Services	
		Undertake PPB culture assessment	Number of culture non conformities	To be undertake	Zero	Zero	Zero	Zero	Zero	Zero	Human Resource	Corporate Services	
		Undertake employee satisfaction survey	Percentage level staff satisfaction	To be determined	80%	60%	65%	70%	75%	80%	Human Resource	Corporate Services	
		Implement diversity and national values policies	% level on implementation	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
		Develop and implement a plan on team building	% level on implementation	0	100%	100%	100%	100%	100%	100%	Human Resource	Corporate Services	
Objective 3.4: Enhance financial resources and probity for sustainability in			% of surplus to revenue (Profit margin)	To be determined	10%	10%	10%	10%	10%	10%	Finance	Finance and Admin	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
service delivery													
	Enhance effective budget management		% Number of management weaknesses identified in management audit and addressed within 6 months	To be determined	100%	100%	100%	100%	100%	100%	Finance	Finance and Admin	
		Develop and implement budgetary process, procedures and structure	% Compliance to budgetary process, procedures and structure	0	100%	100%	100%	100%	100%	100%	Finance/All Directors	Finance and Admin	
		Develop implement, monitor and take corrective action on budget variance	% Compliance to budget	0	95%	95%	95%	95%	95%	95%	Planning/All Directors	Corporate Services	
		Report on progress of budget implementation to the BOD	Timely reporting	1 week before Board/relevant Committee meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	Finance	Finance	
	Enhance resource mobilization		% of surplus to revenue (Profit margin)		10%	10%	10%	10%	10%	10%	Finance	Finance and Admin	
		Develop and implement business plan	% implementation of the business plan	0	95%	15%	20%	20%	20%	20%	Finance		
		Develop and implement framework for revenue generation	% compliance with framework	0	95%	95%	95%	95%	95%	95%	Finance	Finance/All Directorates	
		Identify and utilize new revenue opportunities	% growth in revenue collection	0	10% Annually	10%	10%	10%	10%	10%	Finance		
		Optimize revenue collection	% growth in revenue	To be determined	10% Annually	10%	10%	10%	10%	10%	Finance	Finance and All Directorate	
		Enhance partnership for resource mobilisation	% increase of partnership	To be determined	5% Annually	5%	5%	5%	5%	5%	Finance	Finance /All Directorate	
		Fund raising and donor funding	% increase in donor funds	To be determined	5% Annually	5%	5%	5%	5%	5%	Finance and Admin	Finance/ All Directorates	
	Cost rationalization and management		Value for Money	100%	100%	100%	100%	100%	100%	100%	Finance and Admin	Finance/ All Directorates	
		Implement business processes that are cost efficient and maximize value to	Cost to revenue ratio	To be determined	85%	85%	85%	85%	85%	85%	Finance	Finance and Admin	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		PPB stakeholders											
		Develop and implement efficient internal controls	% of major finance controls weaknesses addressed within 6 months	To be determined	100%	100%	100%	100%	100%	100%	Finance	Finance and Admin	
		Undertake value for money audit	Number of major finance non conformities	0	0	0	0	0	0	0	Internal Auditors	External Auditors	
		Monitor and report on progress in implementation of finance strategy to the CEO and finance committee of the Board	Timely reporting	1 week before Board/ Committee meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	Finance and Admin	CEO	
	Enhance stewardship, accountability and value for money in Procurement		% of procurement activities satisfying value for money Audit as per internal and external auditor	To be determined	100%	100%	100%	100%	100%	100%	Procurement	CEO	
		Develop, implement and monitor procurement processes, systems and internal controls	% compliance with procurement processes	0	100%	100%	100%	100%	100%	100%	Procurement	CEO	
		Ensure cash value for money in procurement	% Cash savings in spending against budget	To be determined	5%	≥5%	≥5%	≥5%	≥5%	≥5%	Procurement	CEO	
Objective 3.5: Improve accountability and risk management			% compliance to internal controls	10%	95%	95%	95%	95%	95%	95%	Internal Audit and Risk	CEO	111
	Assess the adequacy of good stewardship of both financial, personnel and other resources;		% of control weaknesses and audit queries identified by internal and external audit that are dealt with in 6 months		95%	95%	95%	95%	95%	95%	Internal Audit and Risk	CEO	
		Develop and implement relevant internal controls	% compliance to internal controls	10%	95%	95%	95%	95%	95%	95%	Internal Audit and Risk	CEO	
		Develop and implement an Enterprise Risk Management (ERM)	% compliance with ERM framework	0%	95%	95%	95%	95%	95%	95%	Internal Audit and Risk	CEO	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement mitigation measures for identified risks	% of mitigation measures implemented within 6 months	0%	100%	100%	100%	100%	100%	100%	Internal Audit and Risk	CEO	
		Monitor and report on progress in implementation of oversight recommendations to Board	Timely reporting	1 week before Board/ Committee meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	2weeks before relevant board meeting	Internal Audit and Risk	CEO	
		Develop and implement an efficient and effective Ethics and Integrity framework;	% compliance to framework	0%	95%	95%	95%	95%	95%	95%	Internal Audit and Risk	CEO	
Goal 4: Promote a pharmacy practice that provides the highest attainable standards of healthcare.													
Objective 4.1: Enhance the competence and capacity of pharmacy workforce			% Increase in competence level of workforce	To be determined	10% annually	10%	10%	10%	10%	10%	Head, CPD	Director, Pharmacy Practice	422
	Implement relevant Continuing Professional Development (CPD) program		Percentage of pharmacy practitioners determined to be fit to practice	To be determined	80%	20%	40%	50%	65%	80%	Head, CPD	Director, Pharmacy Practice	
		Identify Continuing Professional Development needs of pharmacy practitioners	% of needs identified and addressed annually	0	80%	20%	40%	50%	65%	80%	Head, CPD	Director, Pharmacy Practice	
		Develop and apply rules and regulations for CPD	% compliance with rules and regulations for CPD	0	80%	20%	40%	50%	65%	80%	Head, CPD	Director, Pharmacy Practice	
		Accredit CPD providers and programs	No. of accredited CPD providers and programs	29	50	30	35	40	45	50	Head, CPD	Director, Pharmacy Practice	
	Review and re-orient pharmacy practice consistent with UHC and overall health needs of the country		Percentage of pharmacy professionals fit for UHC and countries health needs	To be determined	80%	50%	60%	70%	75%	80%	Good Pharmacy Practice	Director, Pharmacy Practice	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement a roadmap for cascading pharmacy services to community level	% implementation of the roadmap	0	100%	0%	10%	25%	50%	100%	Good Pharmacy Practice	Director, Pharmacy Practice	
		Promote implementation of human resource for health norms	% of health centres with at least one pharmaceutical technologist per health Centre (level 3)	0	50%	0%	10%	20%	30%	50%	Good Pharmacy Practice; county governments	Director, Pharmacy Practice	
		Deployment of pharmacist interns to primary healthcare facilities	number of interns posted serving at primary healthcare facilities annually	158	500	360	400	440	480	500	Training and Good Pharmacy Practice	Director, Pharmacy Practice	
		Increase access to pharmacy services at primary healthcare level offered by appropriate pharmacy personnel	Number of pharmaceutical technologists offering services at primary healthcare level;	0	400	50	100	150	250	400	Good Pharmacy Practice; county governments	Director, Pharmacy Practice	
	Diversification of career tracks in pharmacy (including clinical, industrial, public health, supply chain management and research)		Number of pharmacy workforce with clinical capability	To be determined	250	50	100	150	200	200	Good Pharmacy Practice	Pharmacy Practice	
		Develop and implement a road map for conversion of B. Pharm. to Pharm. D program	% implementation of the roadmap	0	100%	0%	10%	25%	50%	100%	Good Pharmacy Practice	Director, Pharmacy Practice	
		Develop and apply rules and regulations for diversification of career tracks in pharmacy	% compliance with the rules	0	100%	0%	10%	25%	50%	100%	Good Pharmacy Practice	Director, Pharmacy Practice	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement competence framework for Pharmacists	% compliance with competence framework	0	100%	0%	10%	25%	50%	100%	Training and CPD	Director, Pharmacy Practice	
		Develop and implement core curriculum for Pharm. D program (patient-centred)	Number of universities implementing Pharm. D program	0	5	0	0	1	2	5	Training and CPD	Director, Pharmacy Practice	
		Develop and implement a program for career conversion of pharmaceutical technologists to pharmacists	Number of pharmaceutical technologists converting to pharmacists	0	400	0	50	100	100	150	Training and CPD	Director, Pharmacy Practice	
		Review and implement the regulatory framework to prescribe relevant entry level for pharmacy practice	% compliance with the regulatory framework	To be determined	100%	0%	10%	25%	50%	100%	Training and Good Pharmacy Practice	Director, Pharmacy Practice	
	Abolition of Diploma in Pharmacy program		Percentage implementation	0	100%	20%	40%	60%	80%	100%	Director Training	Deputy CEO, Pharmacy Practice	
		Develop and implement a strategy for abolishment of Diploma in Pharmacy program	Percentage implementation	0	100%	20%	40%	60%	80%	100%	Director Training	Deputy CEO, Pharmacy Practice	
		Develop and implement the regulatory framework to support abolition of Diploma program	Percentage compliance	0	100%	0	40%	80%	100%	100%	Director Training	Deputy CEO, Pharmacy Practice	
Objective 4.2: Enhance and refocus the role of pharmacy practice in national healthcare			Percent implementation of policies on training and pharmacy practice	0	100%	0%	10%	25%	50%	100%	GPP and Training	Director Pharmacy Practice	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
	Enhance pharmacy practice regulatory environment		Percent implementation of policies on training and pharmacy practice	0	100%	0%	10%	25%	50%	100%	GPP	Pharmacy Practice	
		Determine the national training and practice requirements for pharmacy workforce	Percentage completion	0	100%	100%	0	0	0	0	Training and GPP	Director, Pharmacy Practice	
		Develop and implement policies on training and pharmacy practice	Percent implementation of the policy document	0	100%	0%	10%	25%	50%	100%	Training and GPP	Director, Pharmacy Practice	
		Develop, review and implement standards and requirements in respect of the education, training, acquisition of experience acceptable as the minimum entry level into pharmacy practice	Per cent implementation of the Standards on minimum entry to practice pharmacy	0	100%	0%	10%	25%	50%	100%	Training and GPP	Director, Pharmacy Practice	
		Develop, review and implement standards and requirements in respect to pharmacy practice including good pharmacy practice	Percent implementation of the standards on good pharmacy practice	0	100%	0%	10%	25%	50%	100%	Training and GPP	Director, Pharmacy Practice	
		Develop and implement a mechanism of self-regulation for pharmacy professionals	Percent implementation of self-regulation mechanism	0	100%	20%	40%	60%	80%	100%	Training and GPP	Director, Pharmacy Practice	
	Increase access to Medication Therapy Management at community pharmacy level		%of community pharmacy that offer Medication Therapy Management	To be determined	95%	30%	40%	50%	70%	95%	GPP/Training and	Director, Pharmacy Practice	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Define, implement and enforce standards of levels of pharmacy practice and specializations	% Compliance with standards	0	100%	0%	0%	20%	50%	100%	GPP	Director, Pharmacy Practice	
		Develop and implement policy guidelines on patient medication therapy management at community pharmacy level;	% compliance with guideline	To be determined	80%	20%	40%	60%	70%	80%	GPP	Director, Pharmacy Practice	
		Develop and maintain a National Pharmacy Care system	% Implementation of the system	0	20%	0%	0%	5%	10%	20%	GPP	Director, Pharmacy Practice	
		Develop and implement regulations on determining fitness to practice	% overall compliance with regulations by Pharmacists, pharmaceutical technologists and premises	To be determined	90%	0%	5%	25%	50%	90%	GPP	Director, Pharmacy Practice	
		Develop and implement regulations regarding online pharmacies.	% compliance with online pharmacies regulations	0	100%	0%	5%	50%	80%	100%	GPP	Director, Pharmacy Practice	
	Foster ethical practice and professionalism		% annual reduction in documented unethical practices	To be determined	10%	10%	10%	10%	10%	10%	GPP	Director, Pharmacy Practice	
		Review and implement a framework for handling complaints and concerns relating to pharmacy professionals and pharmacy businesses	% Annual decrease in Number of complaints and concerns relating to pharmacy profession	To be determined	0.2	10% of BS	30% of BS	50% of BS	70% of BS	90% of BS	Pharmacy Practice & Training	Director, Pharmacy Practice	

Goal/Objective	Key Strategies	Activities	Indicator for Key Strategies and Activities	Baseline	Target	2020	2021	2022	2023	2024	Primary Responsibility	Secondary Responsibility	Budget (KSH. Million)
		Develop and implement a roadmap for stepwise quality improvement of Good Pharmacy Practice	% of premises complying with Good Pharmacy Practice	To be determined	100%	50%	60%	70%	80%	100%	Pharmacy Practice	DISE	
		Develop and implement guidelines on ethical conduct for pharmacy practice	% compliance with guidelines	To be determined	100%	50%	60%	70%	80%	100%	Pharmacy Practice	Director, Pharmacy Practice	
		Develop and implement collaborative framework with other healthcare providers	% implementation of the collaborative framework	To be determined	80%	20%	40%	60%	70%	80%	GPP	Director, Pharmacy Practice	
		Subject all professional misconduct cases to Enquiries and Disciplinary Committee (EDC)	% professional cases handled by EDC	To be determined	100%	100%	100%	100%	100%	100%	DISE	Director, Pharmacy Practice	
TOTAL : KSH 12,010,000,000													

PPB STRATEGIC PLAN (2020-2025)

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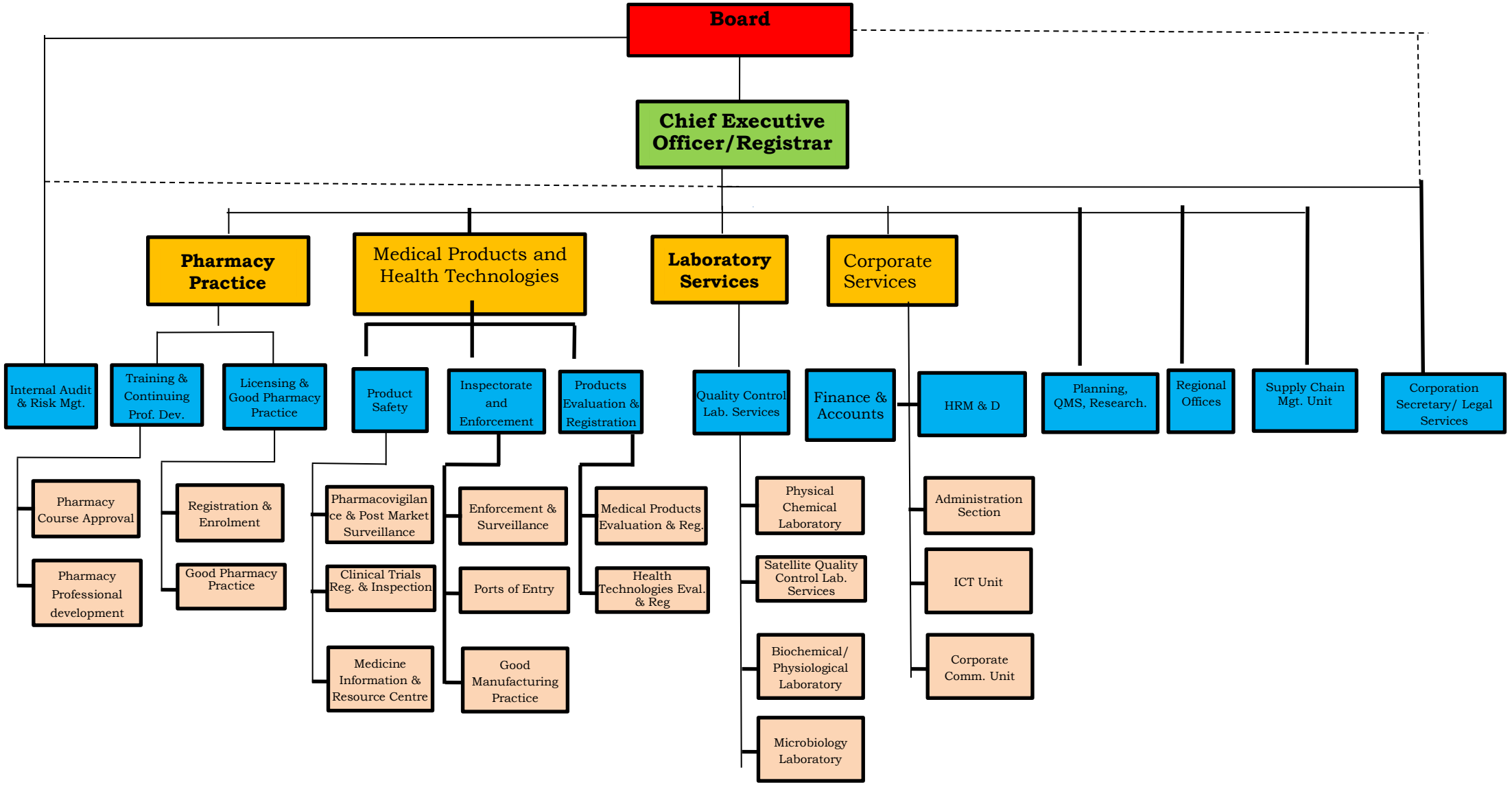
FIG 1: APPROVED ORGANIZATIONAL STRUCTURE FOR PPB



Republic of Kenya
Ministry of Health