



# STRATEGIC PLAN

2023/24 - 2027/28





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**2023/24 - 2027/28**



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# FOREWORD

Pharmacy and Medicines Regulatory Authority (PMRA) shoulders the daunting task of ensuring that the public has access to medicines and allied substances that are safe, efficacious and of acceptable quality. This noble duty is in line with Enabler 5: Human Capital Development of the Malawi 2063 Agenda which aims at ensuring universal health coverage with quality, available, equitable and affordable health care for all Malawians.

The new 2023/24 -2027/28 Strategic Plan is part of the major strides the Authority is undertaking in its quest to further enhance the medicine regulatory system in the country. The SP comes at a time when PMRA has undergone functional review aimed at establishing new organizational structure in line with the PMRA Act, 2019 and formal WHO global benchmarking whose outputs include an institutional development plan (IDP) and a roadmap towards achieving WHO Maturity Levels II & III of a functioning national regulatory authority.

In addition to taking on board the strategic aspirations of the retiring Strategic Plan (2023-2028), the new SP incorporates findings of the WHO benchmarking report and emerging priorities emanating from the envisioned strategic direction of the Authority in line with the PMRA Act, 2019.

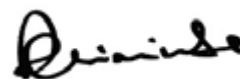
Therefore, the 2023/24-2027/28 SP identifies four (4) strategic priorities which will be the focus of PMRA for the next five (5) years. These are:

1. Strengthen systems for efficient delivery of regulatory services.
2. Entrench client-centric systems and mainstream technology.
3. Establish fit-for-purpose governance, human resource and organizational development structures.
4. Enhance resource mobilization and financial management.

Among others, these strategic priorities will see PMRA implementing quality management system covering all functions, decentralizing systems of service delivery, developing and implementing functional monitoring and evaluation framework, as well as mainstreaming technology in all functions and processes for enhanced service delivery and client experience.

The development of this SP has been done through a participatory process that entailed stakeholders' mapping and engagement with partner organizations. The Board of Directors pledge their full support towards successful implementation of the SP.

The Authority is indebted to the generous support by USAID through the Promoting the Quality of Medicines (PQM) Plus for sponsoring the entire development process of this SP.



Frider Chimimba

BOARD CHAIRPERSON



## PREFACE

The review of the retiring 2018-2023 Strategic Plan and subsequent development of the new 2023 – 2028 Strategic Plan for the PMRA have been necessitated by both the Authority's quest to effectively respond to the demands of the fast changing pharmaceutical regulatory landscape and the shift in strategic direction in line with the requirements of the PMRA Act of 2019.

Whereas the 2018-2023 Strategic Plan was developed and implemented at a time the organization operated as a Board and in the legal context of the Pharmacy, Medicines and Poisons Act of 1988, the current strategic blue print comes at a time when the Authority is putting in place structures to aid full implementation of the PMRA Act, 2019.

The new SP comes at an opportune time when the Authority recently underwent formal benchmarking by the World Health Organization (WHO), an exercise which culminated into development of Institutional Development Plan (IDP) for PMRA for the next five years. Thus, the SP carries PMRA's aspirations to strengthen its regulatory systems through attainment of WHO Maturity Level II and Maturity Level III of a functional national regulatory authority by 2025 and 2028, respectively.

The SP has been developed through a consultative process that sought to assess the achievements made in implementing the past Strategic Plan (2018-2023), the challenges experienced, and the lessons learnt as well as the opportunities that the Authority can tap into the future.

During the consultations, the board, the management team at PMRA, the staff and various key stakeholders were involved through key informant interviews, focus group discussions, workshops, and online surveys. In addition, macro and micro-economic issues that underpin the Authority's operating context were reviewed in a systematic organizational assessment and situational analysis.

It is PMRA's conviction that successful implementation of the new SP will transform the organization towards full implementation of its regulatory mandate of ensuring that Malawians access medicines and allied substances that are safe, efficacious and of acceptable quality and that the overall standards of pharmacy practice in the country are improved.

The PMRA's Board of Directors, Management and staff are committed to the successful implementation of this strategic plan. It must be mentioned that the SP will require huge investment, both in terms of financial and technical capacity. Thus, the Authority invites development partners and key stakeholders to assist PMRA to realize its dream as espoused in this ambitious but achievable plan.

Mphatso Kawaye

DIRECTOR GENERAL

# ACKNOWLEDGEMENTS



The Pharmacy and Medicines Regulatory Authority (PMRA) would like to acknowledge the support of the U.S. Agency for International Development (USAID) through its Promoting the Quality of Medicines Plus (PQM+) program, which is led by U.S. Pharmacopeia, and the USAID Global Health Supply Chain program-Procurement and Supply Management (GHSC-PSM) project. PMRA is grateful for PQM+'s assistance in developing this 2023/24-2027/28 Strategic Plan.

The Authority is very grateful to the Ministry of Health and Department of Statutory Corporations

for providing policy guidance during the formulation of this Strategic Plan.

The PMRA would also like to acknowledge the valuable contributions of all stakeholders for their input and feedback as their diverse perspectives enriched the strategic discussions and helped identify new opportunities for growth and improvement.

Lastly, the Authority is indebted to management and all members of staff for their dedication, expertise, and hard work throughout the entire process of developing this Strategic Plan.



# ABBREVIATIONS AND ACRONYMS

AfCFTA	African Continental Free Trade Area
AU	African Union
BEEM	Build, Eliminate, Exploit, Mitigate
BCP	Business Continuity Planning
CDC	Centre for Disease Control
CEO	Chief Executive Officer
CPD	Continuing Professional Development
DG	Director General
GMP	Good Manufacturing Practice
HR	Human Resources
HSSP	Health Sector Strategic Plan
ICT	information communication technology
IDP	Institutional Development Plan
IGA	income-generating activity
ISO	International Standards Organization
KPI	key performance indicator
M&E	Monitoring and Evaluation
MGDS	Malawi Growth and Development Strategy
ML	Maturity Level
MoH	Ministry of Health
MoJ	Ministry of Justice
NAC	National AIDS Commission
PESTLE	Political, Economic, Social, Technological, Legal, Environment
PMPB	Pharmacy, Medicines, and Poisons Board
PMRA	Pharmacy and Medicines Regulatory Authority
QMS	Quality Management System
R&D	Research and Development
SADC	Southern African Development Community
SP	Strategic Plan
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TCMs	Traditional and Complementary Medicines
TNA	Training Needs Assessment
UHC	Universal Health Coverage
USAID	United States Agency for International Development
USP	United States Pharmacopeial
WHO	World Health Organization
YoY	Year on Year

# EXECUTIVE SUMMARY

The development of this Strategic Plan (SP) 2023/24–2027/28 of the Pharmacy and Medicines Regulatory Authority (PMRA, or “the Authority”) coincides with Malawi and the rest of the world recovering from the ravaging effects of the COVID-19 pandemic and an imminent global economic recession. The SP will also be the first to anchor the PMRA Act of 2019; the previous plan was developed when the organization was operating as a board.

The SP’s development occurred through a consultative process to assess achievements toward implementing the past Strategic Plan (2018-2023), including challenges, lessons learned, and future opportunities. The Board, PMRA management team, staff, and various key stakeholders took part through key informant interviews, focus group discussions, workshops, and online surveys. In addition, macro- and microeconomic issues that underpin the Authority’s operating context were reviewed in a systematic organizational assessment and situational analysis. COVID-19 was indicated to have disrupted the effective implementation of the retiring plan. It was agreed that the strategic aspirations of the 2018-2023 SP remain largely relevant and would be carried forward into the new planning period. In addition, emerging priorities from the envisioned strategic direction of the Authority and the PMRA Act 2019 have been incorporated into the new SP.

Consequently, the 2023/24-2027/28 SP identifies four strategic priorities that will be the focus of PMRA for the next five years. The four strategic priorities are to:

- 1 Strengthen systems for efficient delivery of regulatory services.
- 2 Entrench client-centric systems and mainstream technology.
- 3 Establish fit-for-purpose governance, human resource and organizational development structures.
- 4 Enhance resource mobilization and financial management.

Section 3 of this SP details the strategic objectives, activities, and key performance indicators for each of the above strategic priorities. An implementation matrix and a monitoring and evaluation framework have also been provided to ensure that the plan’s implementation is effectively tracked and measured.

The implementation of the SP (2023/24-2027/28) is estimated to cost USD \$3,045,250 for the five years, beyond the Authority’s standard operating budget, with 46 percent budget geared toward strengthening systems for efficient delivery of regulatory services and 36 percent toward making the Authority more client-centric and leveraging technology. However, the USD \$ 3 million budget excludes USD \$28 million that is projected to be the amount that it will cost for the Authority to develop its strategic city centre plot; an investment that will straddle this strategic plan and the subsequent one. The development of the city centre plot is aimed at not only creating extra office space for the Authority but as a strategic sustainability plan by commercially leasing part of the space for revenue generation.

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**“ It was agreed that the strategic aspirations of the 2018-2023 SP remain largely relevant and would be carried forward into the new planning period.”**

# 1 | INTRODUCTION

## 1.1 BACKGROUND

Malawi's Constitution refers to the state's obligation to ensure equality of opportunity in access to basic health services and to undertake policy and legislative measures to facilitate the realization of these goals. Malawi's long-term development blueprint, Malawi Vision 2063, which envisions "An Inclusively Wealthy and Self-Reliant Nation" and assigns a pivotal role to universal health coverage with quality, equitable, and affordable health care for all Malawians. The blueprint envisions achieving this by providing a comprehensive health care system through interventions that will address, among others, improving the availability and quality of the health infrastructure, medical equipment, medicines, and medical supplies. Ideally, every constituency in the country will have well-equipped and staffed hospitals and health centers with commensurate investment in public health and medical health programmes, including e-health.

Further, the country's Health Sector Strategic Plan 2023-2030 (HSSP III) seeks to align with the respective period's Malawi Growth and Development Strategy (MGDS) III and global strategies, like the U.N.'s Sustainable Development Goals (SDGs). State agencies under the MoH implement programmes and execute mandates that help in promoting and safeguarding the public. The Pharmacy and Medicines Regulatory Authority (PMRA) is one of them.

PMRA is critical to ensuring the achievement of the objectives across the nine priorities of the HSSP III, but especially objectives 1 (service delivery), 3 (infrastructure and medical equipment), 5 (medical products and technology), 6 (digital health), and 7 (research).

PMRA is a body corporate with perpetual succession and a common seal; it will have power to sue and be sued in its corporate name and to acquire, hold, and dispose of movable and immovable property for its own purposes. The Minister of Health appoints members to its Board of the Authority.



## HISTORY AND JOURNEY OF PMRA

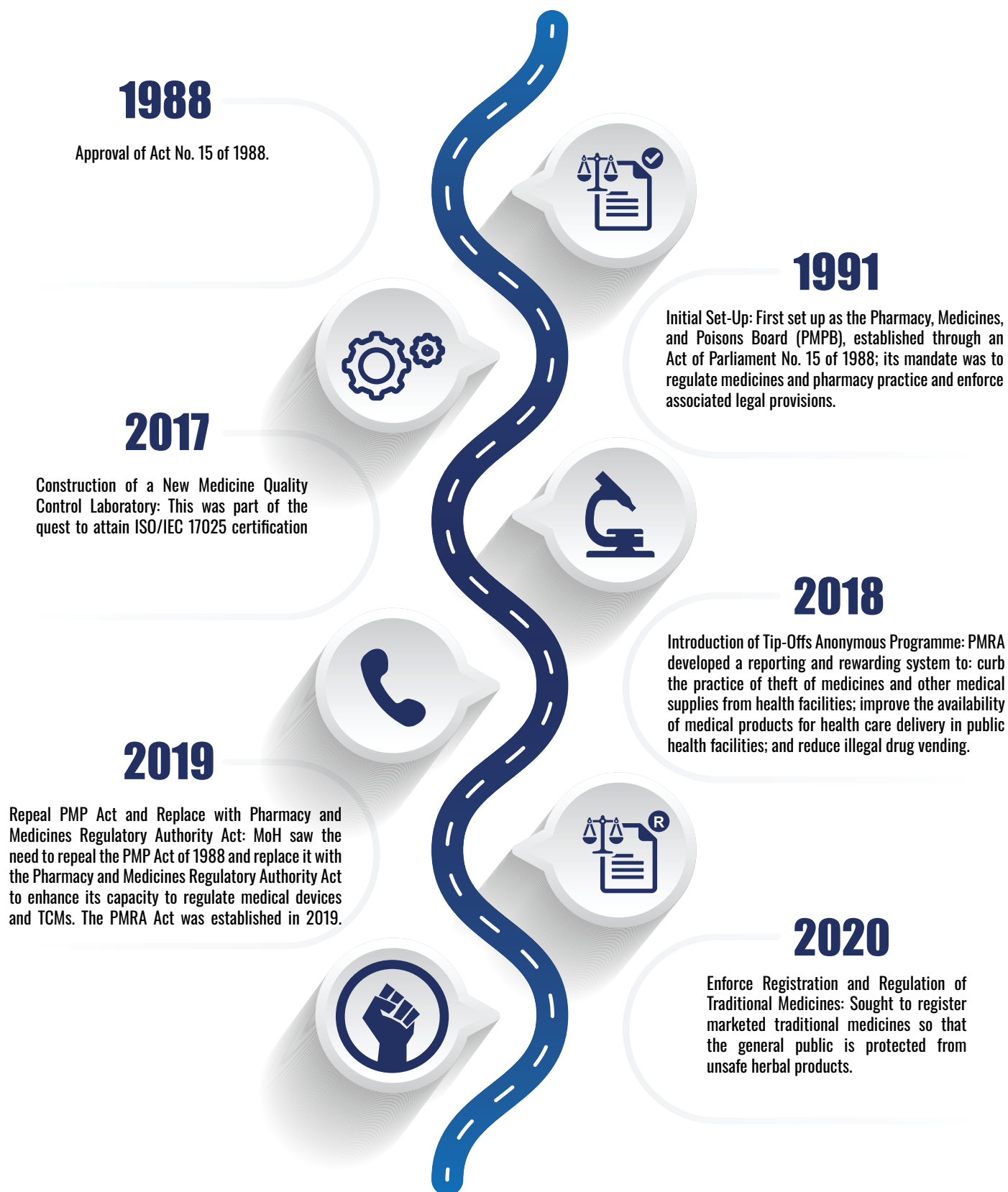
The organization was initially the Pharmacy, Medicines, and Poisons Board (PMPB), established through Act of Parliament No. 15 of 1988. The Board's mandate was to regulate medicines and pharmacy practice and enforce associated legal provisions.

The Pharmacy and Medicines Regulatory Authority Act No.9 of 2019 established PMRA to regulate medicines and allied substances and the practice of the pharmaceutical profession in Malawi through the following functions:

- i. Grant pharmaceutical licenses and marketing authorizations;
- ii. Inspect any premises used for the purpose of manufacturing, distribution, sale, importation, or exportation of medicines or allied substances or for any other purposes regulated under the Act;

- iii. Regulate and control the manufacture, importation, exportation, distribution, and sale of medicines and allied substances and veterinary products;
- iv. Regulate and control the advertising and promotion of medicines and allied substances.
- v. Register and regulate pharmacy practice premises and personnel and their training;
- vi. In consultation with the relevant professional bodies, establish, maintain, and develop standards for the operation of pharmacy practice premises and the pharmacy profession in general;
- vii. Serve and protect the public interest in all matters relating to the sale of medicines and allied substances;
- viii. Issue clinical trial licenses and monitor the conduct of clinical trials;
- ix. Establish, maintain, and enforce standards relating to the manufacture, importation, exportation, distribution, and sale of medicines and allied substances;
- x. Approve the use of unregistered and unauthorized medical products for trial or for compassionate use;
- xi. Establish a functional system for pre- and post-marketing surveillance of safety, quality, efficacy, and effectiveness of medical products and to optimize the risk-benefit balance;
- xii. Establish, maintain, and enforce standards for medicine quality control laboratories;
- xiii. Formulate, disseminate, and advise the Minister on policies relating to the regulation and control of medicines and allied substances;
- xiv. Collaborate with corresponding medicines regulatory authorities in other countries;
- xv. Continuously review rules, regulations, guidelines, and procedures pertaining to the implementation of this Act and make amendments where necessary in order to keep pace with changing times and pharmaceutical industry demands;
- xvi. In consultation with relevant research institutions, determine national priorities in pharmaceutical research;
- xvii. Share data on pharmacy practice or medicine with other countries, provided that the Authority shall ensure that such data is protected;
- xviii. Perform all such things that are connected with or incidental to the functions of the Authority under the Act.

The following is a timeline series of the journey that PMRA has travelled so far.



## 1.2 METHODOLOGY USED FOR THE DEVELOPMENT OF THE SP (2023/24-2027/28)

The following is a tabular summary of the process of developing the PMRA Strategic Plan.

PHASE	ACTIONS UNDERTAKEN
Phase 1: Initiation and preparatory April 2023	Participants at a joint preparatory meeting explored expectations, including the actual scope of work, and discussed the process and planning requirements. This helped forge a common understanding of the SP development process. At this stage, participants agreed on the type of tools and list of stakeholders to be consulted in the process.
Phase 2: Desk-reviews and development of consultation tools April 2023	A desk review of existing literature aimed to create a comprehensive picture of the context in which PMRA has been operating; the general Malawi context; the Authority's strengths, weaknesses, opportunities, and threats (SWOT); and the political, economic, social/cultural, technological, legal/regulatory, and environmental factors (PESTLE) that are likely to shape the Authority's operations and existence in the next five years, as well as their implications. The key documents reviewed include the 2018-2023 SP, the PMRA Act 9 of 2019, Malawi Vision 2063, the Functional Review Report, 2015 PQM Assessment Report of PMPB, the recent WHO GBT Assessment of PMRA (27-31 March 2023), the National Medicines Policy 2015, the Government of the Republic of Malawi HSSP III 2023-2030, SADC Medicines Regulatory Harmonization Strategic Plan 2023-2027, and other local, regional, and global relevant literature. A comprehensive synthesis of the emerging lessons, successes, and challenges and insights related to the future outlook was developed.
Phase 3: Stakeholders' engagement April/May 2023	<p>The key stakeholders identified and involved in the process were:</p> <ul style="list-style-type: none"> <li>• PMRA's board and the heads of board committees.</li> <li>• PMRA's director general (DG), senior management, and staff.</li> <li>• Selected PMRA clients (both institutional and professionals).</li> <li>• Relevant Government of Malawi representatives.</li> <li>• Development partners.</li> <li>• Comparable professional bodies and regulators, e.g., the Medical Council of Malawi, the Nurses and Midwives Council of Malawi (NMCM), and the Pharmaceutical Society of Malawi (PHASOM).</li> </ul> <p>Two consultative workshops took place: one with the management team members and the other with the board members where the preliminary organizational assessment and situation analysis report were presented, and the draft SP priorities and framework were agreed upon.</p>
Phase 4: Draft preparation May/June 2023	A small working group from the management team of PMRA collaborated with the consultants to refine the strategic priorities, the implementation matrix, and the first draft of the SP at large.
Phase 5: Finalization of the strategic plan July-September 2023	<p>This entailed the presentation of the first draft of the SP to PMRA's senior management team members, the Finance and Administration (F&amp;A) Committee of the Board, and the full board. Subsequently, the following steps were taken:</p> <ul style="list-style-type: none"> <li>• Incorporation of feedback on the first draft.</li> <li>• The refinement of the first-year operational plan, the M&amp;E framework, and the SP budget.</li> <li>• Presentation of the final draft in a stakeholders' validation workshop.</li> <li>• Incorporation of feedback from the stakeholders' workshop.</li> <li>• Submission of the final draft to PMRA's senior management team for launch and dissemination.</li> <li>• Review and sign-off.</li> <li>• Launch of the 2023/24-2027/28 Strategic Plan.</li> </ul>

The development of this SP involved a participatory process that entailed stakeholders' mapping and engagement with partner organizations.

### 1.3 A SUMMARIZED REVIEW OF THE IMPLEMENTATION OF THE LAST SP

Implementation of the last SP (2018-2023) occurred against the backdrop of COVID-19, the enactment of the PMRA Act 2019, and changes in the position of the Director General; leading to observable derailments. Despite these challenges, the Authority remained stable, especially in the delivery of services to Malawians as well as its ability to finance its own operations without government funding. It also includes lessons learned and what the PMRA can build on in its continued endeavour to achieve its mandate. Based on an online survey administered to members of staff and the senior management team, the majority of the respondents rated the implementation of the 2018-2023 SP at “below average” to “average,” with most of the contemplated strategies rated as “not at all implemented” to “averagely implemented.”

#### ✓ **ACHIEVEMENTS**

- ✓ Provision of services in line with PMRA’s mandate as outlined in the Act.
- ✓ Development and maintenance of a robust and integrated financial management information system (73 percent of online survey respondents considered this average in its implementation).
- ✓ Building and operation of a WHO/ISO-certified laboratory for credible quality control testing (47 percent of respondents noted a general positive direction toward achievement of this strategic objective and

said it was implemented to an above average or excellent extent).

- ✓ Development and enforcement standards of education and practice for pharmacy personnel (27 percent of respondents ranked this at above average or excellent in its implementation).

#### ✗ **MISSED OPPORTUNITIES:**

- ✗ Installation and maintenance of a functional online registration and certification system (portal) for both personnel and products.
- ✗ Establishment of a decentralized pharmacovigilance and post-marketing surveillance (PMS) system at the district level and ports of entry.
- ✗ Development of a robust M&E framework of all PMRA functions and activities.
- ✗ Development and implementation of internal and external communication policy and strategy.
- ✗ Establishment and maintenance of a functional information and communication technology (ICT) and public relations office.
- ✗ Development and maintenance of a robust and integrated HR information management system.
- ✗ Institution of a robust and fair performance management system for staff members.
- ✗ Obtaining ISO certification for the organization.

## 2 | SITUATION ANALYSIS

During the process of developing this SP, PMRA and its stakeholders considered the question of what issues and trends should shape its thinking about the future. This included both internal and external considerations. PMRA acknowledges the competitive, complex, and dynamic environment in which it operates, where emerging trends present potential opportunities as well as challenges to its ability to carry out its mission. The situation analysis clearly demonstrates the need for PMRA to carefully prioritize, focus, and ultimately decide on what is most strategic to pursue in its continued endeavours to fulfill its mandate.

### 2.1 GENERAL CONTEXTUAL ANALYSIS

#### I. GLOBAL CONTEXT

The PMRA SP 2023/24-28 was developed amid the beginnings of the global economic recession prospected by the International Monetary Fund (IMF)<sup>1</sup> and the United Nations (UN).<sup>2</sup> The recession is projected to contribute to increasing inequalities in the use of health services, therefore creating a demand for new management and health planning strategies such as hospitalization at home and new models of integrated care and pharmaceutical management to help achieve greater equity and equality in health. Further, the COVID-19 pandemic shaped and continues to influence global public health discourse. It clearly reinforced the importance of a multilateral and multi-sectorial approach to pandemics. Reinforcing this is the WHO Strategic Preparedness and Response Plan (SPRP) for 2023-2025,<sup>3</sup> which seeks to support countries with longer-term sustained COVID-19 disease prevention, control, and management. Closer to home, the place of building stronger public health systems that can

respond effectively became prominent.

WHO is also implementing One Health, an integrated, unified approach to balance and optimize the health of people, animals, and the environment. It is particularly important to prevent, predict, detect, and respond to global health threats such as the COVID-19 pandemic. The approach mobilizes multiple sectors, disciplines, and communities at varying levels of society to work together. With this approach, new and better ideas will address root causes and create long-term, sustainable solutions.

#### II. REGIONAL AND NATIONAL CONTEXT

The African Union is implementing the Agenda 2063, which is a blueprint and master plan for transforming Africa into the global powerhouse of the future. It is a strategic framework that aims to deliver on its goal for inclusive and sustainable development. Health falls under the social pillar and the target is to have a people-centred development. The work is coordinated under the Department of Health, Humanitarian Affairs, and Social Development (HHS) which works to promote the AU's health, labour, employment, migration, social development, drug control, crime prevention, sport, and cultural agenda.

The African Union Development Agency-NEPAD (AUDA-NEPAD) has consultatively outlined strategies to develop and implement the Pharmaceutical Manufacturing plan for Africa (PMPA) with support of relevant partners. The PMPA outlines measures for effective industrial coordination and good policies and practices in the manufacturing sector, which are critical for Africa's local pharmaceutical production. Further, the plan aims to facilitate improved access to affordable essential medicines and catalyze local production in Africa through increased political commitments and workable solutions.<sup>4</sup>

1 Global Economic Recession \_ IMF

2 Global Economic Recession \_ UN.

3 Strategic Preparedness and Response Plan (SPRP) for 2023-2025 \_ WHO

4 Health Care Africa



The COVID-19 pandemic created an accelerated need for a joint response at the AU level. The Africa CDC exists to strengthen the capacity and capability of Africa's public health institutions as well as partnerships to detect and respond quickly and effectively to disease threats and outbreaks, based on data-driven interventions and programmes.

Among the Africa CDC's programmes is Laboratory Systems and Networks, which supports patient-centred, integrated point-of-care diagnostic testing for syndromes management and surveillance at the community level. The programme's goal is strengthened clinical and public health laboratory systems and networks through continued improvements in workforce competency to assure quality and safety. In addition, the SADC Medicines Regulatory Harmonization Strategic Plan (2023–2027) acknowledges that the region grapples with challenges especially in the medicines regulatory landscape including: Lack of a formal governance structure causing difficulties in requiring central registration, lack of a centralized submission and tracking system for applications, failure by countries to implement *Zazibona Collaborative Process*<sup>5</sup> recommendations to register products in a timely manner, different labelling requirements among participating countries, lack of clarity on the *Zazibona* operating model as well as information on its process, among others. The regional SP identifies seven strategic pillars as crucial in from 2023 to 2027. The pillars are: policy, people, processes, technology, governance, sustainability, and finance.

The World Bank's *Malawi Outlook 2023*<sup>6</sup> projected that the country's economy will grow by 1.4 percent in 2023, assuming gradual macroeconomic stabilization and resumed electricity generation. However, Malawi will remain vulnerable to external shocks. This, as well as factors like inflation and slow growth, are likely to contribute to a poverty rate increase to 72 percent in



The development of the SP was done through a consultative process

2023. Part of the impact of the increased poverty rates will be people's inability to access health care. Malawi Vision 2063<sup>7</sup> assigns a pivotal role to universal health coverage under the Human Capital Development pillar. The goal is to attain universal health coverage with quality, equitable, and affordable health care for all Malawians. A recent government directive regarding consolidation of all accounts under the Reserve Bank may have implications on the financial autonomy of the Authority, although there are assurances from the government that this may not be the case.

A report by USAID indicated that Malawi has achieved dramatic gains in most health indicators by focusing on the improved delivery of essential health services, including achieving Millennium Development Goal 4, "Reduce child mortality" by 2015,<sup>8</sup> reduced maternal and child mortality rate, reduced prevalence of HIV/ AIDS, and increased life expectancy. However, the country still faces serious gaps in the health sector therefore, development of this plan by PMRA is one step toward consolidating gains and positioning the sectors to deliver better for the people.

<sup>5</sup> The *Zazibona* process is a collaboration between national medicines regulatory authorities (NMRAs) in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Tanzania, Malawi, DRC, Mozambique, and Malawi (active countries), as well as Eswatini, Angola, Seychelles and Madagascar (non-active). Source: <https://www.bomra.co.bw/zazibona-collaborative-process>.

<sup>6</sup> *Malawi Outlook 2023* \_ World Bank

<sup>7</sup> *Malawi Vision 2063*

<sup>8</sup> <https://research.un.org/en/docs/dev/2000-2015>.

The formal WHO benchmarking on PMRA in March 2023 aimed to identify the status of the medicines regulatory system in Malawi and PMRA's overall maturity level, establish an institutional development plan (IDP) to build on identified strengths and address found and/or potential gaps, and develop an agreement between PMRA and WHO on future activities to further enhance the regulatory system in Malawi. The findings of the report have been included in developing this strategic plan for the next five years. Challenges highlighted by the report on key indicators were:

1. Lack of regulations complementing the existing PMRA Act:
  - Lengthy and complicated processes for issuing and approving regulations.
  - Tendency to call for “too-detailed” regulations.
  - Under-utilization of binding regulatory guidelines.
2. Ineffective organizational structure:
  - Not fit for purpose.
  - Not serving the effective and efficient conduct of different regulatory functions.
3. Lack of proper human resources:
  - Insufficient number of regulatory staff.
  - Unsuccessful analysis of workload vs. workforce.
  - Undedicated staff not enabling deep knowledge and experience with assigned functions.
  - Absence of a well-established training programme.
4. Insufficient financial resources:
  - Inability to retain and manage the surplus of PMRA funds (even in part).
5. Absence of quality management system (QMS):
  - Improper documentation practices (per WHO-defined good documentation practices) including archiving and retrieval of sensitive regulatory information.
  - Lack of systematic definition and management of regulatory processes and their interactions.
  - Absence of a process approach.
  - Absence of performance-based evaluations.
6. Lack of application of risk-based approach to regulatory activities:
  - Product vigilance activities.
  - Market quality surveillance programme.
  - Laboratory testing policy.
  - Inspection scheduling, including overseas GMP inspections.
7. Improper data management:
  - Lack of basic automation modalities.
  - High risk of losing critical, confidential, and sensitive regulatory information.
  - Outdated electronic registration and alternative dispute resolution management systems.

## 2.2 STRENGTHS, WEAKNESSES, OPPORTUNITIES, AND THREATS (SWOT) ANALYSIS

A SWOT analysis assisted with deepening the understanding of PMRA’s operational context. The internal environment entailed the identification of issues within the organization classified as strengths

or weaknesses that positively or negatively affected its performance. The external analysis also involved an assessment of the political, legal, social-economic, and technological environments.

Following is a summary of the SWOT assessment that PMRA will either need to build on, eliminate, exploit, or mitigate (BEEM) to achieve its strategic aspirations.

STRENGTH		STRATEGIC IMPLICATIONS
1.	Clear and compelling mandate (PMRA Act 2019).	<ul style="list-style-type: none"> <li>Lobby for expedited development of regulations to operationalize the implementation of the Act.</li> <li>Leverage this for resource mobilization locally and internationally.</li> <li>Deepen partnerships and linkages.</li> <li>Profile the work of PMRA to build its reputation and visibility.</li> <li>Participate in key events and platforms to increase the stakeholder credibility and buy-in.</li> </ul>
2.	Well-equipped laboratory.	<ul style="list-style-type: none"> <li>Finalize the ISO 17025 certification process and achieve certification.</li> <li>Pursue WHO accreditation.</li> <li>Build on it to attract, grow, and develop capacity for the region.</li> <li>Develop training programmes that can bring resources to the institution.</li> <li>Leverage it to deliver better services and increase income.</li> </ul>
3.	Committed leadership and dedicated staff.	Improve the regulatory system and reach a higher ML.
4.	Well-established key regulatory functions and activities.	<p>A perfect basis for further strengthening and enhancement of other functions:</p> <ul style="list-style-type: none"> <li>QMS within the laboratory.</li> <li>Licensing establishments.</li> <li>Authorization of generic/multisource medicines.</li> </ul>
5.	Own building and land.	<ul style="list-style-type: none"> <li>Physical expansion and diversified revenue source.</li> </ul>
6.	Current financial stability.	<ul style="list-style-type: none"> <li>Prudently manage resources for enhanced ability to fulfill its mandate.</li> </ul>

WEAKNESS		STRATEGIC IMPLICATIONS
1.	Leadership gaps.	<ul style="list-style-type: none"> <li>Develop proper procedures, guidelines, and policies to govern PMRA activities.</li> <li>Establish a training and leadership development programme for both technical and non-technical staff.</li> </ul>
2.	Organizational structure that is not well-tailored for purpose:	<ul style="list-style-type: none"> <li>Leverage the SP (2023/24-2027/28), the WHO benchmarking report, and the Functional Review Report to inform a fit-for-purpose organizational structure.</li> <li>Increase staff numbers and competencies match the demand of the Authority’s mandate, e.g., capacity for testing the quality of vaccines and biologics.</li> <li>Raise resources to facilitate hiring more staff.</li> <li>Engage partners who can support creative ways of service delivery over and above PMRA’s core staff, e.g., collaborate with public pharmacists and allied health workers across Malawi.</li> </ul>

WEAKNESS		STRATEGIC IMPLICATIONS
3.	Absence of a QMS.	<ul style="list-style-type: none"> <li>Implement an organization-wide QMS (ISO 9001:2015 standard).</li> <li>Pursue automation and integration of processes across the Authority.</li> <li>Implement robust and automated data management systems.</li> </ul>
4.	Limited physical presence (only located in the Lilongwe).	<ul style="list-style-type: none"> <li>Decentralize PMRA's offices.</li> <li>Collaborate with other government public health services providers for countrywide reach/access.</li> </ul>
5.	Lack of an in-house legal department.	<ul style="list-style-type: none"> <li>Establish a legal department.</li> </ul>
6.	Inadequate capacity for regulation of herbal, cosmetics, and allied products.	<ul style="list-style-type: none"> <li>Build collaborations and capacity for regulation of herbal, cosmetics, and allied products.</li> </ul>
7.	Non-application of risk-based regulatory approaches.	<ul style="list-style-type: none"> <li>Develop and implement a risk-based approach to delivering regulatory functions.</li> </ul>
8.	Lack of a clear business continuity and crisis management plan.	<ul style="list-style-type: none"> <li>Develop and implement a robust Business Continuity Policy and Plan including a disaster recovery plan and sites.</li> </ul>
9.	Lack of a clear performance management system.	<ul style="list-style-type: none"> <li>Develop and implement a clear performance management system.</li> </ul>
10.	Low proactive engagement with customers and other key stakeholders.	<ul style="list-style-type: none"> <li>Entrench a customer-centric culture across all functions.</li> <li>Schedule engagements with stakeholders through diverse channels (physical meetings, media, etc.).</li> </ul>

OPPORTUNITY		STRATEGIC IMPLICATIONS
1.	Current financial autonomy.	<ul style="list-style-type: none"> <li>Be able to execute its mandate.</li> <li>Exercise prudent stewardship of its resources.</li> </ul>
2.	Current financial management system which allows for direct engagement with donors.	<ul style="list-style-type: none"> <li>Build partnerships at the local and international levels.</li> <li>Organize and participate in collaborative programming and resource mobilization.</li> </ul>
3.	Regional collaboration and "cross-pollination" under Zazibona.	<ul style="list-style-type: none"> <li>Actively participate in the regional initiatives with peer regulators.</li> <li>Leverage the regional platform for capacity development, standardization, research, and development of PMRA's work.</li> </ul>
4.	Growing population.	<ul style="list-style-type: none"> <li>Educate Malawians on the quality of medicines and allied substances.</li> <li>Create continued awareness on its work and develop a positive image with the public.</li> </ul>
5.	Interest and willingness of several partners to strengthen and support the regulatory system in Malawi.	<ul style="list-style-type: none"> <li>Develop and implement a partnership strategy.</li> </ul>
6.	Technology.	<ul style="list-style-type: none"> <li>Adopt and mainstream facilitatory technologies for increased usage, access, and quality of its regulatory services.</li> </ul>

THREAT		STRATEGIC IMPLICATIONS
1.	Regulatory gaps (e.g., clarity on traditional medicines, regulating online pharmaceutical trade, and potential or actual overlaps between PMRA and Cannabis Regulatory Authority on the medicinal use of Cannabis, among others).	<ul style="list-style-type: none"> <li>Establish a legal office/department for proactive counsel on emerging legal issues.</li> <li>Proactively engage with relevant government actors to expedite the development of regulations to operationalize the PMRA Act 2019.</li> <li>Structure collaborations with complementary regulators and actors for effective delivery of services.</li> </ul>

THREAT		STRATEGIC IMPLICATIONS
2.	Past high turnover at the DG level.	<ul style="list-style-type: none"> <li>Leverage current stability at the DG level for expedited implementation of strategic interventions that the turnover hampered in the past period.</li> </ul>
3.	Negative perceptions.	<ul style="list-style-type: none"> <li>Hold regular stakeholder engagements and consultations.</li> <li>Effectively disseminate the 2023/24-2027/28 SP to critical constituents.</li> <li>Execute sustained and diversified media campaigns and awareness creation.</li> <li>Build credibility and profile, and document and share success stories to forge partnerships with communities.</li> </ul>
4.	Mushrooming of medicines stores.	<ul style="list-style-type: none"> <li>Tighten surveillance and inspections.</li> <li>Create awareness among the public to entrench a quality-consciousness culture.</li> </ul>
5.	Increasing use of herbal products.	<ul style="list-style-type: none"> <li>Deliver awareness campaigns to educate the public on the dangers of herbal products.</li> <li>Create structures and build capacity to regulate herbal products.</li> </ul>
6.	Litigations interest/pressure groups.	<ul style="list-style-type: none"> <li>Ensure consistent and well-informed implementation of the Authority's mandate.</li> <li>Pursue collaborations and partnerships.</li> </ul>

## 2.3 POLITICAL, ECONOMIC, SOCIAL, TECHNOLOGICAL, LEGAL, ENVIRONMENT (PESTLE) ANALYSIS

POLITICAL		STRATEGIC IMPLICATIONS
1.	Political reforms.	<ul style="list-style-type: none"> <li>Engage in policymaking processes to secure the mandate of the institution.</li> <li>Demonstrate the authority's value to the health system to advance its cause.</li> <li>Contribute knowledge to shape policymaking, vital to secure the space and place of the institution.</li> <li>Governance will be central, particularly in ensuring that it is solid and well placed to serve the purpose and mandate of the institution.</li> <li>Partner with CSOs in the health sector, a key to building and consolidating support and goodwill for the institution.</li> <li>Deliver public education and sensitization about the critical nature of the work.</li> </ul>
2.	Political interference.	<ul style="list-style-type: none"> <li>The huge funds in the health sector attract political interests and possible interferences; monitor this area.</li> </ul>
3.	Political and government's focus.	<ul style="list-style-type: none"> <li>The institution should position itself and align to the Vision 2063 and the National Planning Commission Guidance as well as the vision of the current administration.</li> <li>Effectively launch and disseminate this strategic plan to the political sector.</li> </ul>
4.	Health as a priority (demonstrated by strategic initiatives like UHC and Malawi Vision 2063).	<ul style="list-style-type: none"> <li>Harness the political goodwill around health to propel the agenda of the institution to the next level.</li> <li>Lobby for secured resources to support the mandate of the institution.</li> <li>Partner with the key drivers and movers of UHC in the administration.</li> </ul>

ECONOMIC		STRATEGIC IMPLICATIONS
1.	Inflation.	<ul style="list-style-type: none"> <li>Donor support for the health sector has gone down, affecting resource mobilization.</li> <li>Structure and enhance resource mobilization to secure non-traditional resourcing.</li> <li>Disseminate best practices, successes, and lessons learned strategically and widely.</li> <li>Prioritize media engagement to raise PMRA's profile.</li> </ul>
2.	Regional initiatives – Zazibona, AfCFTA, etc.	<ul style="list-style-type: none"> <li>Actively engage in partnerships and collaborations within the regional platforms for continued learning, lobbying, resource mobilization, and capacity development.</li> <li>Position PMRA as a benchmark institution within the region.</li> </ul>
3.	Slowed economic growth	<ul style="list-style-type: none"> <li>High unemployment among the youth and a high dependency ratio require that the Authority use innovative and cost-effective ways of reaching and engaging them.</li> <li>Play a pivotal role in ensuring the healthy nation that can result in a wealthy and inclusive nation.</li> </ul>
4.	Disruptions from COVID-19.	<ul style="list-style-type: none"> <li>Shape recovery efforts to position the work as part of economic recovery.</li> </ul>

SOCIAL		STRATEGIC IMPLICATIONS
1.	High unemployment among youth and high dependency ratios.	<ul style="list-style-type: none"> <li>This affects savings and access to health care.</li> <li>Provide internship opportunities for young people entering the job market.</li> </ul>
2.	Increased reporting of health care related issues.	<ul style="list-style-type: none"> <li>Increased demand for health care means the public is receptive to public sensitization and education.</li> </ul>
3.	Right to information (access and use) – people want to know.	<ul style="list-style-type: none"> <li>Package information and knowledge in ways the public can understand and engage in.</li> <li>Research and knowledge generation.</li> </ul>

TECHNOLOGICAL		STRATEGIC IMPLICATIONS
1.	Rapid technological advancements.	<ul style="list-style-type: none"> <li>An opportunity to explore ways of mainstreaming technology within the outreach, operational, and financial functions of the Authority.</li> </ul>
2.	An increased uptake of digital services.	<ul style="list-style-type: none"> <li>Integrate technology in health delivery and with an emphasis on PMRA's work.</li> </ul>
3.	Mobile telephony penetration.	<ul style="list-style-type: none"> <li>An opportunity to increase information access and inquiry by the public.</li> <li>Good resource mobilization opportunity: People can make inquiries using a phone.</li> <li>Platform for exploiting the potential of tested/quality-assured medical and allied substances as part of its core mandate.</li> </ul>

LEGAL		STRATEGIC IMPLICATIONS
1.	Increased litigation from pressure and interest groups.	<ul style="list-style-type: none"> <li>Commit to judicious execution of the Authority's mandate.</li> <li>Increase in-house legal capacity.</li> </ul>
2.	Formation of regional medicine procurements and testing bodies.	<ul style="list-style-type: none"> <li>Opportunity to mobilize resources, even externally.</li> <li>Have PMRA officers at the borders.</li> </ul>
3.	Change in government trade, financial, and human resources policies.	<ul style="list-style-type: none"> <li>Work closely with various stakeholders and build linkages to ensure effective consultations and collaborations.</li> </ul>

ENVIRONMENTAL		STRATEGIC IMPLICATIONS
1.	The Constitution guarantees the right to a peaceful and secure environment.	<ul style="list-style-type: none"> <li>Processes and practices should ensure "no harm" to the environment.</li> <li>Build environmentally friendly practices into all operations.</li> </ul>
2.	Climate change and likelihood of natural disasters, e.g., disease outbreak/ pandemic disasters/ environmental disasters like Cyclone Freddy.	<ul style="list-style-type: none"> <li>Review and adjust the Authority's operations in light of the climate change agenda.</li> <li>Develop policies and systems for climate change adaptation and effective disaster management/response.</li> </ul>
3.	Dumping.	<ul style="list-style-type: none"> <li>The institution can create awareness on the health-related implications of dumping in light of its mandate and provide proper advice on effective waste disposal of HPT-related substances.</li> </ul>

# 3 | STRATEGIC FRAMEWORK (2023/24-2027/28)

## 3.1 MISSION, VISION AND CORE VALUES

### OUR MISSION



To safeguard the health of the population of Malawi through assurance of the quality, safety, and efficacy of medicines, allied substances, and the pharmacy practice.






### OUR VISION



The trusted and independent regulator of medicines, allied substances, and the pharmacy profession in Malawi.

### OUR VALUES



-  **Professionalism:** We are competent, highly motivated, and result oriented.
-  **Client-centrism:** We are customer-centred and we communicate openly and in a timely manner.
-  **Teamwork:** We embrace collaboration and partnerships within and without.
-  **Integrity:** We are confidential, honest, accountable and transparent.
-  **Innovation:** We continuously learn and improve.

**TAGLINE** Quality Medicines for Malawi



### 3.2. STRATEGIC PRIORITIES

Based on the desk reviews and broad consultations with the board, management, and staff of PMRA and other key internal and external stakeholders, during 2023/2024 to 2027/2028 PMRA will focus on the following strategic priorities:



Strengthen systems for efficient delivery of regulatory services.



Entrench client-centric systems and mainstream technology.



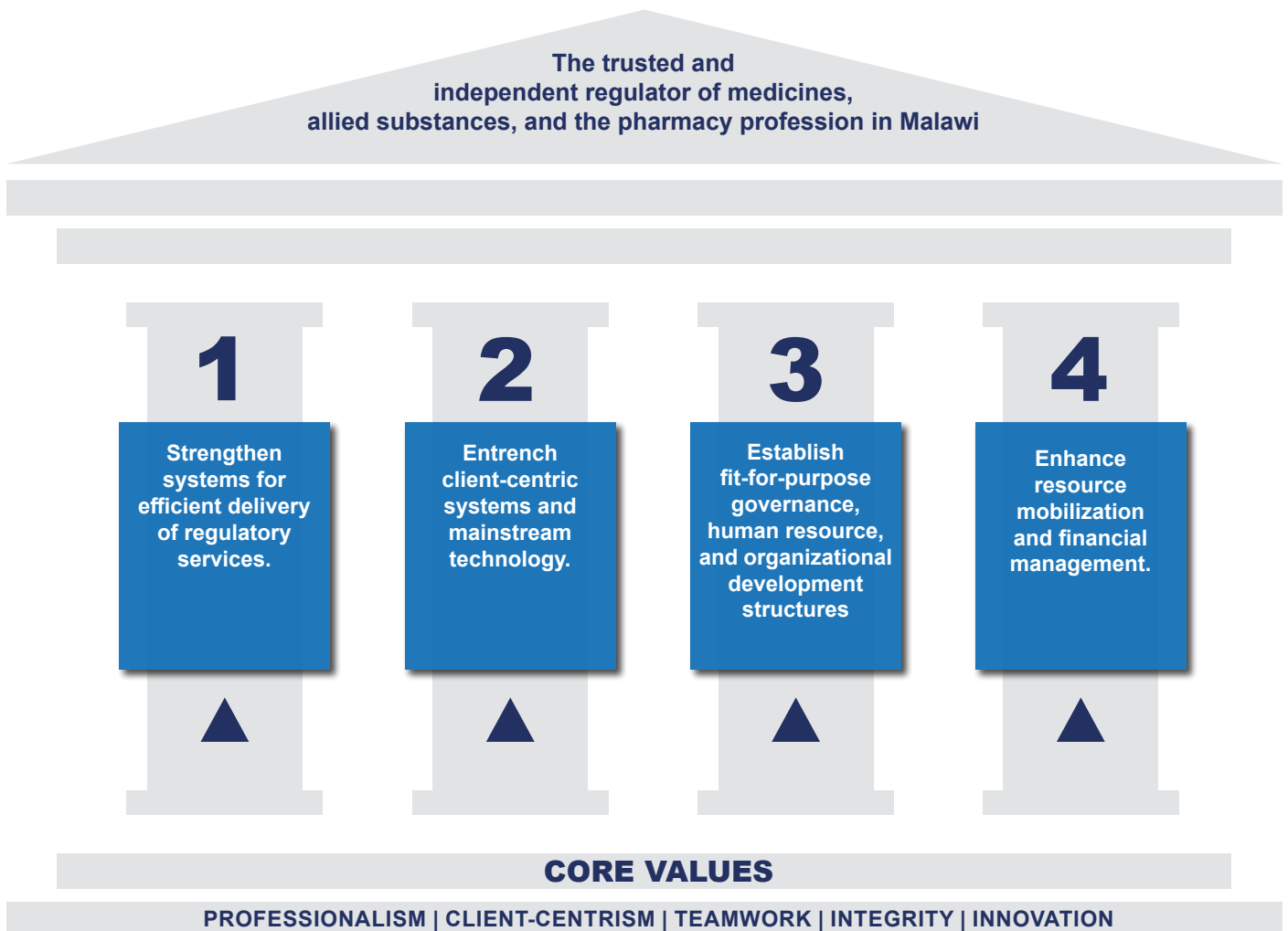
Establish fit-for-purpose governance, human resource, and organizational development structures.



Enhance resource mobilization and financial management.

The strategic objectives and activities under each of these strategic priorities have been covered in the implementation matrix and the monitoring and evaluation framework in this document.

### 3.3 STRATEGY ILLUSTRATION



## 3.4 STRATEGIC PRIORITIES, OBJECTIVES AND STRATEGIES

Strategic Priority	Strategic Objectives	Key Strategies
Strengthen systems for efficient delivery of regulatory services.	<p>Enhanced capacity for the implementation of the PMRA Act 2019.</p> <p>ISO 17025 accreditation attained by December 2023 and a QMS (ISO 9001) implemented and certification attained.</p>	<ul style="list-style-type: none"> <li>Collaborate with the MoH, MoJ and other actors for prompt gazettelement of regulations.</li> <li>Enhance good regulatory practices.</li> <li>Establish regulatory mechanisms for herbal medicines, nutritional supplements, and medical devices.</li> <li>Continuously develop and strategically position pharmacy practice.</li> <li>Implement systematic definitions and management of regulatory processes and their interactions.</li> <li>Implement appropriate documentation, archiving, and information retrieval practices.</li> <li>Pursue ISO 17025 accreditation for the laboratory.</li> </ul>
	Decentralized systems of service delivery operationalized by 2028.	<ul style="list-style-type: none"> <li>Partner with relevant government professionals (pharmacists, etc.) to decentralize key functions (pharmacovigilance, inspections, post-marketing surveillance) countrywide using a risk-based approach.</li> <li>Establish prioritized regional and inland port-of-entry offices.</li> </ul>
	Attain Maturity Level 2 by 2025 and Maturity Level 3 by 2028.	<ul style="list-style-type: none"> <li>Implement the PMRA's IDPs from the WHO global benchmarking report.</li> <li>Budget and mobilize resources for the WHO IDPs implementation.</li> </ul>
Entrench client-centric systems and mainstream technology.	Technology mainstreamed in all key functions and operations by 2028.	<ul style="list-style-type: none"> <li>Automate all key functions and operations.</li> </ul>
	Increased level of awareness of PMRA across the country to 70% by 2028.	<ul style="list-style-type: none"> <li>Conduct awareness campaigns and stakeholders' engagements through targeted channels (print and electronic media, physical meetings, etc.).</li> <li>Partner with relevant community-based organizations, institutions, public health programmes, and "goodwill ambassadors" to carry out sensitizations and public education.</li> <li>Regularly update the public through diverse channels with lists of registered, deregistered, withdrawn, and recalled medicines, allied substances, clinical trials, premises, and professionals.</li> <li>Institutionalize a flagship corporate social responsibility activity/event.</li> <li>Contract/retain the services of a public relations agency for improved publicity.</li> </ul>

Strategic Priority	Strategic Objectives	Key Strategies
	<p>A client-centric culture among all the Authority's staff built.</p> <p>Increased access points to the Authority's services.</p>	<ul style="list-style-type: none"> <li>• Embed client-centrism in products and service delivery of the Authority.</li> <li>• Develop and implement a customer service charter.</li> <li>• Implement programs to build a client-centric culture among staff.</li> <li>• Develop and maintain a functional online application portal for registration of clinical trials, pharmacy professionals, pharmaceutical establishments, medicines, and allied substances.</li> </ul>
<p>Establish fit-for-purpose governance, human resource, and organizational development structures.</p>	<p>Strengthened governance structures and processes.</p> <p>Adequate, competent, and motivated staff.</p> <p>An effective performance management system established and implemented.</p> <p>A robust risk management system developed and implementation rolled out.</p> <p>An integrated financial management system developed and implemented.</p>	<ul style="list-style-type: none"> <li>• Develop a mechanism for the monitoring, review, and reporting of the Strategic Plan's implementation.</li> <li>• Enhance internal audit capacity.</li> <li>• Implement an integrated human resource management system.</li> <li>• Carry out a jobs evaluation and workload analysis across the Authority's current and future functions.</li> <li>• Build staff capacity and motivation across all functions.</li> <li>• Establish a leadership development programme (LDP).</li> <li>• Establish knowledge management mechanisms/system.</li> <li>• Promote a strong value-based and performance-driven organizational culture.</li> <li>• Entrench enterprise risk-management.</li> <li>• Develop and implement quality risk-based management frameworks across all functions.</li> <li>• Automate the financial management system (FMS).</li> <li>• Enhance stewardship and accountability.</li> <li>• Develop and implement a rationalized and adjustable fee calculation model.</li> <li>• Leverage partnerships for intensified fees' collection.</li> <li>• Automate fees' collection.</li> </ul>
<p>Enhance resource mobilization and financial management.</p>	<p>15% annual internal revenue growth.</p> <p>Non-fees revenue (of an average of 5% of fees revenue) generated</p> <p>Authority's plot in area 13 developed.</p> <p>Strategic partnerships and collaboration established.</p>	<ul style="list-style-type: none"> <li>• Enhance resource mobilization capacity.</li> <li>• Mobilize resources for development of PMRA's plot and commercialize the developments.</li> <li>• Leverage partnerships in strategic areas (standards, regional, veterinary, herbal medicines, enforcement, capacity development, resource mobilization, regulators, academia).</li> </ul>

## 3.5 2023/24-2027/28 IMPLEMENTATION MATRIX

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
<b>Objective 1: Enhanced capacity for the implementation of the PMRA Act 2019</b>									
Collaborate with the MoH, MoJ and other actors for prompt gazettlement of regulations.	Lobby the relevant government ministries and agencies to fast-track the gazettlement of the regulations.	Regulations to operationalize the PMRA Act of 2019 gazetted.						DG	F & A
	Strengthen internal regulatory skills capacity	Reduced timeline for registration (months)	6	6	6	6	6	Heads of technical departments	Medicines & Pharmacy
Enhance good regulatory practices	Develop tools for effective reviews and inspections.	Tools for review of small molecules and biosimilars developed.			By Q4				
		Tools for GCP and GMP inspections developed.		By Q4				DG	F & A
	Establish regional collaborations for enhancement of regulatory functions.	No. of mutual agreements (reliance) signed.		1 MoU	1 MoU	1 MoU			
	Introduce a procedure for authorization of medicines and vaccines for emergency use.	Procedures for authorization of medicines and vaccines for emergency use developed.	Q4					Head of Registration dept.	Medicines

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Establish regulatory mechanisms for herbal medicines, nutritional supplements and medical devices.	Mapping up relevant government enforcement agencies to partner with in the regulation of herbal medicines, nutritional supplements and medical devices.	Map of all relevant government enforcement agencies for partnerships completed.	Q4					Head of Registration dept.	Allied Substances
	Develop guidelines, procedures, MOUs and other tools for collaboration with relevant partners in regulation of herbal medicines, nutritional supplements and medical devices.	Guidelines, procedures, MOU and other tools developed.							
	Establish annual schedules for regulatory enforcement activities for the herbal medicines, nutritional supplements and medical devices.	Annual schedules for regulatory enforcement activities established.							
	Identify and hire additional human resources for the regulation of herbal medicines, nutritional supplements and medical devices.	Additional human resources identified and hired.		Q2				Head of HR & Admin	F & A
Continuously develop and strategically position pharmacy practice.	Develop and publicize scopes of practice for the pharmacy profession.	Scopes of practice developed and publicized.		Q2				Head of Inspections dept.	Pharmacy Committee
	Introduce a register for specialist pharmacists.	Registered for specialist pharmacists introduced.		Q1				Head of Inspections dept.	Pharmacy Committee
	Finalize the development of standards for education and practice for pharmacists.	Standards for education and practice for pharmacists completed.		Q3				Head of Inspections dept.	Pharmacy Committee
	Enhance/review pharmacy curriculum in line with current and future needs.	No. of pharmacy curricula reviews		Q2				Head of Inspections dept.	Pharmacy Committee
	Enforce the implementation of the harmonized standards for education and practice of pharmacy.	Level of compliance with harmonized standards for education and practice of pharmacy.	100%	100%	100%	100%	100%	Head of Inspections dept.	Pharmacy Committee

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
<b>Objective 2: ISO 17025 accreditation attained by December 2023 and a QMS (ISO 9001) implemented and certification attained</b>									
Implement systematic definitions and management of regulatory processes and their interactions.	Map all the Authority's regulatory processes in relation to the QMS and identify interactions.	Clear map of the processes in relation to the QMS and their interactions.		By Q1				Head of QA dept. Head of Technical depts.	F & A
	Review processes and develop appropriate guidelines and SOPs including but not limited to those outlined in the March 2023 WHO GB Report.	Guidelines and SOPs developed.		By Q2					
		Compliance levels to SOPs' defined turnaround times for sampled processes.		80%	85%	90%	90%		
Implement appropriate documentation, archiving and information retrieval practices.	Upgrade the clinical trials, professionals, medicines and allied substances' MIS.	Upgraded, interactive and accessible clinical trials, professionals, medicines and allied substances' MIS.		By Q4				Head of Registration dept. Head of ICT	F & A
	Assess the data management situation and identify gaps.			Q1				Head of HR & Admin dept.	
Pursue ISO 17025 accreditation for the laboratory.	Develop a prioritized plan to close the documentation, archiving, security and retrieval gaps identified.	An automated data management system implemented.		Q1				Head of ICT unit	F & A & Medicines
	Respond to and close gaps arising from the preparations for the ISO 17025 audit process.	ISO 17025 accreditation attained.	Q4					Head of QA dept.	
<b>Objective 3: Decentralized systems of service delivery operationalized by 2028.</b>									

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Partner with relevant Government professionals (pharmacists, etc) to decentralize key functions (pharmacovigilance, inspections, post-market surveillance) across the country using a risk-based approach.	Map out the potential government health professionals across the country.	Map of all potential government health professionals across the country completed		By Q4				Heads of Technical depts.	Medicines & Pharmacy
	Benchmark with comparable actors e.g. the Medical Council of Malawi and map out key functions for collaboration and establish a framework for the partnerships.	Benchmark report completed (functions and partnership framework).		By Q4				Heads of depts.	
	Develop guidelines, procedures, and other tools for collaboration with relevant government professionals.	Guidelines, procedures, tools and a services' decentralization framework developed.		By Q4				Heads of depts.	
	Roll-out the partnerships, regularly review progress and take remedial action for effective execution.	Total no. of active professional partners.	14	28	42	42	Heads of Technical depts.		
Establish prioritized regional and inland port of entry offices	Establish criteria for offices' establishment.	Map of areas and criteria for establishment of offices developed	Q4					Head of HR & Admin dept.	F & A
	Map potential areas for offices' establishment using established criteria.							Head of Inspections dept.	
	Explore co-sharing/partnership options with established government actors, e.g., MBS, MRA, etc.							Head of HR & Admin	
	Open own-offices in critical areas/regions.	No. of regional offices established.		2				Head of HR & Admin	
		No. of inland ports of entry offices established.		3				Head of HR & Admin Head of Inspections	

Objective 4: Attain maturity level 2 by 2025 and maturity level 3 by 2028.

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
Implement the PMRA's IDPs from the WHO GB report.	Establish an interdepartmental team to oversee and regularly report on the implementation of the IDPs in the WHO report.	Interdepartmental team established.	Q3					DG		
	Develop a road-map for the IDPs' implementation.	Road-map for the IDPs' implementation developed.	Q3					Interdepartmental team		
	Conduct semi-annual reviews of the progress towards goals till maturity level achievement.	Maturity level achieved.			ML 2		ML 3		F & A	
Budget and mobilize resources for the WHO IDPs implementation	Cost the implementation of the WHO IDPs.	% of budget provided for the IDPs' implementation.	100	100	100	100	100	DG		
	Develop and execute a resource mobilization plan for the IDPs' budget.									

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY										
Strategies	Key Activities	KPI	2023/ 24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
<b>Objective 1: Technology mainstreamed in all key functions and operations by 2028.</b>										
Automate all key functions and operations	Develop an ICT strategy to highlight all the ICT needs and the work plan to implement the automation.	ICT strategy developed and approved		By Q1						
	Conduct capacity building for ICT staff to manage the systems.	Capacity building for ICT staff conducted.								
	Upgrade and/or acquire necessary ICT equipment (e.g. laptops, desktops, etc).	ICT equipment (as per the strategy) acquired.		By Q3					Head of HR & Admin & Head of ICT	
	Develop IT capacity (infrastructure/platforms) for online services delivery.	Capacity for online services delivery developed.		By Q4						
	Safeguard data integrity and international quality standards.	Level of compliance to data integrity and quality standards	Baseline	80%	90%	98%	98%			



STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY									
Strategies	Key Activities	KPI	2023/ 24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
<b>Objective 2: Increased level of awareness of PMRA across the country to 70% by 2028.</b>									
Conduct awareness campaigns and engagements through targeted channels (print and electronic media, physical meetings, etc).	(i) Conduct a baseline survey targeting the general public to establish the current level of awareness of PMRA and its functions.	(Baseline (2024) and bi-annual brand awareness survey (2026))	Q4			Q4		Head of HR & Admin & Head of PR	F & A
	Develop and implement an annual calendar for awareness creation through diverse channels.	Annual awareness creation calendar in place.	Q4	Q1	Q1	Q1	Q1		
	Implement brand awareness interventions as will have been identified through the brand awareness survey and the communication strategy.	No. of awareness-creation activities.	2	2	2	2	2		
	Conduct an annual forum with the pharmaceutical licence holders (manufacturers, clinical research organizations, wholesalers, retail pharmacies, medicine stores) and pharmacy professionals.	Annual forum conducted	Q4	Q4	Q4	Q4	Q4		
Partner with relevant community-based organizations, public health programmes and "goodwill ambassadors" to carry out sensitizations and public education.	Develop an annual calendar for community engagements.	Annual calendar for community engagements in place.	Q4	Q1	Q1	Q1	Q1		
	Develop a structure for engagement of goodwill ambassadors in the communities for sensitization and information sharing.	No. of goodwill ambassadors engaged.		10	15	20	28		
	Implement partnerships with public health programmes and institutions.	No. of new collaborations with public health programmes and institutions.	1	3	4	2			

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY									
Strategies	Key Activities	KPI	2023/ 24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Regularly update the public through diverse channels with lists of registered, de-registered, withdrawn, re-called medicines, allied substances, clinical trials, premises and professionals.	(i) Publish the list of registered, de-registered, withdrawn, recalled medicines, allied substances and clinical trials on quarterly basis. (ii) Establish a database which can be queried by the public for duly registered and up-to-date list of professionals, premises, medicines, allied substances and clinical trials	(i) List of registered medicines, allied substances and clinical trials published on quarterly basis. (ii) Publicly accessible database of duly registered and up-to-date products and professionals implemented.		Q1	Q1	Q1	Q1	Head of Medicines Registration dept. Head of Inspection dept. Head of ICT	
Institutionalize a flagship corporate social responsibility activity/ event	Operationalize an annual flagship CSR activity.	Annual CSR activity established and implemented.		Q4	Q4	Q4	Q4	Head of HR & Admin Head of PR	
Contract/retain the services of a public relations agency for improved publicity.	Develop ToR for a PR agency and contract services. Roll-out PR campaigns on alternate years.	PR agency contracted. Level of brand awareness.		Q2	Q2	Q2	>70%		
<b>Objective 3: A client-centric culture among all the Authority's staff built.</b>									

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
Embed client-centrism in products and service delivery of the Authority.	Review the products, services delivery and processes to identify areas of improvement.	Products reviewed done		Q1		Q1		Head of HR & Admin & Head of PR	Board Committee	
	Develop SOP and other relevant tools for customer satisfaction survey	SOP and other tools for CSS developed	Q4							
	Conduct an annual customer satisfaction survey.	Customer Satisfaction Index	80% (Q4)	80%	80%	80%	80%			
Develop and implement a customer service charter	Map all the services.							Head of HR & Admin & Head of QA	F & A	
	Establish feasible delivery TATs.	Customer Service Charter developed and communicated at all customers' touch points	Q4							
	Communicate appropriate fees.									
Implement programs to build a client-centric culture among staff	Publish the resolved customer service charter in all touch points (website, flyers and via media).							Head of HR & Admin & Head of PR	F & A	
	Conduct staff training on responsive customer service.	% of staff trained in customer service per year		100%	100%	100%	100%			
	Establish channels for customers to communicate with the Authority (hotline, e-mails, suggestion boxes, etc)	Customer hotline and suggestion boxes in place.	Q2- Boxes	Q1- Hotline						
	Incentivize outstanding service delivery	Service delivery incentives scheme established.		Q1						
	Conduct monthly customer issues/delivery meetings and implement findings	Minutes of monthly customer satisfaction review meetings.		12	12	12	12	Heads of Technical depts. Head of HR & Admin		

Objective 4: Increased access points to the Authority's services

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Develop and maintain a functional online application portal for registration of clinical trials, pharmacy professionals, pharmaceutical establishments, medicines and allied substances.	(i) Develop specifications for the portal. (ii) Procure a consultant to develop the portal. (iii) Test, publicize and fully roll-out portal usage	A fully functional online application portal for registration developed and implemented.						Heads of Technical depts. Head of HR & Admin Head of ICT	F & A

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
<b>Objective 1: Strengthened governance structures and processes.</b>										
Develop a mechanism for the monitoring, review and reporting of the Strategic Plan's implementation.	Establish a function for coordination of planning, monitoring, evaluation, research and innovation.	Planning, monitoring, evaluation, research, and innovation functions established.		Q1						
		Annual corporate scorecards developed.	By Dec 23					DG		
		Quarterly SP implementation reports presented to the Board.	Qrtly	Qrtly	Qrtly	Qrtly	Qrtly	Qrtly	Head of HR & Admin dept.	F & A
		Independently facilitated annual SP implementation review carried out.	Annual	Annual	Annual	Annual	Annual	Annual	Head of Finance dept.	
		Level of closure for identified gaps.	100%	100%	100%	100%	100%	100%		
Implement remedial measures to close gaps identified in both quarterly and annual SP implementation reports.										

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Enhance internal audit capacity.	Procure software for internal audit.	Software for internal audit procured.		Q3					
	Recruit additional internal audit human resource as per approved functional review.	Additional audit staff recruited.		Q1				Head of Internal Audit & Head of HR & Admin	F & A
	Conduct capacity building for internal audit team	Number of trainings conducted per year		1	1	1	1		
<b>Objective 2: Adequate, competent and motivated staff</b>									
Implement an integrated human resource management system.	Develop and implement a HR Strategy to guide implementation of a full-cycle talent agenda.	HR strategy developed and implemented.		Q1				Head of HR & Admin dept.	
	Assess the HR requirements across all the functions in the organization.	Job evaluation and work load analysis conducted.							
	Determine the HR gaps (number and competencies)	Level of implementation of the findings.			Q1				F & A
Carry out a jobs' evaluation and workload analysis across the Authority's current and future functions.	Review and update JDs for all the staff								
	Implement the findings of the job evaluation & work load analysis.								

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
Build staff capacity and motivation across all functions	Carry out training needs assessment aligned to the strategy and staff performance scorecards.	Annual Training Needs Assessment (TNAs) conducted	Q4	Q4	Q4	Q4	Q4		F & A	
		Annual Training Calendar in place	Q4	Q4	Q4	Q4	Q4			
		Level of implementation of TNAs' recommendations	50%	100%	100%	100%	100%			
	Facilitate staff to attend relevant skills development trainings (for both technical and administrative staff).	% of staff attending skills development training	30%	40%	50%	70%	70%			
		Approvals for CPD points awarding for internal training programs for relevant/select departments.								
	Develop and implement a team building plan.	Establish links to (seek approval for) CPD accreditation mechanisms for internal training programs for relevant/select departments.	% of staff participating in team building activities/year	90%	90%	90%	90%	90%		
			% level of employee satisfaction.	60%	65%	70%	75%	80%		
Establish a leadership development programme (LDP).	Conduct an employee satisfaction survey and implement findings.	Leadership development programme operationalized.		Q4						
		% of board members and supervisory staff developed through the programme.			30%	50%	80%			
	Establish partnerships with local, regional and international like-minded organizations to support the implementation of the leadership development programme.	No. of partnerships forged for the LDP.		1	1	1	1			

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Establish knowledge management system	Develop knowledge management mechanisms/ system.	Knowledge management mechanisms/ system developed.		Q4					
<b>Objective 3: An effective performance management system established and implemented</b>									
Promote a strong value-based and performance-driven organizational culture	Disseminate the 2023/24-2027/28 SP	Level of SP awareness among staff.	Q3						
		% of staff on strategy-linked performance management plan	100%	100%	100%	100%	100%		
	Adopt and implement an appropriate performance management system	Performance appraisals conducted/staff per year	1	2	2	2	2	Head of HR & Admin & Heads of all depts.	F & A
		% of departments with at least 1 active and well-trained change champions.		50%	100%	100%	100%		
	Build the performance management capacity of the management team and staff	% of managers/supervisors trained on performance management	100%	100%	100%	100%	100%		
<b>Objective 4: A robust risk management system developed and implementation rolled out</b>									

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES									
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee
Entrench enterprise risk-management.	Conduct org-wide risk assessment and profiling	An org-wide risk-management framework established.	Q4					Head of QA	F & A
	Develop and implement risk registers across all departments.	% of departments with updated risk registers	20%	80%	100%	100%	100%	Heads of Technical functions	
	Appoint and train risk-management champions in all departments.	% of departments with trained and active risk management champions.	20%	80%	100%	100%	100%		
	Develop (i) a business continuity and (ii) crisis management policy and plan	A (i) business continuity and (ii) crisis management policy and plan developed. (ii) Business continuity policy & plan developed. (iii) Disaster Recovery Systems and Sites established. (iv) Back-up systems and plans established.			50%	80%	100%	100%	
Develop and implement quality risk-based management frameworks across all functions.	Conduct quarterly risk review meetings for monitoring and forward risk mitigation planning	Minutes of quarterly risk review meetings	2	4	4	4	4		
	Assess and profile risks for all functions	A risk-management framework established.	Q4						
	Adopt a risk-based approach in line with the risk-management framework across all the regulatory functions.	Risk-based approach adopted	20%	80%	100%	100%	100%		



STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
<b>Objective 1: An integrated financial management system developed and implemented</b>										
Automate the financial management system (FMS)	Map all the financial processes.	Automated FMS developed and implemented.	Q4							
	Develop specifications for the financial management system.									
	Procure the FMS development services. Test and roll-out the automated FMS.		Q2							
Enhance stewardship and accountability	Develop/review policies and guidelines to strengthen internal controls.	Internal control policies developed/ reviewed.	Q1							
	Implement cost rationalization strategies.		50%	75%	90%	100%				
	Ensure value for money in procurement.		78%	75%	72%	70%		Head of Finance & Head of ICT	F & A	
Develop and implement a rationalized and adjustable fee calculation model.	(i) Review the current fee policy in line with regional and international standards.	Report on the reviewed fee policy.	Q4							
	(ii) Develop a business case for fees' adjustment model and seek approval.		10%	12%	15%	18%				
	(iii) Develop and implement a fee calculation model and tool based upon the approved case.		80%	75%	72%	70%				
<b>Objective 2: 15% annual internal revenue growth</b>										
Leverage partnerships for intensified fees' collection.	Identify loopholes for fees' collection.	MOU with complementary bodies signed.	Q4						Head of Finance	F & A
	Seek partnerships with complementary bodies for enforcement of fees' collection e.g. for professionals.									

STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT										
Strategies	Key Activities	KPI	2023/24	2024/25	2025/26	2026/27	2027/28	Responsible - Secretariat	Board Committee	
Automate fees' collection	Identify areas for fees' collection process improvement.	% increase in specific revenue streams.	Q4	Q3				Head of Finance & Head of ICT		
	Develop and implement automated fees' collection channels.									
	Publicize the automated channels.									
<b>Objective 3: Non-fees revenue (of an average of 5% of fees revenue) generated</b>										
Enhance resource mobilization capacity	Develop internal capacity for bankable proposals' writing.	(i) Interdepartmental working team on project proposal writing established.	Q4					Head of Finance	F & A	
	Respond to solicited and initiate unsolicited proposals to generate non-fees' revenue.	(ii) Total fees revenue.	5%	5%	5%	5%				
<b>Objective 4: Authority's plot in area 13 developed</b>										
Mobilize resources for development of PMRA's plot and commercialize the developments.	Set up a team to mobilize resources and oversee the development of the land.	Plot development team established	Q4					DG & Head of Finance	F & A	
	Source for funds and/or partnerships for the development -	Amount of funds raised USD 28M	Q4							
	Develop the plot.	Plot developed.				Q2				
	Commercialize the developed plot (2028).	Income generated from the commercialized developments.				Q4				
<b>Objective 5: Strategic partnerships and collaborations established</b>										
Leverage partnerships in strategic areas (standards, regional, veterinary, herbal medicines, enforcement, capacity development, source mobilization, regulators, academia)	Identify potential areas for partnerships.	Partnerships strategy developed		Q3				Head of Finance & Head of HR & Admin	F & A	
	Develop a partnerships' strategy				Q1					
	Contract competent human resource responsible for partnerships and resource mobilization.	No. of strategic partnerships forged.	1	2	2	2	2			
	Implement strategic partnerships.									

# 4 | BUDGET PROJECTIONS (2023/24-2027/28)

The following are the financial projections for the implementation of the strategic plan for the period 2023/24 to 2027/28. The projections are in USD.

ESTIMATED BUDGET FOR IMPLEMENTATION OF THE 2023/24-2027/28 STRATEGIC PLAN					
STRATEGIC PRIORITY	2023/24	2024/25	2025/26	2026/27	2027/28
1	759,500	219,050	216,000	47,000	172,500
2	131,000	439,000	183,000	198,000	140,000
3	45,000	167,700	48,500	53,500	18,500
4	95,000	83,000	23,000	3000	3000
<b>TOTAL (USD)</b>	<b>1,030,500</b>	<b>908,750</b>	<b>470,500</b>	<b>301,500</b>	<b>334,000</b>

## 5 YEARS TOTAL BY STRATEGIC ISSUE

STRATEGIC PRIORITY	2023/24-27/28 TOTAL (USD)	% OF TOTAL BUDGET
1	1,414,050	46%
2	1,091,000	36%
3	333,200	11%
4	207,000	7%
<b>TOTAL (USD)</b>	<b>3,045,250</b>	<b>100%</b>

The implementation of the Strategic Plan (2023/24-2027/28) is estimated to cost USD \$3,045,250 for the five years, over and above the standard operating budget of PMRA. From a budgetary perspective, the thrust of the 2023/24-2027/28 Strategic Plan will be Strategic Priority 1: Strengthen systems for efficient delivery of regulatory services, which takes 46 percent

of the budget, with Strategic Priority 2: Entrench client-centric systems and mainstream technology taking the next largest budget at 36 percent. Of the total budget, 24 percent (USD \$724,000) will go to ICT infrastructure development and related strategies geared toward the enhancement in quality and access of the Authority’s services.

## 5 | ORGANIZATIONAL STRUCTURE

Based on the strategic direction contemplated within this Strategic Plan and arising from the extensive consultations during the strategic planning process, human resource was identified as a strategic issue that will need to be addressed within the 2023/24-2027/28 Strategic Plan period for PMRA to effectively carry out its mandate. As part of the SP development process, the Functional Review Report approved in 2023 included an organizational structure deemed appropriate for the implementation of the Strategic Plan (2023/24-2027/28). Further, the Functional Review Report's recommendation on alternative arrangements to address human resource constraints was also considered relevant in line with the spirit of Malawi's ongoing public service reforms agenda, which advocates for lean and versatile structures for state institutions. Per the Functional Review Report, the recommended arrangements could include:

- i. Using registered pharmacists in other public institutions to support some functions on behalf of PMRA. This has already started for pharmacovigilance and some inspection functions. The Authority will continue to train registered pharmacists in public health facilities to carry out the tasks applying necessary control measures to safeguard the Authority's duty to the public's safety and its reputation.
- ii. Engaging experts from academia, research institutions, professional associations, etc., to help with specific regulatory activities.
- iii. Entrenching a risk-based approach in carrying out the Authority's function: This will entail prioritizing and streamlining work processes to enhance efficiency, with each product or facility classified according to its "risk." Under such a scheme, products and facilities classified as low risk receive less-intense scrutiny, freeing staff for high-risk targets.



Human resource was identified as a strategic issue that will need to be addressed within the 2023/24-2027/28 Strategic Plan period

- iv. Training staff to enable them to carry out several regulatory functions (multi-skilling) while ensuring that checks and balances are not compromised and accountability for the functions remains clear.
- v. Using a mixed-team approach in carrying out regulatory functions so that the available employees are fully engaged.

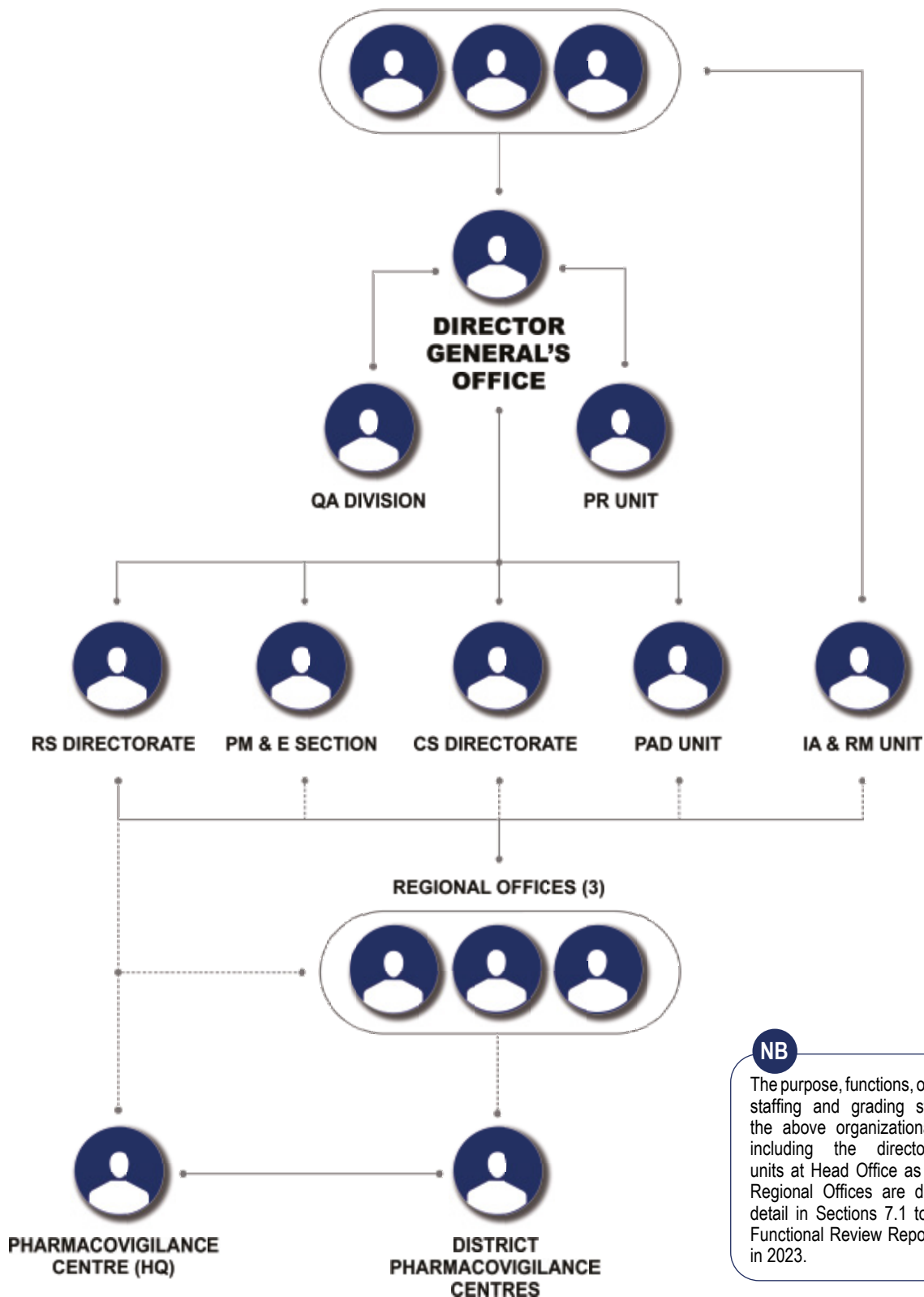
While endorsing the recommendations of the Functional Review Report, this Strategic Plan (2023/24-2027/28) emphasizes the need for the establishment and resourcing of a Planning, Monitoring and Evaluation function, the elevation of ICT by strategically positioning the head of this function within the recommended "Corporate Services" directorate, and the consideration of an in-house Legal Officer or Assistant to work with the outsourced Legal Counsel.

The recommended organizational structure per the Functional Review Report is on the following page.

## ORGANIZATIONAL STRUCTURE

(as per the Functional Review Report approved in 2023).

### BOARD OF DIRECTORS



**NB**

The purpose, functions, organization, staffing and grading structure for the above organizational structure including the directorates and units at Head Office as well as the Regional Offices are discussed in detail in Sections 7.1 to 8.5 of the Functional Review Report approved in 2023.

# 6 | KEY RISKS TO THE IMPLEMENTATION OF THE SP 2023/25-2027/28

No	Risk	Likelihood	Impact	Mitigating Measures
1	Low stakeholders' buy-in	Low	High	<ul style="list-style-type: none"> <li>Proactively advocate and lobby for the SP.</li> <li>Disseminate the SP to key stakeholders.</li> <li>Continuously engage with stakeholders</li> </ul>
2	Low visibility	Moderate	Moderate	<ul style="list-style-type: none"> <li>Establish a client/citizen engagement and feedback mechanism.</li> <li>Participate in relevant symposia.</li> <li>Establish scheduled CSR activities.</li> </ul>
3	Inadequate funding resources	High	High	<ul style="list-style-type: none"> <li>Leadership proactively implements the contemplated strategies for fee collection.</li> <li>Closely monitor income vs. expenditure.</li> <li>Employ tight controls over spending commitments.</li> <li>Diversify sources of funds.</li> <li>Develop and implement a resource mobilization plan.</li> <li>Improve service delivery to increase internal revenues.</li> </ul>
4	Unfavorable changes in the regulatory landscape	Low	High	<ul style="list-style-type: none"> <li>Institute proactive legal and regulatory scanning and engagement.</li> <li>Align policy and processes to the changing legal environment.</li> <li>Establish a legal function.</li> </ul>
5	Failure to fully implement the strategic plan	Low	Moderate	<ul style="list-style-type: none"> <li>Adopt a comprehensive implementation programme that will involve awareness creation to all staff.</li> <li>Link the SP to the annual work plans and performance contracting targets.</li> <li>Regularly review SP implementation for both control and relevance.</li> <li>Participate in the Ministry of Health medium-term budgeting process to identify its strategic direction and be strategically aligned.</li> <li>Widely disseminate the strategic plan to partners and seek their involvement in the development of annual work plans.</li> <li>Rigorously monitor and evaluate implementation status.</li> </ul>
6	Political instability in Malawi	Low	High	<ul style="list-style-type: none"> <li>Continuously scan the political landscape in Malawi.</li> <li>Implement contingency measures based on areas of operation.</li> </ul>

No	Risk	Likelihood	Impact	Mitigating Measures
7	Major project costs over-runs or disallowed costs	Moderate	High	<ul style="list-style-type: none"> <li>• Effective project specification should include creating decision points.</li> <li>• Regularly analyze budget vs. spending.</li> <li>• Develop clear, comprehensive, and well-communicated policies.</li> </ul>
8	Operational risks	High	high	<ul style="list-style-type: none"> <li>• Optimize staff establishment through recruitment of adequate and competent staff.</li> <li>• Continuously develop staff.</li> <li>• Establish a succession management plan</li> </ul>
9	Technological risks/ rapid change in technology	High	High	<ul style="list-style-type: none"> <li>• All staff embrace new technology.</li> <li>• Build staff capacity.</li> <li>• Strengthen ICT infrastructure.</li> </ul>
10	Relational challenges and mandate overlaps with other complementary institutions	Low	High	<ul style="list-style-type: none"> <li>• Pursue good relationships and collaboration with complementary bodies and proactively clarify on roles where there are potential or actual overlaps.</li> </ul>

## 7 | KEY GENERAL ASSUMPTIONS

1. PMRA's revenue generation will be stable and continue growing.
2. The macro-economic conditions will remain stable both for Malawi and the current and potential donor community.
3. All key stakeholders will buy into this Strategic Plan.
4. The political environment in Malawi will be stable and supportive of PMRA's operations.
5. The legal and regulatory landscape in Malawi will remain stable and the regulations to operationalize the PMRA Act 2019 will be enacted.
6. PMRA will get additional human resources and increase its output/efficiency.
7. Improved efficiency at PMRA following automation of key processes will increase its internal revenues and/or reduce its expenditure hence costs-savings or containment.
8. Awareness about PMRA will increase in the country and the region.
9. PMRA will initiate the process of developing its vacant land and potentially generate own-revenue within the plan period, apart from decongesting its staff.



# 8 | MONITORING AND EVALUATION

## 8.1 INTRODUCTION

The monitoring and evaluation function of this Strategic Plan will assist in assessing the progress, performance, and impact of the strategy. Its overall goal will be to provide quality information related to the performance of PMRA in line with the set targets as well as the continued relevance of the strategic plan to result in timely and appropriate decisions. Monitoring and evaluation form the basis of any modification of interventions and verification of the quality of the activities being conducted.

The M&E framework consists of responsibilities, key performance indicators, timelines, and budgets as defined in the Implementation Matrix and the Budget of this Strategic Plan.

## 8.2 M&E ROLES AND RESPONSIBILITIES

The responsibilities for monitoring this plan are based on the following guidelines:

- It is the ultimate responsibility of the Director to monitor the overall performance of PMRA in the implementation of this Strategic Plan.
- It is the responsibility of the senior management team, including heads of departments, to monitor the performance of their areas of jurisdiction in implementing this Strategic Plan.
- The Strategic Plan recommends the recruitment of a Planning, Monitoring, and Evaluation Officer to work with a Strategic Plan Monitoring and Evaluation Team (SPMET), whose responsibilities will be to:
  - a. Develop a reporting template and other M&E tools.
  - b. Collect/receive reports and analyze,

consolidate, summarize, and forward them on a timely basis to the respective heads, per specific timelines.

- c. Develop mid-term, end-term, and ad hoc evaluations.
- d. Report on performance contract targets.

## 8.3 INDICATORS AND OUTPUTS

The targets will be on:

- Objectives in the Implementation Matrix.
- Activities in the Implementation Matrix

## 8.4 COLLECTION AND MAINTENANCE OF PERFORMANCE DATA

- i. The performance data on each indicator will be identified.
- ii. Collection of monitoring data will be done on a continuous basis.
- iii. A database for maintaining this data will be established.

## 8.5 REPORTING

The SPMET will submit reports on a quarterly and annual basis to the designated Senior Management team member in-charge of performance management after analyzing, summarizing and consolidating all the reports after which he/she will escalate the reports or sections thereof to the Board through the relevant Board Committee for appropriate action.

## 8.6 EVALUATIONS

- i. An end-of-year evaluation of the implementation of the Strategic Plan will be part of the development of the following year's annual operational plan.

- ii. In case of significant unexplained variation in performance, especially on critical performance areas (either positive or negative), PMRA's leadership will take appropriate action. This may include a deeper interrogation and adjustment on the relevance of the Strategic Plan and the contemplated deliverables.
- iii. A mid-term evaluation will on the implementation of this Strategic Plan will be facilitated by an external evaluator/consultant around September or October 2025.
- iv. An end-term evaluation will occur at the end of the plan period as part of the development of the subsequent Strategic Plan.

# ANNEXES

## ANNEX 1: FIRST-YEAR (2023/24) OPERATIONAL PLAN

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES					Key Performance Indicators			
Strategies	Activities	2023/24				Key Performance Indicators		
		Q1	Q2	Q3	Q4			
<b>Objective 1: Enhanced capacity for the implementation of the PMRA Act 2019</b>								
Collaborate with the MoH, MoJ and other actors for prompt gazettlement of regulations.	Lobby the relevant Government ministries and agencies to fast-track the gazettlement of the regulations.	✓	✓	✓	✓	Regulations to operationalize the PMRA Act of 2019 gazette.		
Enhance good regulatory practices	Strengthen internal regulatory skills capacity	✓	✓	✓	✓	Reduced timeline for registration.		
Establish regulatory mechanisms for herbal medicines, nutritional supplements and medical devices.	Mapping up relevant government enforcement agencies to partner with in the regulation of herbal medicines, nutritional supplements and medical devices.			✓	✓	Map of all relevant government enforcement agencies for partnerships completed.		
Continuously develop and strategically position pharmacy practice.	Enforce the implementation of the harmonized standards for education and practice of pharmacy.	✓	✓	✓	✓	Level of compliance with harmonized standards for education and practice of pharmacy.		
<b>Objective 2: ISO 17025 accreditation attained by December 2023 and a QMS (ISO 9001) implemented and certification attained</b>								
Pursue ISO 17025 accreditation for the laboratory.	Respond to and close gaps arising from the preparations for the ISO 17025 audit process.				✓	ISO 17025 accreditation attained.		
<b>Objective 3: Decentralized systems of service delivery operationalized by 2028.</b>								
Establish prioritized regional and inland port of entry offices	Establish criteria for offices' establishment.				✓	Map of areas and criteria for establishment of offices developed.		
	Map potential areas for offices' establishment using established criteria.				✓			
	Explore co-sharing/partnership options with established Government actors e.g. MBS, MRA, etc.				✓			
<b>Objective 4: Attain maturity level 2 by 2025 and maturity level 3 by 2028.</b>								
Implement the PMRA's IDPs from the WHO GB report.	Establish an interdepartmental team to oversee and regularly report on the implementation of the IDPs in the WHO report.			✓		Interdepartmental team established.		
	Develop a road-map for the IDPs' implementation.			✓		Road-map for the IDPs implementation developed.		

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
	Conduct semi-annual reviews of the progress towards goals till maturity level achievement.			✓		Maturity level achieved.
Budget and mobilize resources for the WHO IDPs implementation.	Cost the implementation of the WHO IDPs.					% of budget provided for the IDPs implementation.
	Develop and execute a resource mobilization plan for the IDPs' budget.					

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
<b>Objective 1: Technology mainstreamed in all key functions and operations by 2028.</b>						
Automate all key functions and operations	Conduct capacity building for ICT staff to manage the systems.	✓	✓	✓	✓	Capacity building for ICT staff conducted.
	Safeguard data integrity and international quality standards.	✓	✓	✓	✓	Level of compliance to data integrity and quality standards (baseline established)
<b>Objective 2: Increased level of awareness of PMRA across the country to 70% by 2028.</b>						
Conduct awareness campaigns and stakeholders' engagements through targeted channels (print and electronic media, physical meetings, etc).	Conduct a baseline survey targeting the general public to establish the current level of awareness of PMRA and its functions.				✓	Baseline brand awareness survey conducted
	Develop and implement an annual calendar for awareness creation through diverse channels.				✓	Annual awareness creation calendar in place.
	Implement brand awareness interventions as will have been identified through the brand awareness survey and the communication strategy.			✓	✓	No. of awareness-creation activities.
	Conduct an annual forum with the pharmaceutical licence holders (manufacturers, clinical research organizations, wholesalers, retail pharmacies, medicine stores) and pharmacy professionals.				✓	Annual forum conducted.

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
Partner with relevant community-based organizations, institutions, public health programmes and "goodwill ambassadors" to carry out sensitizations and public education.	Develop an annual calendar for community engagements.				✓	Annual calendar for community engagements in place.
	Implement partnerships with public health programmes and institutions.				✓	No. of new collaborations with public health programmes and institutions.
<b>Objective 3: A client-centric culture among all the Authority's staff built.</b>						
Embed client-centrism in products and service delivery of the Authority.	Develop SOP and other relevant tools for customer satisfaction survey.				✓	SOP and other tools for CSS developed
	Conduct an annual customer satisfaction survey.				✓	Customer Satisfaction Index
Develop and implement a customer service charter.	Map all the services.				✓	Customer Service Charter developed and communicated at all customers' touch points.
	Establish feasible delivery TATs.				✓	
	Communicate appropriate fees.				✓	
	Publish the resolved customer service charter in all touch points (website, flyers and via media).				✓	
Implement programs to build a client-centric culture among staff.	Establish channels for customers to communicate with the Authority (hotline, e-mails, suggestion boxes, etc) – Boxes in Year 1 (Q2)		✓			Customer hotline and suggestion boxes in place.

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
<b>Objective 1: Strengthened governance structures and processes.</b>						
Develop a mechanism for the monitoring, review and reporting of the Strategic Plan's implementation.	Develop annual corporate scorecards (work plans) derived from the strategic plan.			✓		Annual corporate scorecards developed.

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
	Prepare and present quarterly SP implementation reports to the Board.		✓	✓		Quarterly SP implementation reports presented to the Board.
	Conduct and document annual SP reviews (ideally facilitated by an independent resource person).			✓		Independently facilitated annual SP implementation review carried out.
	Implement remedial measures to close gaps identified in both quarterly and annual SP implementation reports.			✓		Level of closure for identified gaps.
<b>Objective 2: Adequate, competent and motivated staff.</b>						
Build staff capacity and motivation across all functions.	Carry out training needs assessment aligned to the strategy and staff performance scorecards.			✓		Annual TNAs conducted
						Annual Training Calendar in place
						Level of implementation of TNAs' recommendations
	Facilitate staff to attend relevant skills development trainings (for both technical and administrative staff).			✓		% of staff attending skills development training.
	Develop and implement a team building plan.	✓	✓	✓		% of staff participating in team building activities/year
	Conduct an employee satisfaction survey and implement findings.				✓	% level of employee satisfaction.
<b>Objective 3: An effective performance management system established and implemented.</b>						
Promote a strong value-based and performance-driven organizational culture.	Disseminate the 2023/24-2027/28 SP			✓		Level of SP awareness among staff.
	Adopt and implement an appropriate performance management system	✓	✓	✓		% of staff on strategy-linked performance management plan
					✓	Performance appraisals conducted/staff per year

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
	Build the performance management capacity of the management team and staff.	✓	✓	✓	✓	% of managers/supervisors trained on performance management.
Objective 4: A robust risk management system developed and implementation rolled out						
Entrench enterprise risk-management.	Conduct org-wide risk assessment and profiling				✓	An org-wide risk-management framework established.
	Develop and implement risk registers across all departments.	✓	✓	✓	✓	% of departments with updated risk registers
	Appoint and train risk-management champions in all departments.	✓	✓	✓	✓	% of departments with trained and active risk management champions.
	Conduct quarterly risk review meetings for monitoring and forward risk mitigation planning.			✓	✓	Minutes of quarterly risk review meetings.
Develop and implement quality risk-based management frameworks across all functions.	Assess and profile risks for all functions				✓	A risk-management framework established.
	Adopt a risk-based approach in line with the risk-management framework across all the regulatory functions.			✓	✓	Risk-based approach adopted

STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
Objective 1: An integrated financial management system developed and implemented						
Automate the financial management system.	Map all the financial processes.				✓	Map of all financial processes developed.
	Develop specifications for the financial management system.				✓	Specifications of the FMS developed.
Enhance stewardship and accountability.	Implement cost rationalization strategies.	✓	✓	✓	✓	Cost to revenue ratio
	Ensure value for money in procurement.	✓	✓	✓	✓	% savings in expenditure vs. budget
Develop and implement a rationalized and adjustable fee calculation model.	Review the current fee policy in line with regional and international standards.				✓	Report on the reviewed fee policy.

STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT						
Strategies	Activities	2023/24				Key Performance Indicators
		Q1	Q2	Q3	Q4	
<b>Objective 2: 15% annual internal revenue growth.</b>						
Leverage partnerships for intensified fees' collection.	Identify loopholes for fees' collection.					MOU with complimentary bodies signed.
	Seek partnerships with complimentary bodies for enforcement of fees' collection e.g. for professionals.					
Automate fees' collection.	Identify areas for fees' collection process improvement.					% increase in specific revenue streams.
	Develop and implement automated fees' collection channels.					
	Publicize the automated channels.					
<b>Objective 3: Non-fees revenue (of an average of 5% of fees revenue) generated.</b>						
Enhance resource mobilization capacity.	Develop internal capacity for bankable proposals' writing.					(i) Interdepartmental working team on project proposal writing established. (ii) Total fees revenue.
	Respond to solicited and initiate unsolicited proposals to generate non-fees' revenue.	✓	✓	✓	✓	
<b>Objective 4: Authority's plot in area 13 developed.</b>						
Mobilize resources for development of PMRA's plot and commercialize the developments.	Set up a team to mobilize resources and oversee the development of the land.					Plot development team established.
<b>Objective 5: Strategic partnerships and collaborations established.</b>						
Leverage partnerships in strategic areas (standards, regional, veterinary, herbal medicines, enforcement, capacity development, source mobilization, regulators, academia).	Contract competent human resource responsible for partnerships and resource mobilization.					No. of strategic partnerships forged.



## ANNEX 2: MONITORING AND EVALUATION FRAMEWORK

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
<b>Objective 1: Enhanced capacity for the implementation of the PMRA Act 2019.</b>												
Regulations to operationalize the PMRA Act of 2019 gazetted.	-	By Q4										
Reduced timeline for registration (months).		6		6		6		6		6		6
Tools for review of small molecules and biosimilars developed.	-					By Q4						
Tools for GCP and GMP inspections developed.	-											
No. of mutual agreements (MOUs) signed.	-			1		1		1		1		
Procedures for authorization of medicines and vaccines for emergency use developed.	-	By Q4										
Map of all relevant government enforcement agencies for partnerships completed.	-	By Q4										
Guidelines, procedures, MOU and other tools developed.	-					By Q4						
Annual schedules for regulatory enforcement activities established.	-					Annual		Annual		Annual		Annual
Additional human resources identified and hired.	54							By Q2				
Scopes of practice developed and publicized.	None							Q2				
Register for specialist pharmacists introduced.	None							Q1				
Standards for education and practice for pharmacists completed.	-							Q3				
No. of pharmacy curricula reviews.	-							Q2				Q1
Level of compliance with harmonized standards for education and practice of pharmacy.	-	100%						100%		100%		100%
<b>Objective 2: ISO 17025 accreditation attained by December 2023 and a QMS (ISO 9001) implemented and certification attained</b>												
Clear map of the processes in relation to the QMS and their interactions.	-							By Q1				
Guidelines and SOPs developed.	-							By Q2				
Compliance levels to SOPs' defined turnaround times for sampled processes.	-							80%		85%		90%

STRATEGIC PRIORITY 1: STRENGTHEN SYSTEMS FOR EFFICIENT DELIVERY OF REGULATORY SERVICES												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
Upgraded, interactive and accessible clinical trials, professionals, medicines and allied substances' MIS.	-			By Q4								
An automated data management system implemented.	-			Q1								
ISO 17025 accreditation attained.	-	Q3										
<b>Objective 3: Decentralized systems of service delivery operationalized by 2028.</b>												
Map of all potential government health professionals across the country completed.	-			By Q4								
Benchmark report completed (functions and partnership framework).	-			By Q4								
Guidelines, procedures, tools and a services' decentralization framework developed.	-			By Q4								
Total no. of active professional partners.				14		28		42			42	
Map of areas and criteria for establishment of offices developed.	-	By Q4										
No. of regional offices established.	0			2								
No. of inland ports of entry offices established.	0			3								
<b>Objective 4: Attain maturity level 2 by 2025 and maturity level 3 by 2028.</b>												
Interdepartmental team established.	-	Q3										
Road-map for the IDPs implementation developed.	-	Q3										
Maturity level achieved.	ML 1			ML 2		ML 3						
% of budget provided for the IDPs implementation.	-	100%		100%		100%		100%		100%		

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
<b>Objective 1: Technology mainstreamed in all key functions and operations by 2028.</b>												
ICT strategy developed and approved	-			By Q1								
Capacity building for ICT staff conducted.	-	By Q4		By Q4		By Q4		By Q4		By Q4		
ICT equipment (as per the strategy) acquired.	-			By Q3								
Capacity for online services delivery developed.	-			By Q4								
Level of compliance to data integrity and quality standards	-	Baseline		80%		90%		98%		98%		
<b>Objective 2: Increased level of awareness of PMRA across the country to 70% by 2028.</b>												
(Baseline (2024) and bi-annual brand awareness survey (2026)	-	Q4						Q4				
Annual awareness creation calendar in place.	-	Q4		Q1		Q1		Q1		Q1		
No. of awareness-creation activities.	-	2		2		2		2		2		

STRATEGIC PRIORITY 2: ENTRENCH CLIENT-CENTRIC SYSTEMS AND MAINSTREAM TECHNOLOGY													
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28			
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual		
Annual forum conducted.	-	Q4		Q4		Q4		Q4		Q4			
Annual calendar for community engagements in place.	-	Q4		Q1		Q1		Q1		Q1			
No. of goodwill ambassadors engaged.	-		10	10		15		20		28			
No. of new collaborations with public health programmes and institutions.	-	1		3		4		2					
(i) List of registered medicines, allied substances and clinical trials published on quarterly basis.	-	-		Q1		Q1		Q1		Q1			
(ii) Publicly accessible database of duly registered and up-to-date products and professionals implemented.	-	-		Q4		Q4		Q4		Q4			
Annual CSR activity established and implemented.	-	-		Q2		Q2		Q2		Q2			
PR agency contracted.	-	-											
Level of brand awareness.	-	-				>70%				>70%			
<b>Objective 3: A client-centric culture among all the Authority's staff built.</b>													
Products review conducted	-			Q1				Q1					
SOP and other tools for CSS developed	-	Q4											
Customer Satisfaction Index	-	80% (Q4)		80%		80%		80%		80%			
Customer Service Charter developed and communicated at all customers' touch points.	-	Q4											
% of staff trained in customer service per year	-			100%		100%		100%		100%			
Customer hotline and suggestion boxes in place.	-	Q2 (Boxes)		Q1 (Hotline)									
Service delivery incentives scheme established.	-					Q1							
Minutes of monthly customer satisfaction review meetings.	-			12		12		12		12			
<b>Objective 4: Increased access points to the Authority's services</b>													
A fully functional online application portal for registration developed and implemented.	-							X					

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES													
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28			
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual		
<b>Objective 1: Strengthened governance structures and processes.</b>													
Planning, Monitoring, Evaluation, research and innovation function established.	-			Q1									

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
Annual corporate scorecards developed.	-	By Dec 23										
Quarterly SP implementation reports presented to the Board.	-	4		4		4		4		4		
Independently facilitated annual SP implementation review carried out.	-	Annual		Annual		Annual		Annual		Annual		
Level of closure for identified gaps.	-	100%		100%		100%		100%		100%		
Software for internal audit procured	-			Q3								
Additional audit human resource recruited.	-			Q1								
Number of trainings conducted	-			4		4		4		4		
<b>Objective 2: Adequate, competent and motivated staff</b>												
HR strategy developed and implemented.	-			Q1								
Job evaluation and work load analysis conducted.	-			Q1		Q1						
Level of implementation of the findings.	-					Q1						
Annual TNAs conducted	-	Q4		Q4		Q4		Q4		Q4		
Annual Training Calendar in place	-	Q4		Q4		Q4		Q4		Q4		
Level of implementation of TNAs' recommendations	-	50%		100%		100%		100%		100%		
% of staff attending skills development training.	-	30%		40%		50%		70%		70%		
Approvals for CPD points awarding for internal training programs for relevant/select departments.	-			Q4								
% of staff participating in team building activities/year	-	90%		90%		90%		90%		90%		
% level of employee satisfaction.	-	60%		65%		70%		75%		80%		
Leadership development programme operationalized.	-			Q4								
% of board members and supervisory staff developed through the program.	-					30%		50%		80%		
No. of partnerships forged for the LDP.	-					1		1		1		
Knowledge management mechanisms/system developed.	-			Q4								
<b>Objective 3: An effective performance management system established and implemented</b>												
Level of SP awareness among staff.		Q3										
% of staff on strategy-linked performance management plan		100%		100%		100%		100%		100%		
Performance appraisals conducted/staff per year		1		2		2		2		2		
% of departments with at least 1 active and well-trained change champions.				50%		100%		100%		100%		

STRATEGIC PRIORITY 3: ESTABLISH FIT-FOR-PURPOSE GOVERNANCE, HUMAN RESOURCE AND ORGANIZATIONAL DEVELOPMENT STRUCTURES												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
% of managers/supervisors trained on performance management.		100%		100%		100%		100%		100%		
<b>Objective 4: A robust risk management system developed and implementation rolled out</b>												
An org-wide risk-management framework established.	-	Q4										
% of departments with updated risk registers	-	20%		80%		100%		100%		100%		
% of departments with trained and active risk management champions.	-	20%		80%		100%		100%		100%		
A (i) business continuity and (ii) crisis management policy and plan developed.	-			BC & CM policies and plans		DRS & Sites		Back-up System				
(iii) Disaster Recovery Systems and Sites established.	-											
(iv) Back-up systems and plans established.	-											
Minutes of quarterly risk review meetings.	-	2		4		4		4		4		
A risk-management framework established.	-	Q4										
Risk-based approach adopted	-	20%		80%		100%		100%		100%		

STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT												
Measure of Success	Base-line	2023/24		2024/25		2025/26		2026/27		2027/28		
		Target	Actual	Target	Actual	Target	Actual	Target	Actual	Target	Actual	
<b>Objective 1: An integrated financial management system developed and implemented.</b>												
Financial processes mapped	-	Q4										
Specifications for the FMS developed	-	Q4										
FMS development services procured	-			Q2								
FMS tested and fully rolled-out	-			Q3								
Internal control policies developed/reviewed.	-			Q1								
Reduction in major finance non-conformities.	-	80%		50%		75%		90%		100%		
Cost to revenue ratio	-	10%		78%		75%		72%		70%		
% savings in expenditure vs. budget	-	Q4		12%		15%		18%		20%		
Report on the reviewed fee policy.	-			Q3								
Approved business case for fees' adjustment.	-											
Adjustable fees' calculation tool/model developed and implemented.	-					Q1						
<b>Objective 2: 15% annual internal revenue growth</b>												
MOU with complimentary bodies signed.	-	Q4										
% increase in specific revenue streams.	-	Q4		Q3								

STRATEGIC PRIORITY 4: ENHANCE RESOURCE MOBILIZATION AND FINANCIAL MANAGEMENT						
Measure of Success	Base-line	2023/24	2024/25	2025/26	2026/27	2027/28
<b>Objective 3: Non-fees revenue (of an average of 5% of fees revenue) generated.</b>						
Interdepartmental working team on project proposal writing established.	-	Q4				
% of total fees revenue.	-	5%	5%	5%	5%	5%
<b>Objective 4: Authority's plot in area 13 developed.</b>						
Plot development team established.	-	Q4				
Amount of funds raised	-		USD 28m			
Plot developed.	-					Q2 Q4
Income generated from the commercialized developments.	-					
<b>Objective 5: Strategic partnerships and collaborations established.</b>						
Potential areas of partnerships developed.	-		Q3			
Partnerships strategy developed.	-			Q1		
No. of strategic partnerships forged.	-	1	2	2	2	2





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