ZAMBIA MEDICINES REGULATORY AUTHORITY

2022-2026 STRATEGIC PLAN

Prepared by:

Zambia Medicines Regulatory Authority in collaboration with Management Development Division, Cabinet Office

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TABLE OF CONTENTS

ACRONYMS

AMA	African Medicines Agency
BSC	Balanced Scorecard
CEO	Chief Executive Officer
CRO	Clinical Research Organisation
DG	Director-General
8NDP	Eighth National Development Plan
GCP	Good Clinical Practice
ICT	Information and Communication Technology
IRIMS	Integrated Regulatory Information Management System
ISO	International Organisation for Standardisation
IA	Institutional Assessment
MA	Marketing Authorisation
MASA	Medicines and Allied Substances Act
M&E	Monitoring and Evaluation
NDQCL	National Drug Quality Control Laboratory
NHSP	National Health Strategic Plan
OD	Organisational Development
PESTEL	Political, Economic, Social, Technological, Environmental and Legal
SMART	Specific, Measurable, Achievable, Realistic and Time bound
SP	Strategic Plan
SWOT	Strength, Weakness, Opportunity and Threat
USAID	United States of America International Development
WHO	World Health Organisation
ZAMRA	Zambia Medicines Regulatory Authority

BOARD CHAIRPERSON'S REMARKS

I am pleased to unveil the third Zambia Medicines Regulatory Authority (ZAMRA) Strategic Plan for the period 2022 to 2026. This Strategic Plan provides the strategic direction for ZAMRA in executing its mandate.

The Plan was developed through a robust consultative process with involvement of both external and internal stakeholders, thus giving them a significant stake in the strategic intent of the Authority. The participation of staff did not only build impetus and commitment but also enhanced ownership and accountability.

A two-phased approach was used in developing the Strategic Plan, comprising of Institutional Assessment and Organisational Development, underpinned by the Balanced Scorecard principles. The Institutional Assessment involved undertaking a Performance Assessment, conducting an internal capability assessment to establish the Authority's distinctive competencies, as well as, analysing the macro-environment.

The vision to be pursued by the Authority during this Strategic Plan period is to be: "A credible regulator ensuring the protection of human and animal health". To realise this vision, the Authority identified three thematic areas of focus and which are; Institutional capacity; Regulatory service excellence and Stakeholder Management.

As a Board, we are fully dedicated to supporting the implementation of this Strategic Plan and undertake to work with all stakeholders to ensure that the strategic objectives are actualised.

Finally let me extend my sincere gratitude to the Board Members for their valuable support and guidance given during the time of developing the Strategic Plan. I also wish to take this opportunity to commend all those who gave their vital input and more specifically members of staff who worked diligently to produce this Strategic Plan

Robert Simeza SC
BOARD CHAIRPERSON

DIRECTOR-GENERAL

The ZAMRA Strategic Plan for 2022-2026 has been formulated to effectively and efficiently execute the Authority's regulatory functions at both National and International levels. This is in line with the Eighth National Development Plan (8NDP) and the 2022 to 2026 National Health Strategic Plan (NHSP).

To ensure that all medicines and allied substances conform to the set standards of quality, safety and efficacy throughout the supply chain, the strategic Plan provides an operational framework which forms a critical component in the Authority's execution of its mandate. The Plan clearly spells out ZAMRA's strategic focus in its vision, mission, core values, objectives and Strategies.

The Plan's intended Strategic results are; to attain effective and efficient service delivery; ensure that all clients comply to set standards and regulations; and enhance public confidence in the role of the Authority.

These strategic results will be accomplished through attainment of the following objectives:

a. Enhance regulatory functions;
b. Improve stakeholder collaboration;
c. Increase revenue base;
d. Improve resources stewardship;
e. Improve operational efficiency;
f. Improve Tools, Equipment and infrastructure;
g. Improve work culture;
h. Improve staff competences; and
i. Improve Organisational Structure.

I am confident that this Plan will propel our aspirations of attaining the WHO bench marking, ISO 9001:2015 certification and ISO 17025:2017 accreditation.

It is my sincere belief that, given the support of all stakeholders and indeed the commitment of ZAMRA Board and staff, the objectives set out in this Strategic Plan will be attained and thus contribute to the realisation of the Authority's mission statement which is to "effectively regulate medicines and allied substances for quality, safe and efficacious medical products on the Zambian market".

Makomani Siyanga (Mr)
ACTING DIRECTOR-GENERAL

ACKNOWLEDGEMENTS

The Authority would like to express sincere gratitude to the Board for entrusting us with the responsibility of developing the Strategic Plan and for its continued guidance and insights during the entire strategic planning process.

We would like to extend a deep note of thanks to the staff and external stakeholders who contributed to the development of this strategic plan. The Authority is grateful to them for generously investing their time, energy and ideas in ensuring that the development of the Plan became a reality.

A debt of gratitude is specially owed to the core strategic planning team who tirelessly devoted their time and efforts in ensuring completion of this Strategic Plan.

EXECUTIVE SUMMARY

The Zambia Medicines Regulatory Authority (ZAMRA) is mandated by the Medicines and Allied Substance Act No. 3 of 2013 to ensure that medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

This Strategic Plan provides the strategic direction for ZAMRA in executing its mandate for the period 2022 to 2026.

The methodology used to develop the ZAMRA Strategic Plan involved a two-phased approach comprising the Institutional Assessment and Organisational Development underpinned by the Balanced Scorecard principles. The Institutional Assessment involved undertaking a Performance Assessment, conducting an internal capability assessment to establish the Zambia Medicines Regulatory Authority's distinctive competencies, as well as, analysing the macro-environment. The McKinsey 7s Model, Lewin's Simple Change Management Model, Objective and Problem Trees, SWOT and PESTEL Analyses were used in the assessment.

Based on these analyses ZAMRA has set out a strategic operational framework for the period 2022 to 2026 comprising the following:

Vision: "A credible regulator ensuring the protection of human and animal health".

To realise the vision, the Authority has identified three thematic areas of focus and their related strategic results as follows:

a) **Theme** Institutional Capacity **resulting** in effective and efficient service delivery

b) **Theme** Regulatory Service Excellence **resulting** in all clients complying to set standards and regulations; and

c) **Theme** Stakeholder Management **resulting** in resulting in public confidence in the role of the Authority

To ensure that the Authority performs well in the three thematic areas, it has set for itself a **Mission,** which *is* **"**To effectively regulate medicines and allied substances for quality, safe and efficacious medical products on the Zambian market".

In executing the mission, the Authority has committed to observing the following Core Values, namely; customer focus, ingenuity, integrity, excellence, transparency, teamwork and impartiality.

The following objectives will be used to improve service delivery:

a) Enhance regulatory functions;
b) Improve stakeholder collaboration;
c) Increase revenue base;
d) Improve resources stewardship;
e) Improve operational efficiency;
f) Improve Tools, Equipment and infrastructure;
g) Improve work culture;
h) Improve staff competences; and
i) Improve Organisational Structure.

To facilitate implementation, the Strategic Plan will be operationalised through costed Annual Departmental and Individual work plans. In order to ensure successful implementation and realisation of the desired impact, the implementation of the Plan will be monitored continuously, to undertake necessary interventions. At the end of the plan period, a final review will be undertaken to establish the extent of the Strategic Plan implementation and its impact.

1. INTRODUCTION

1.2 Background

The Zambia Medicines Regulatory Authority (ZAMRA) was established through the Medicines and Allied Substances Act (No. 3) of 2013 as a body corporate with perpetual succession, and a common seal capable of suing and of being sued in its corporate name, and with powers, subject to the provisions of the Act to do all such things as a body corporate may by law do or perform.

ZAMRA's Strategic Plan for the period of 2022 to 2026 builds on the foundations laid down by previous strategies. The vision and mission, respond to the need to modify, refocus, and build capacity to meet existing and new challenges and opportunities.

This Plan presents the key priorities that the Authority will focus on over the next five years;

a) Strengthening institutional capacity to deliver the required services;
b) Collaboration and partnerships with other agencies both locally and internationally to leverage synergies;
c) Strengthening institutional sustainability; and
d) Enhancing internal operational systems.

1.3 Statutory Mandate

The Zambia Medicines Regulatory Authority was established under the Medicines and Allied Substances Act No.3 of 2013 and is mandated to ensure that medicines and allied substances being made available to the Zambian people consistently meet the set standard of quality, safety and efficacy. To achieve this mandate, ZAMRA has put in place an efficient and effective regulatory system that meets the highly varied expectations of our stakeholders.

1.4 Specific Functions

Section 5 of the Medicines and Allied Substances Act, No. 3 of 2013 provides for the following functions of the Authority:

a) grant pharmaceutical licences and marketing authorisations;
b) 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 this Act;
c) regulate and control the manufacture, importation, exportation, distribution and sale of medicines and allied substances;
d) regulate and control the advertising and promotion of medicines and allied substances;
e) register and regulate pharmacies, health shops and agro-veterinary shops;
f) in consultation with the relevant professional bodies, establish, maintain and develop standards for the operation of pharmacies, health shops and agro-veterinary shops;
g) serve and protect the public interest in all matters relating to the sale of medicines and allied substances;
h) regulate and monitor the conduct of clinical trials;
i) establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances;
j) conduct post-marketing surveillance;
k) establish, maintain and enforce standards for drug quality control laboratories;
l) advise the Minister on policies relating to the regulation and control of medicines and allied substances;
m) collaborate with corresponding medicines regulatory authorities in other countries;
n) in consultation with relevant research institutions, determine national priorities in pharmaceutical research; and
o) do all such things as are connected with, or incidental to, the functions of the Authority under the Act.

1.5 Management and Operational Structure

The Board provides strategic oversight to the Authority, in the execution of ZAMRA's mandate by:

a) reviewing policy and strategic direction of the Authority;
b) overseeing implementation and successful operation of the policy and functions of the Authority;
c) approving the annual budget and plans of the Authority;
d) monitoring and evaluating the performance of the Authority against budgets and plans;
e) establishing and issuing guidelines and standards; and
f) establishing and approving rules and procedures for the appointment, discipline, termination and terms and conditions of service of the staff of the Authority.

For operations, the Authority is headed by the Director-General (DG) who is the Chief Executive Officer (C.E.O) appointed by the Board provides oversight on the day to day operations. The Director-General is supported by three (3) Directors responsible for Medicines Control, Corporate Services and Laboratory Services.

ZAMRA has its head office in Lusaka off Kenneth Kaunda Airport Road and currently has regional offices in Chipata and Ndola and sub-regional offices in Kasama, Livingstone and Solwezi. It also has offices at the ports of entry in Chirundu, Kenneth Kaunda Airport and Nakonde.

1.6 Strategic Operational Linkages

The Authority collaborates with the following Government Ministries, Departments and other Institutions as it carries out its mandate:

1. Ministry of Justice
2. Ministry of Health
3. Ministry of Livestock and Fisheries
4. Zambia Revenue Authority
5. Zambia Environmental Management Agency

6. Drug Enforcement Commission
7. Health Professionals Council of Zambia
8. Veterinary Association of Zambia
9. Veterinary Council of Zambia
10. Pharmaceutical Society of Zambia
11. USAID
12. World Health Organisation
13. Global Fund
14. European Union
15. Zambia Bureau of Standards
16. Zambia Police
17. National Health Research Authority
18. National Prosecutions Authority
19. Anti-Corruption Commission

The main area of collaboration includes; policy, enforcement, quality assurance, technical and financial support.

1.7 Rationale for Developing the 2022 – 2026 Strategic Plan

The development of the ZAMRA 2022 – 2026 Strategic Plan (SP) provides for the attainment of the next milestone towards realising the Authority's vision of being a credible regulator in ensuring the protection of human and animal health. The Strategic Plan has been developed with emphasis on the Authority's responsibility to contribute to national development by aligning it to the Eighth National Development Plan (8NDP) and the dictates of the 2022 -2026 National Health Strategic Plan (NHSP).

1.8 Methodology

The strategic planning approach used to develop the 2022 - 2026 Strategic Plan is the integrated Institutional Assessment/Organisation Development – Balanced Scorecard (IA/OD-BSC). The IA/OD BSC is a two-phased approach that takes into consideration a critical analysis of the Zambia Medicines Regulatory Authority 's operations including its achievements and challenges with proposed recommendations for improved performance.

The first phase, the Institutional Assessment (IA) involved conducting an internal capability assessment to establish ZAMRA's distinctive competencies, as well as, analysing the macro-environment. The various tools applied were the McKinsey 7s Model; Objective and Problem Trees; Strengths, Weaknesses, Opportunities and Threats (SWOT); and Political/Policy, Economic, Social, Technological, Environmental/Ecological and Legal (PESTEL) Analyses. In addition, various stakeholders were engaged to solicit for information on the current and future outlook of the Institution and to suggest areas of focus to enhance the execution of the Authority's mandate.

The second phase, the Organisation Development (OD) involved determining the strategic direction of the Institution. The information collected from the Institutional Assessment facilitated the Organisational Development process of determining the strategic direction for ZAMRA for the period 2022 – 2026 in relation to its Vision, Mission, Core Values, Strategic Themes and Strategic Objectives. The strategic direction was based on the Balanced Scorecard (BSC) principles, which takes a holistic approach in mapping the strategic direction and provides a framework for measuring the performance of an institution.

The Strategic Plan was developed with technical support from Management Development Division of Cabinet Office and spearheaded by a Core Team composed of members of staff from all the Departments and Units of ZAMRA.

2. ENVIRONMENTAL ANALYSIS

2.1 External Environmental Analysis

The analysis of the ZAMRA's external environment focused on Political/Policy, Economic, Social, Technological, Environmental/Ecological and Legal (PESTEL) developments that had or may have an impact on the operations of the Authority. The analysis also included taking into account stakeholders' interests and clients' needs.

2.1.1 PESTEL Analysis

a. Political

i. Launch of the Eighth National Development Plan 2022 - 2026

The launch of the Eighth National Development Plan 2022-2026 provides ZAMRA with a clear focus and an opportunity to contribute to national development under Strategic Development Area No. 2: Human and Social Development; Development Outcome No. 2: Improved Health, Food and Nutrition for the next five years. In this regard, the Authority will review and operationalise the organisational structure and enhance collaboration with the pharmaceutical industry and other stakeholders.

ii. Establishment of the African Medicines Agency

At continental level, Governments established the African Medicines Agency (AMA) under the African Medicines Treaty Alliance. This provides an opportunity for the harmonisation of regulatory processes among member states; and expedited access to quality assured medicines and allied substances. Zambia ratified the Treaty and the Authority will leverage on the mechanism of the AMA once fully operational.

iii. Presidential Speech of the opening of the 2nd session of the 13th National Assembly, 2022

During the official opening of the 2nd session of the 13th National Assembly, 2022, His Excellency, the President of the Republic of Zambia, Mr. Hakainde Hichilema in his Speech, indicated that to ensure steady supply and availability of essential medicines and medical supplies, government procured a year's supply of essential medicines and medical supplies, while promoting local manufacturing of pharmaceutical products and other medical supplies.

To support this undertaking, the Authority will strengthen the monitoring mechanisms to ensure adherence to the requirements in the Medicines and Allied Substances Act.

b. Economic

i. Fluctuations in the exchange and inflation Rates

The fluctuation in the exchange rate as evidenced by the kwacha depreciating to K16.6/$ in 2021 and the higher inflation rate of 22% negatively affected the operations of the Authority as it resulted into higher costs for goods and services. In this regard, there is need for ZAMRA to step up its revenue mobilisation in order to generate the required resources to finance operations. Further, it is imperative to streamline programme planning and implementation to ensure prudence in the utilisation of institutional resources. In addition, there is need to explore alternative sources of income to supplement the Authority's revenue base.

c. Social Developments

i. Mushrooming of illegal outlets

The Authority requires that only registered pharmaceutical establishments deal in medicines and allied substances. However, in as much as there is a reasonable number of registered outlets, there is also prevalence of unregistered (illegal) outlets which has resulted in; supply of substandard medicines; irrational use of medicines; increased pilferage of public sector medicines and increase in anti-microbial resistance. To curb the illegal sale of medicines and allied substances, the Authority will upscale sensitisation on the regulatory requirements and strengthen enforcement of the Law.

ii. Outbreak of COVID- 19 Pandemic

The outbreak of Covid-19 Pandemic in March 2020 impacted negatively on the operations of the Authority. The pandemic disrupted programme planning due to the restrictions which led to failure to achieve some set targets. To mitigate the adverse effects of such pandemics in future, the Authority shall develop and implement an emergency preparedness plan and strengthen adherence to health guidelines. In addition, the Authority shall continue to embrace the usage of various ICTs for continued service provision.

d. Technology

Technological advancements

The advancement in technology has provided an opportunity for automation of business processes. ZAMRA has embraced technology by investing in Information Communication Technology (ICT) infrastructure and implementation of the Integrated Regulatory Information Management System (IRIMS) that has resulted in, among other things; timely delivery of service, easy access to information, better storage and retrieval of information. The Authority will continue to invest in ICTs, building capacities in staff and clients in the use of ZAMRA electronic platforms, integrate ZAMRA system with Health sector systems and enhance security measures to prevent cyber-crimes.

e. Legal

Enactment of the Industrial Hemp Act, No. 34 of 2021 and Cannabis Act, No. 3 of 2021

The enactment of the Industrial Hemp Act, No. 34 of 2021 and Cannabis Act, No. 3 of 2021 provides the Authority with the mandate to regulate the cultivation, manufacture, production, storage, distribution, import and export of industrial Hemp and Cannabis for medicinal, scientific or research purposes. As a lead agency, the Authority will build capacity in the staff to undertake the new functions arising from the two pieces of legislation.

2.1.2 Stakeholder and Client Analysis

a) Clients and their needs

The clients with their respective needs were identified as follows:

SN	Category of clients	Clients' needs
1.	Manufacturers	1. Marketing authorization: • Medicines and Medical Devices • Allied Substances • Priority and locally manufactured medicines 2. Issuance of Good Manufacturing Practice compliance letter. 3. Pharmaceutical license 4. Import and Export Permit 5. Certification of Pharmaceutical Products 6. Approval of advertisements and promotion of Medicines and Allied Substances
2.	Marketing Authorisation Holders	1. Marketing authorization: • Medicines and Medical Devices • Allied Substances 2. Approval of advertisements and promotion of Medicines and Allied Substances 3. Disposal of pharmaceutical waste
3.	Clinical Research Organizations	1. Clinical trial certification 2. Good Clinical Practices Compliance Audits 3. Import permit for investigational medicines and allied substances 4. Disposal of pharmaceutical waste
4.	Principal Investigators	1. Good Clinical Practices Compliance Audits 2. Clinical trial certification 3. Import permit for investigational medicines and allied substances 4. Disposal of pharmaceutical waste
5.	Retailers	1. Agrovets • Registration of agro-veterinary shop • Disposal of pharmaceutical waste

SN	Category of clients	Clients' needs
		2. Pharmacy • Registration of retail pharmacies • Registration of hospital pharmacy • Disposal of pharmaceutical waste 3. Health shops • Registration of Health shops • Disposal of pharmaceutical waste
6.	Health Facilities	1. Import and export permits 2. Disposal of pharmaceutical waste 3. Dispensing certificate
7.	Importers and Exporters of medicines and allied substances	Import and export permits
8.	Wholesale dealers	1. Import and export permits 2. Pharmaceutical licence 3. Disposal of pharmaceutical waste 4. Certificate of Analysis
9.	General Public	1. Permit for personal use import and export 2. Register of Medicines and Allied Substances 3. Certificate of Analysis 4. Regulatory information

b) Stakeholders and their interests

In addition to clients and their needs, an analysis of the stakeholders and their interests was undertaken. The analysis identified the stakeholders and their areas of interest as presented below:

SN	Cluster	Areas of interest
1.	Government Ministries	1. Effective implementation of the Medicines and Allied Substances Act 2. Prudent utilisation of resources 3. Collaboration on:

SN	Cluster	Areas of interest
		• matters of trade in the pharmaceutical industry such as importation and exportation of medicines and allied substances • regulation of Cannabis and industrial hemp • promotion of entrepreneurship in the pharmaceutical industry
1.	Other Government Institutions	1. Collaboration on - • customs clearance of medicines and allied substances consignments • disposal of pharmaceutical waste and regulation of precursor and allied chemicals • regulation of statutory fees relating to regulatory services offered by the Authority • registration of pharmaceutical establishments, Patents and Trade Marks • regulation of Narcotic drugs, psychotropic substances and precursor chemicals • enforcement of Law and order related to medicines and allied substances • quality testing of allied substances • development of quality standards of medical devices and allied products • quality testing of medicines and allied substances • regulation of the health professionals and licensing of health facilities relating to medicines and allied substances • regulation of medicines containing genetically modified materials • surveillance of anti-microbial resistance and diseases of public importance • regulation of compulsory standards on disinfectants, condoms and other allied substances • regulation of blood and blood products and blood establishments • registration of retail and hospital pharmacies • calibration of laboratory equipment 2. Protection of consumer rights relating to medicines and allied substances 3. Adherence to Public procurement regulations and procedures
2.	Associations	Collaboration on • provision of safe, quality and efficacious medicines and allied substances • development of guidelines on medicines and allied substances

SN	Cluster	Areas of interest
3.	Cooperating partners	• Effective execution of mandate • Prudent utilisation of resources
4.	Civil Society Organisations	• Effective execution of mandate • Prudent utilisation of resources
5.	Media	Provision of accurate information on ZAMRA activities

2.2 Internal Analysis

2.2.1 Past Performance

A performance analysis was conducted to determine the extent of achievement of set targets and ultimately establish the overall institutional performance of ZAMRA. A three-tier rating was used to classify the performance of the Authority as highlighted below:

- *Code 1* - *Red* for below Average Performance (0% to 49.9%);
- *Code 2* - *Yellow* for Average Performance (50% to 79.9%); and
- *Code 3* - *Green* for Above Average Performance (80% to 100%).

The Performance is based on the ZAMRA 2020-2021 Strategic Plan. During 2020-2021, the Authority recorded an average performance with rating of 79.64% as shown in the table below.

OVERALL INSTITUTIONAL PERCENTAGE RATING	**79.64%**
RATING AND COLOUR CODE	**2**
AVERAGE PECENTAGE RATING FOR SUPPORT OBJECTIVES	**89.88%**
RATING AND COLOUR CODE	**3**
AVERAGE PERCENTAGE RATING FOR CORE OBJECTIVES	**67.36%**
RATING AND COLOUR CODE	**2**

The above performance was affected by a number of constraining factors which included the following:

i. Inadequate tools and lack of maintenance procedure required to carry out the mandate;
ii. Inadequate operational systems
iii. Inadequate organisational
iv. Inadequacies in upholding the shared values;
v. Inadequate legal frameworks;
vi. Inadequate post-marketing surveillance of medicines and allied substances
vii. Non-availability of some inputs to undertake analysis of samples;
viii. Inadequate office space in the regions;
ix. Inadequate stakeholder awareness and coordination mechanisms;
x. Lack of laboratory accreditation and WHO prequalification;
xi. Increase in the supply of substandard and falsified medicines;
xii. COVID- 19 pandemic;
xiii. Mushrooming of unregistered pharmaceutical outlets; and
xiv. Inadequate capacity among local manufacturers to manufacture medicines and allied substances and non-compliance to regulatory requirements resulting in production of poor-quality products.

2.2.2 Institutional Capability Assessment

The Institutional Capability Assessment conducted provided an in-depth analysis of ZAMRA's status internally. The Internal analysis identified the gaps and provided appropriate interventions as input into the preparation for the 2022 – 2026 Strategic Plan. The analysis was based on the Mckinsey's 7s Model, which established challenges in the seven areas relating to the Strategy, Structure, Systems, Staff, Skills, Shared values and Style of leadership and management. The identified challenges will need to be addressed for ZAMRA to effectively implement its Strategic Plan.

Further, a SWOT analysis was conducted. The analysis identified factors within the Authority in respect of Strengths and Weaknesses that would facilitate or hinder the implementation of the identified interventions. In addition, the analysis identified factors outside ZAMRA in respect of Opportunities and Threats that would facilitate or hinder the implementation of the identified interventions. The analysis revealed the following:

SWOT Analysis

STRENGTH (These are factors within an organisation that gives it an advantage) 1. Functional Board of Directors to provide strategic oversight. 2. Ability to generate and utilise its own financial resources in line with the Statutory Instrument No. 38 of 2016. 3. Availability of committed Staff with technical knowhow. 4. Existence of a National Drug Quality Control Laboratory facility for analysing and testing of medicines for regulatory purposes. 5. Geographical presence - ZAMRA has established regional offices to increase access to regulatory services.	**OPPORTUNITIES** (These are factors outside the Organisation that it can exploit to its advantage) 1. Stakeholder Support 2. Political will 3. Regional and International Collaborations 4. Launch of Local Pharmaceutical Manufacturing Initiative 5. Technological Advancement
WEAKNESSES (These are factors within an organisation that gives it a disadvantage) 1. Inadequate Organisation Structure 2. Inadequate office space in regions 3. Inadequate Operational and Management Systems 4. Inadequate Skills in some members of staff 5. Inadequate operational tools and equipment 6. Inadequate ICT infrastructure 7. Inadequate laboratory equipment 8. inadequate numbers of members of staff 9. poor work culture 10. inadequate stakeholder coordination mechanisms 11. inadequate financial resources	**THREATS** (These are factors outside the organisation that would negatively affect its ability to achieve objectives) 1. Inadequate legal framework 2. Rapid technological advancement 3. Negative public perception 4. Smuggling of medicines and allied substances 5. External interference

3. STRATEGIC DIRECTION

The launch of the Eighth National Development Plan 2022-2026 provides ZAMRA with a clear focus and an opportunity to contribute to national development under Strategic Development Area No. 2: Human and Social Development; Development Outcome No. 2: Improved Health, Food and Nutrition for the next five years. In this regard, the Authority will review and operationalise the organisational structure and enhance collaboration with the pharmaceutical industry and other stakeholders.

Following the analysis of the internal and external environment within which ZAMRA operates, key strategic issues or challenges were identified which form part of the basis of the Strategic Direction. The key strategic issues identified were as follows:

- Weak enforcement of standards of pharmacy practice;
- Inadequate capacity among local manufacturers to manufacture medicines and allied substances;
- Mushrooming of unregistered pharmaceutical outlets;
- Unclear guidelines on marketing authorisation renewal;
- Non-availability of some inputs to undertake analysis of samples;
- Lack of laboratory accreditation and WHO prequalification;
- Inadequate stakeholder coordination mechanisms;
- External interference;
- Inadequate financial resources;
- Inadequate operational and Management systems;
- Inadequate tools and equipment;
- Inadequate staff; and
- Inadequate office infrastructure.

The Authority has therefore set out an operational framework to guide the execution of its Mandate in the next five (5) years. This framework will guide ZAMRA's programmes, decision-making and resource allocation during the period 2022 – 2026 as follows:

3.1. Vision

ZAMRA's Vision is: "***A credible regulator ensuring the protection of human and animal health***". Through this vision, the Authority, will ensure that it embraces strategies that will enhance enforcement and compliance through sampling and quality testing of products thereby reducing the risk of availability substandard products. The Authority will also promote the use of ICTs to improve service delivery and inculcate its core values in members of staff to promote a positive work culture.

3.2. Mission Statement

To realise the vision and achieve the strategic results, ZAMRA commits itself to the following mission statement: ***"To effectively regulate medicines and allied substances for quality, safe and efficacious medical products on the Zambian market".*** Through this mission, the Authority will put in place appropriate operational systems and provide adequate enforcement mechanisms to protect human and animal health.

3.3. Core Values

The operations of the Authority and conduct of staff will be anchored on the following seven (7) core values:

i. **Customer focus:** We treat customers with courtesy in all interactions with them and respond to their needs in a timely manner.
ii. **Ingenuity:** We are proactive, innovative and are always finding new ways of serving our clients better.
iii. **Integrity:** We are honest, morally upright and committed to act in the best interest of the country.
iv. **Excellence**: We perform our tasks to the highest standards of professionalism.
v. **Transparency**: We operate openly, and are consistent and provide accurate information to the relevant stakeholders.
vi. **Teamwork**: We work cooperatively, respect and support one another for a common purpose.
vii. **Impartiality:** We are objective and do not discriminate against anyone in the execution of our duties.

3.4. Strategic Themes and Strategic Results

To realise its Vision, ZAMRA has identified the following three (3) areas of focus (themes) and associated strategic results:

a) ***Institutional Capacity*** resulting in ***effective and efficient service delivery****;*

b) ***Regulatory Service Excellence*** resulting in ***all clients complying to set standards and regulations****;* and

c) ***Stakeholder Management*** resulting in ***public confidence in the role of the Authority*****.**

3.3.1 Strategic Theme 1: Institutional Capacity

The Authority will invest in human resources, operational systems, equipment, ICT and other infrastructure that will translate into effective and efficient service delivery.

3.3.2 Strategic Theme 2: Regulatory Service Excellence

The Authority commits to strengthen the use of electronic platforms, develop regulations and guidelines and strengthen enforcement mechanisms which will result in all clients complying to set standards.

3.3.3 Strategic Theme 3: Stakeholder Management

The Authority will enhance internal and external communication, strengthen collaboration with stakeholders and work towards attaining laboratory WHO Pre-qualification and ISO 17025 accreditation. This will result in restored confidence in the Authority.

3.5. Strategic Objectives, Intended Results, Measures, Targets and Strategies

In the next five (5) years, ZAMRA commits to implement Nine (9) strategic objectives with their associated intended results, measures, targets and strategies (initiatives). The strategic objectives demonstrate the continuous improvements that the Authority will need to achieve the desired results in the areas of focus as follows:

SN	Strategic Objective	Strategic Objective Description
1.	Enhance regulatory functions	The Authority commits to strengthen surveillance and market control, marketing authorisation processes, clinical trial oversight, quality management, legal and regulatory frameworks.
2.	Improve stakeholder collaboration	The Authority will improve stakeholder collaboration through implementation of the Communication and Stakeholder Engagement Strategy.
3.	Increase revenue base	The Authority will broaden its revenue base by developing and implementing a resource mobilisation plan.
4.	Improve resources stewardship	The Authority will improve resources stewardship through implementation of adequate internal controls and appropriate resource allocation mechanisms.
5.	Improve operational efficiency	The Authority will enhance the use of electronic platforms in order to provide its services in a timely manner, and implementing the service charter, M&E framework and re-engineer work processes.
6.	Improve Tools, Equipment and infrastructure	The Authority will invest in tools, equipment and infrastructure. This will create a conducive environment for the members of staff to operate in.
7.	Improve work culture	The Authority shall improve the work culture by developing and implementing a culture remodelling programme and operationalise an integrity Committee. This is to ensure that all members of staff adhere to the shared values.
8.	Improve staff competences	The Authority will improve staff competences by carrying out performance appraisals and providing relevant capacity building programmes for the identified weaknesses in execution of duties.

SN	Strategic Objective	Strategic Objective Description
9.	Improve Organisational Structure	The Authority will review its organisational structure in order to provide for optimal staffing levels for effective execution of its mandate

The detailed 2022 to 2026 ZAMRA Strategic Plan log frame is shown below:

Log frame

Strategic Themes:	**Institutional capacity**		**Regulatory service excellence**	**Stakeholder Management**
Strategic Results:	**Effective and efficient service delivery**		**All clients complying to set standards and regulations**	**Public confidence in the role of the Authority**
Strategic Objective 1: Enhance regulatory functions				
Intended Results	**Measures**	**Baseline 2021**	**Targets**	**Strategies/Initiatives**
Improved compliance levels	% Marketing Authorisations (MAs) applications evaluated	40%	90% of MA applications evaluated annually	• Strengthen surveillance and Market Control • Strengthen clinical trial oversight • Strengthen Marketing Authorisation processes • Strengthen Quality Management • Strengthen legal and regulatory framework
	% Back log of MA related applications	50%	100% back log of MA related applications cleared by December 2024	
	% of Clinical Trial Certificates granted	94%	100% Clinical Trial Certificates granted having met criteria annually	
	% of Clinical trial sites inspected	90%	100% Clinical trial sites inspected in line with Good Clinical Practice (GCPs) requirements annually	
	% Adverse Drug Reaction reports analysed	25%	100% of Adverse Drug Reaction reports analysed annually	

	% of registered outlets complying to standards	63.1%	100 % of registered outlets complying to standards annually	
	% of eligible outlets licenced	70%	100 % of eligible outlets licenced annually	
	% of samples analysed	55%	At least 80% of the samples received analysed annually	
	% Back log of received samples analysed	50%	100% back log received samples cleared by December 2024	
Strategic Objective 2: Improve stakeholder collaboration				
Intended Results	**Measures**	**Baseline 2021**	**Targets**	**Strategies/Initiatives**
Satisfied stakeholders	stakeholder satisfaction index	63.8%	80% stakeholder satisfaction levels achieved annually	Strengthen implementation of the Communication and stakeholder Engagement Strategy
Increased awareness levels	% Stakeholder feedback	62%	80% positive stakeholder feedback annually	
Strategic Objective 3: Increase revenue base				
Intended Results	**Measures**	**Baseline 2021**	**Targets**	**Strategies/Initiatives**
Financial sustainability	Increase in revenue generated	K105,506 ,641(fees)	30 % increase in revenue generated annually	Develop and implement a resource mobilisation Plan
Strategic Objective 4: Improve resource stewardship				
Intended Results	**Measures**	**Baseline 2021**		**Strategies/Initiatives**
Accountability	Number audit reports	1	Clean audit report annually	Strengthen Internal Controls
	% Adherence to approved budget	100%	100% adherence to approved budget annually	
	% Adherence to procurement plan	100%	100% adherence to procurement plan annually	

Strategic Objective 5: Improve operational efficiency				
Intended Results	**Measures**	**Baseline (2021)**	**Targets**	**Strategies/Initiatives**
Timely Services	% of services offered in line with the service charter	50%	100% services offered to in line with the service charter annually	• Develop and implement the service charter • Develop and implement M&E framework • Re-engineer work processes
	% of regulatory services offered electronically	70%	100% of regulatory services offered electronically annually	
Strategic Objective 6: Improve Tools, Equipment and infrastructure				
Intended Results	**Measures**	**Baseline (2021)**	**Targets**	**Strategies/Initiatives**
Conducive work environment	Percentage Staff satisfaction levels	50%	100% staff satisfaction levels attained annually on the working environment	Develop and implement an asset management plan
Strategic Objective 7: Improve work culture				
Intended Results	**Measures**	**Baseline (2021)**	**Targets**	**Strategies/Initiatives**
positive corporate image	% Adherence to core values	10%	100% adherence to core values annually	Develop and implement a culture remodelling programme Establish and operationalise an integrity Committee
Strategic Objective 8: Improve staff competences				
Intended Result	**Measures**	**Baseline (2021)**	**Targets**	**Strategies/Initiatives**

Improved Staff Performance	% Staff performance	86.5%	100% staff performance against set targets annually	• Strengthen implementation of the performance Management System. Develop and implement staff welfare programme • Develop and implement a comprehensive human resource development plan
Strategic Objective 9: Improve Organisational Structure				
Intended Result	**Measures**	**Baseline (2021)**	**Targets**	**Strategies/Initiatives**
Optimal staffing levels	% of staff against establishment	80%	85% staffing levels against approved establishment attained by ?????	• Review and operationalise organisational structure • Strengthen placement and retention policies
	% of staffing levels retained	95%	98% of staff against approved establishment retained annually	

Refer to Appendix I for ZAMRA 2022 to 2026 Balanced Scorecard

4. ENABLING FACTORS

The successful implementation of this Strategic Plan is, to a large extent, dependent on the following pre-conditions and assumptions:

4.1. Pre – Conditions

Pre-conditions are the critical success factors that ZAMRA will need to put in place to ensure the successful implementation of the 2022 - 2026 Strategic Plan. The following are the pre-conditions:

4.1.1. Adequate, competent and committed staff;

4.1.2. Adequate financial resources;

4.1.3. Adequate operating equipment, tools and system;

4.1.4. Adequate office infrastructure; and

4.1.5. Committed and supportive leadership and management.

4.2. Assumptions

These are critical success factors outside the control of the Authority that should prevail for the successful implementation of the Plan. The following are the assumptions:

4.2.1. Political will;

4.2.2. Conducive Policy and Legal Frameworks; and

4.2.3. Economic stability.

5. PLAN IMPLEMENTATION

To operationalise the Strategic Plan, a costed Implementation Action Plan will be broken down into annual work plans and individual work plans, with SMART targets and schedules of activities, taking into account available resources.

The Directorate of Corporate Services will be responsible for the development and implementation of the Action Plan as well as submission of progress reports. The Action Plan will be the basis for monitoring and evaluating the performance of ZAMRA at three (3) levels, namely; Individual, Departmental and Institutional.

5.1. RISK MANAGEMENT

The Authority will ensure timely identification of risks which will be efficiently managed during the implementation of the 2022 - 2026 Strategic Plan. The pre-conditions, assumptions and other factors that may affect the successful implementation of the plan will be monitored regularly. A risk management framework/system will, therefore, be put in place to ensure proper management of risks.

5.2. MONITORING AND EVALUATION

Monitoring and Evaluation (M&E) of the Strategic Plan will be vital for effective implementation and ascertaining its impact. The M&E framework will be developed to track progress and evaluate performance against set strategic results, strategic objectives, intended results and targets as well as institute corrective measures timely. The M&E will be done at individual, departmental and institutional levels. Accordingly, quarterly and annual progress reports on the implementation of the Plan will be coordinated by the Directorate of Corporate Services. The Directorate will ensure that all Directorates prepare progress reports and submit to Management for consideration.

At individual level, the Performance Management System will be strengthened to monitor and evaluate the performance on a continuous basis. At Directorate level, M&E will be carried out on a quarterly basis while at Institutional level it will be carried out annually.

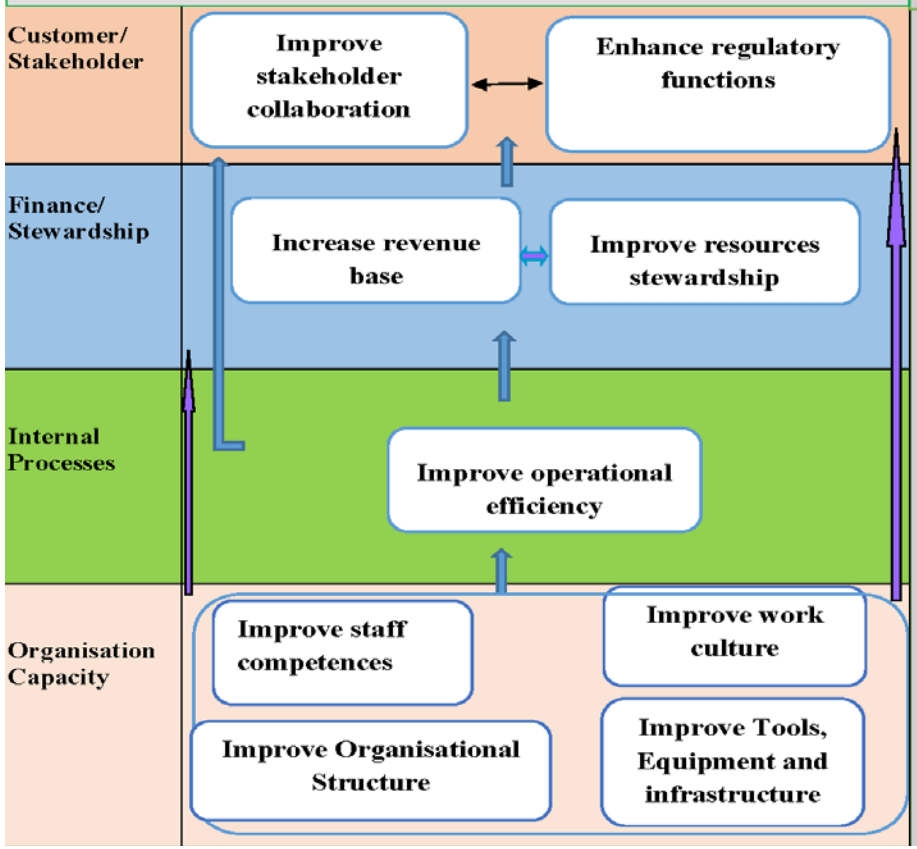
A mid-term review will be undertaken midway through the implementation of the Plan. The review will identify challenges, if any, encountered during implementation and recommend appropriate measures for addressing the challenges where necessary. Consequently, a terminal review will be undertaken at the end of the Plan period to determine the full extent of implementation and the overall impact. The terminal review will inform the preparation of the next Strategic Plan.

APPENDIX I: ZAMRA BALANCED SCORECARD 2022 - 2026

2022 -2026 ZAMBIA MEDICINES REGULATORY AUTHORITY BALANCED SCORE CARD

Vision	A credible regulator ensuring the protection of human and animal health
Core Values	Customer focus, Ingenuity, Integrity, Excellence, Transparency Teamwork, Impartiality
Mission	To effectively regulate medicines and allied substances for quality, safe and efficacious medical products on the Zambian market

Strategic Themes	**Regulatory Service Excellence**	**Stakeholder Management**	**Institutional capacity**
Strategic Results	**All clients complying to set standards and regulations**	**Public confidence in the role of the Authority**	**Efficient and Effective Service Delivery**

Strategic Objectives and Maps	Measures	Targets	Strategies/Initiatives
	• % Marketing Authorisations (MAs) applications evaluated • % Back log of MA related applications • % of Clinical Trial Certificates granted • % of Clinical trial sites inspected • % Adverse Drug Reaction reports analysed • % of registered outlets complying to standards • % of eligible outlets licenced • % of samples analysed • % Back log of received samples analysed • stakeholder satisfaction index • % Stakeholder feedback • Increase in revenue generated • Number audit reports • % Adherence to approved budget • % Adherence to procurement plan • % of services offered in line with the service charte • % of regulatory services offered electronically • Percentage Staff satisfaction levels • % adherence to core values • % staff performance	• 90% of MA applications evaluated annually • 100% back log of MA related applications cleared by December 2024 • 100% Clinical Trial Certificates granted annually • 100% Clinical trial sites inspected in line with Good Clinical Practice (GCPs) requirements annually • 100% of Adverse Drug Reaction reports analysed annually • 100 % of registered outlets complying to standards annually • 100 % of eligible outlets licenced annually • At least 80% of the samples received analysed annually • 100% back log received samples cleared by December 2024 • 80% stakeholder satisfaction levels achieved annually • 80% positive stakeholder feedback annually • 30 % increase in revenue generated annually • Clean audit report annually • 100% adherence to approved budget annually • 100% adherence to procurement plan annually • 100% services offered to in line with the service charter annually • 100% of regulatory services offered electronically annually • 100% staff satisfaction levels attained annually on the working environment • 100% adherence to core values annually • 100% staff performance against set targets annually • 85% staffing levels attained against approved established • 98% of staff against approved	• Strengthen surveillance and Market Control • Strengthen clinical trial oversight • Strengthen Marketing Authorisation processes • Strengthen Quality Management • Strengthen legal and regulatory framework • Strengthen implementation of the Communication and stakeholder Engagement Strategy • Develop and implement a resource mobilisation Plan • Strengthen Internal Controls • Develop and implement the service charter • Develop and implement M&E framework • Re-engineer work processes • Develop and implement an asset management plan • Establish and operationalise an integrity Committee • Develop and implement a culture remodelling programme • Strengthen implementation of the performance Management System • Develop and implement staff welfare programme • Develop and implement a comprehensive human resource development plan • Review and operationalise organizational structure • Strengthen placement and retention policies