



Republic of Zimbabwe



Medicines Control Authority of Zimbabwe

Medicines Control Authority of Zimbabwe Strategic Planning Template

2026-2030

SECTION A: Profile of the Medicines Control Authority of Zimbabwe

i) Foreword

It is my distinct honour and privilege to present the **Medicines Control Authority of Zimbabwe (MCAZ) Strategic Plan 2026–2030**. This Strategic Plan builds upon the solid foundation laid during the implementation of our 2022–2025 Strategic Plan, a period marked by significant institutional growth, strengthened regulatory systems, enhanced stakeholder confidence, and the attainment of critical international benchmarks, including the WHO Global Benchmarking Tool (GBT) Maturity Level 3.

Over the past strategic cycle, MCAZ consolidated its position as Zimbabwe’s national medicines regulatory authority, reinforcing its mandate under the Medicines and Allied Substances Control Act [Chapter 15:03]. The Authority enhanced post-market surveillance, improved inspection coverage across the pharmaceutical value chain, expanded pharmacovigilance activities, and strengthened laboratory capacity in line with WHO Prequalification, ISO 9001 and ISO 17025 standards. These milestones were achieved amid a dynamic macroeconomic environment and evolving public health demands, including the increased complexity of medicines, biologics, vaccines, and medical devices.

The 2026–2030 Strategic Plan charts a bold and forward-looking path. It aligns fully with the Government of Zimbabwe’s Vision 2030 and the National Development Strategy 2 (NDS2), particularly under the Health and Well-being and Public Service Delivery outcomes. This Plan reaffirms MCAZ’s commitment to ensuring equitable access to safe, effective, and quality-assured medical products and allied substances for the protection of public and animal health.

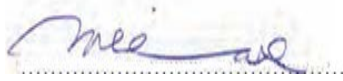
This Strategy is anchored on two core programmes: Governance and Administration; and Medicines and Medical Devices Control. Over the next five years, the Authority will prioritise digital transformation and artificial intelligence integration within our regulatory systems, strengthen data-driven decision-making, enhance regulatory reliance and harmonisation initiatives, and position MCAZ as a continental centre of regulatory excellence. MCAZ will also intensify support for local pharmaceutical production, improve efficiency in registration and licensing processes, and further reinforce port-of-entry screening and enforcement mechanisms to safeguard the public against substandard and falsified medical products.

Importantly, this Plan reflects our ambition to progress toward WHO GBT Maturity Level 4, thereby elevating Zimbabwe’s regulatory credibility on the global stage. Achieving this milestone will require sustained investment in human capital development, infrastructure modernisation, quality management systems, and strategic partnerships at national, regional, and international levels.

The success of this Strategic Plan will depend on the collective efforts of our Board, Management, Staff, the Ministry of Health and Child Care, Government agencies, development partners, industry stakeholders, academia, the media, and, most importantly, the citizens of Zimbabwe. The Authority remains committed to transparency, accountability, innovation, and continuous improvement in all its operations.

The MCAZ is confident that this Strategic Plan provides a clear, measurable, and results-oriented roadmap that will enable MCAZ to fulfil its mandate with excellence and integrity. Together, we will continue to protect public health and contribute meaningfully towards a prosperous and empowered upper-middle-income Zimbabwe by 2030.

MCAZ Board Chairperson



Dr. M. Chiware

ii) Executive Summary

The Medicines Control Authority of Zimbabwe (MCAZ) has finalised its five-year Strategic Plan for the 2026–2030 period, establishing a definitive roadmap for the strategic direction. This plan is the outcome of a rigorous review process, including a comprehensive performance assessment for 2025, target validation, and the subsequent formulation of strategies tailored to the current macroeconomic environment and the evolving paradigm of healthcare access and definition. A cornerstone of this strategy is the explicit focus and alignment with the National Development Strategy 2 (NDS2), particularly the Health and Well-being outcome. The plan reinforces MCAZ’s critical role as the national medicines’ regulator, ensuring the continuous supply of safe, effective, and high-quality medicines and medical devices to the citizens of Zimbabwe.

iii) Introduction

This document details the Medicines Control Authority of Zimbabwe’s (MCAZ) five-year strategic plan. It captures the methodical work undertaken by MCAZ to review its future direction. This process encompassed a comprehensive performance review for the preceding year (2025), meticulous validation of strategic targets, and the formulation of appropriate strategies designed to achieve clearly defined outcomes. All strategic choices were made in the context of the prevailing macroeconomic environment, recognising the evolving definition of healthcare and accessibility within Zimbabwe. A central commitment of this plan is the direct alignment with the National Development Strategy 2 (NDS2) and the fulfilment of MCAZ’s core mandate: to regulate and ensure the safety and quality of medicines and medical devices for the citizenry, thereby supporting the national Health and Well-being outcome.

iv) Background

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory state-owned enterprise, which was established by an Act of Parliament, The Medicines, and Allied Substances Control Act (MASCA) [Chapter 15:03]. MCAZ, through the Ministry of Health and Child Care, has the overall responsibility in protecting health and well-being, safety, efficacy and good quality medicines and related products throughout the pharmaceutical value chain. MCAZ is a successor of the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL). The Government of Zimbabwe, through the Minister of Health and Child Care (‘the Minister’), provides policy direction, legislative oversight, and governance expectations, while MCAZ provides technical, scientific, and regulatory expertise to safeguard public health. The Minister is responsible for appointing board members of the Medicines Control Authority of Zimbabwe, in consultation with the President, overseeing its operations, and ensuring it aligns with national health policy. The Minister approves regulations, receives annual reports, and intervenes when necessary to safeguard public health.

The Medicines Control Authority of Zimbabwe Board enforces compliance, manages finances, submits audited accounts, and advises the Minister on matters of medicines regulation.

National Level Contribution:

a. National Vision: “Towards a Prosperous and Empowered Upper Middle-Income Society by 2030.”

b. National Priorities the Ministry/ Agency is contributing to:

National ref	NPA/s Name	National Key Result Area	National Tertiary Outcome/s	TOUC Reference
8	Social Development, Gender, and Social Protection	Health and Well Being	1. Improved quality of life	27A
10	Good Governance, Institution Building, Peace, and Security	Public Service Delivery	1. Enhanced Inclusive Service delivery	31

v) Sectorial Level Contribution**a. Sectoral Level**

Sect Ref	Sector/s Name	Sector Key Result Area	Sector Intermediate Outcome/s	Reference
14	Social	Health	1. Increased Availability of Medicines	53
15	Good governance	Public Service Delivery	1. Enhanced Inclusive Governance and Accountability 2. Enhanced transparency and accountability	65 66
16	Peace Security and social cohesion	Law and order	3. Enhanced public safety	70

Agency

1. Medicines Control Authority of Zimbabwe

2. Agency Vote Number: 14

3. Agency Vision Statement: “A leading technology-driven regulator in Africa ensuring equitable access to safe, effective, quality-assured medical products and allied substances by 2030.”

4. Agency Mission Statement: “To ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health.”

5. Core Values:

- i. **Customer Focus:** We are reliable, responsive to needs, communicative and create a conducive working environment.
- ii. **Integrity:** We are ethical, professional, objective, honest and adhere to moral values.
- iii. **Continuous Improvement:** We are proactive, dynamic, and adaptive in all we do.
- iv. **Accountability:** We take full responsibility for our actions.
- v. **Innovation:** We are innovative in our problem-solving.
- vi. **Teamwork:** We are collaborative, working together as one in pursuit of defined outcomes.

6. Terms of Reference:

- **Medicines and Allied Substances Control Act [Chapter 15:03]**
- **Dangerous Drugs Act [Chapter 15:02]**

7. Policies Applicable for the MCAZ

	External Policy	Programme	Internal Policy	Programme
1.	Vision 2030	1,2	Human Resource Policy Manual	1,2
2.	National Development Strategy 2	1,2	Finance and Administration Policy Manual	1,2
3.	WHO Global Benchmarking Tool and Guidelines	1,2	ICT Security Policy Manual	1,2
4.	Public Finance Management Act (Chapter 22:19)	1	Enterprise Risk Management Framework	1
5.	Public Entities Corporate Governance Act [Chapter 10:31] and Public Entities Corporate Governance (General) Regulations, S.I 168/2018	1	Integrated Quality Policy Manual	1,2
6.	Public Procurement and Disposal of Public Assets Act [Chapter 22:23]	1	Information Disclosure and Communication Policy	1,2

	External Policy	Programme	Internal Policy	Programme
7.	Public Procurement and Disposal of Public Assets (General) Regulations, S.I 5/2018	1		
8.	ISO/IEC 9001:2015 Standard for Requirements for Quality Management Systems	1,2		
9.	ISO/IEC 17025: 2017 Standard for the requirements for the competence of testing and calibration laboratories	2		
10.	ISO /IEC 4074 Standard for Natural Latex Rubber Condoms- Requirements and Test Methods	2		
11.	a. Labour Act (Chapter 28:01) and amendments b. National Employment Code of Conduct Regulations 2006 (SI 15 of 2006)	1		
12.	International Financial Reporting Standards	1		
13.	Cyber and Data Protection Act [Chapter 12:07] and Cyber and Data Protection (Licensing of Data Controllers and Appointment of Data Protection Officers) Regulations, S.I 155/2024	1		
14.	National Drug Policy	2		

8. Overall Functions:

- a. Control of clinical trials.
- b. Registration of medicines and medical devices.

- c. Licensing and controlling premises and persons handling medicines.
- d. Safety and effectiveness monitoring of medicines and medical devices.
- e. Import/export control of medicines.
- f. Quality control of medicines and medical devices.
- g. Management of Dangerous Drugs Act and Regulations and international conventions
- h. Control of promotion and advertising of medicines
- i. Provision of Medicines Information and promotion of rational use of medicines.
- j. Post Market Surveillance activities.

9. MCAZ Programmes and their functions:

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
1. GOVERNANCE AND ADMINISTRATION	THE LEGAL UNIT	i. To constantly review legislation to ensure that it suits the changing needs of the industry. Where gaps are identified, to draft the necessary legislation/amendments to the legislation gazetted. ii. Ensure compliance with the corporate governance framework.
	ICT	i. To define the ICT policies and strategies of the Authority, as well as ensuring their implementation and providing daily technical support to users of ICT infrastructure and technology within the Authority, so that the MCAZ achieves on its vision and mission. ii. Develop a robust Integrated Regulatory Management system to manage and maintain key regulatory activities and decisions in line with MASCA and the WHO Global Benchmarking Tool iii. To provide an automated and Digitalised platform to enable decision making to be data driven enabling fast and efficient decision making. iv. Lead in the adoption of Artificial intelligence in the Authority and identify use cases for efficiency and optimisation of processes. v. To champion a cyber safe ICT environment that is cyber secure and ICT Compliant including Data governance and management in line with the Data Protection Act.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
1. GOVERNANCE AND ADMINISTRATION		
	INTERNAL AUDIT UNIT	i. The scope of internal audit work includes the review of internal control systems, risk management procedures, information system, financial systems, and governance process. This work also involves periodic testing of transactions, best practice reviews, special investigations, appraisals of regulatory requirements, and measures to help prevent and detect fraud.
	HUMAN CAPITAL	i. To provide leadership and guidance in, and have control over, all the Human Resources affairs of the Authority through policies and procedures designed to ensure that the Authority achieves its objectives. ii. To facilitate strategic human resource planning at all levels and the development of appropriate activities to attract highly competent talent. iii. To continuously develop and facilitate performance management methods and processes throughout the organization and communicating outcomes for further HR planning. iv. To identify and facilitate relevant training and developmental opportunities in terms of the overall learning and growth strategy of the organization. v. To champion a culture that encourages and rewards individual growth. vi. To facilitate the design and implementation of recognition and reward systems that maximise staff retention and contribution. vii. To promote a culture of harmonious industrial relations climate.
	FINANCE	Finance i. Budget planning and management - prepares the annual budget for MCAZ and monitors expenditure against approved budgets.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
	FINANCE <i>(cont...)</i>	ii. Revenue collection and management-manages all income generated by MCAZ and ensures timely invoicing, receipting and banking of funds. iii. Expenditure Control –processes and authorises payments for goods and services. iv. Cashflow Management - ensures that MCAZ maintains sufficient liquidity to meet its operational, regulatory, and statutory obligations while optimizing the use of financial resources through accurate forecasting, monitoring, and timely decision-making. v. Managing the Authority`s investments – by ensuring that MCAZ`s financial resources are prudently invested in line with approved policies, statutory requirements, and the Authority`s mandate. vi. Financial and Management Accounts Reporting – prepares financial statements ensuring compliance with international accounting standards and provides financial performance reports to management and the MCAZ Board. vii. Policy and compliance- ensures strict adherence to the Finance Policy Manual, and all relevant financial regulations, thereby promoting accountability, sound governance in the management of MCAZ`s resources. Projects i. Grant and Project Management – coordinate, planning, implementation and monitoring of donor /partner funded projects. (e.g., UNDP, UNICEF). ii. Ensure projects are compliant with donor/partner requirements. iii. Resource mobilization – actively identify and pursue potential funding opportunities to support MCAZ`s regulatory and institutional priorities.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
	PUBLIC RELATIONS AND COMMUNICATIONS UNIT	i. Planning, development and implementation of the Authority's public relations and communications strategies. ii. Undertakes research and produces presentations and press releases. iii. Organizes events, press conferences, exhibitions, and press tours. iv. Media relations v. Ensures the Authority achieves customer satisfaction through a customer focused service delivery that is oriented by a high-performance culture. In this regard the Unit actively seeks customer feedback to improve the Authority's systems. The Unit also evaluates, investigates, and resolves customer complaints to ensure that the Authority maintains good and mutually beneficial relationships with its stakeholders and customers. vi. MCAZ communications aligns with national health priorities set by the Government, particularly those of the Ministry of Health and Child Care, ensuring that public messaging supports broader public health strategies and national development goals.
	PROCUREMENT AND ADMINISTRATION	i. Procurement of goods and services ii. Maintenance of infrastructure iii. Administration of goods and services
	QUALITY UNIT (QU)	i. Quality oversight for the Integrated Quality Management System (IQMS) at MCAZ. ii. Development of IQMS, Integrated Quality Policy Manual, and global procedures as guided by the various standards and guidelines in relation to the Authority's functions. iii. Implementation of standards and guidelines requirements to ensure that the system is delivering the intended results. iv. Facilitation and coordination of the implementation of the MCAZ's strategic plan.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
		v. Internal auditing of the IQMS to check for compliance to all the standards, statutory and regulatory requirements relevant to the Units/Divisions. vi. Organisational performance management (Regulatory and Key Performance Indicators monitoring and evaluation) vii. Oversight of risk management system
2. MEDICINES AND MEDICAL DEVICES CONTROL	EVALUATION AND REGISTRATION DIVISION (EVR)	i. Registration of human and veterinary medicines. ii. Approval of complimentary medicines. iii. Maintain drug registers. iv. Lifecycle management i.e., variations, re-registrations, reinstatements v. Issue emergency use authorizations when necessary.
	PHARMACOVIGILANCE AND CLINICAL TRIALS (PVCT)	i. Pharmacovigilance (PV) (safety monitoring of medicines, vaccines & medical devices) including active PV programs & projects. ii. Data analysis of drug safety data, publications & WHO shared databases, Vigiflow, Vigilyze and Cemflow. iii. Communication of drug safety information in a way that improves therapeutics & patient safety. iv. Drug information bulletin publications. v. Training of PV & GCP to relevant stakeholders internal & external. vi. Monitoring product defects & recalls. vii. Regulation of clinical trials of medicines, vaccines & medical devices, including Good Clinical Practice (GCP) inspections. viii. Post-registration processes such as: (i) Application for amendments to registered medicines. (ii) (iii) Annual retention of registered medicines (iii) Registered medicines cancellations or withdrawals (iv) Medicines safety reviews ix. Harmonisation and keeping abreast with global standards.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
	LICENSING AND ENFORCEMENT(LED)	i. Processing applications for new premises, conducting inspections and tabling the reports before the Licensing & Advertising Committee. a. Issuing and renewal of licences and permits. b. Inspection of all premises across the supply chain (pharmacies, wholesalers, manufacturers etc) to ensure compliance. ii. Conducting Market Surveillance activities and investigation of product defects. iii. Processing applications for import and export permits for medicines and allied substances. iv. Clearing consignments for medicines and allied substances at designated ports of entry. v. Processing applications for import and export licences for all narcotics, psychotropics and related substances. vi. Processing applications for import and export permits for precursor substances. vii. Conducting enforcement activities. viii. Assessing and processing applications for the importation of unregistered medicines. ix. Recording minutes and executing decisions of the Licensing & Advertising Committee. x. Recording minutes and executing decisions of the Controlled Substances Committee. xi. Administering of forensics examinations
	LABORATORY SERVICES DIVISION	The overall function is to ensure quality, safety and efficacy of medicines in the nation through testing. Chemistry Unit Samples analysed are for purposes of i. Registration of medicines ii. Post-market surveillance iii. Pre-distribution analysis iv. Quality checks after adverse drug reaction on the market.

PROGRAMME	UNIT/ DIVISION	FUNCTIONS
		Medical Devices Unit: i. Regulation and Quality Conformity Assessment of male condoms in accordance with SI 183 of 2005 ii. Regulation and Quality Conformity Assessment of medical gloves in accordance with SI 1 of 2006 iii. Factory inspections (cGMP) of condom and glove manufacturing facilities. Microbiology Unit: i. Quality Conformity Assessment of medicines and allied substances ii. Quality Conformity Assessment of complementary medicines iii. Evaluation of vaccine Summary lot protocols.

10. State Enterprises and Parastatals, Statutory Bodies and Grant Aided Institutions under MCAZ and their functions- None.

11. Environmental Scan

PESTLEG ANALYSIS

FACTOR	ISSUE	IMPACT
Political	Alignment with Vision 2030 & NDS2 (Health and Well-being) Supportive Government Policies for local production and pharmaceutical value chain	i. Easier approval of sector policies, regulations, and fee reviews through MoHCC and Cabinet structures. ii. Strengthening legislative reform, ICT investments (IRMIS, ZIMDIS) and Post-market surveillance (PMS). iii. Increased GMP inspections, registrations, and post-market surveillance iv. Reduced timelines and reliance. v. Pressure to “support industry” may create perceived or real conflicts between facilitation and strict enforcement.

FACTOR	ISSUE	IMPACT
Economic	Inflation and currency volatility	i. Encourages MCAZ to intensify cost control, efficiency gains and digitalisation to lower operating costs per decision.
	Budget constraints	ii. Diversification of revenue streams
Social	Health-conscious public	i. Higher Adverse Drug Reaction (ADR)/Adverse Events Following Immunisations (AEFIs) reporting, public engagement supporting Pharmacovigilance (PV) and Post Marketing Surveillance (PMS) outcomes.
	Expectations for transparency New medicines for emerging disease patterns (Non-Communicable Diseases (NCDs), cancers, emerging infections) and emergency preparedness Informal medicines markets	ii. Stronger justification for public-facing communication, dashboards and risk communication. iii. Reinforced strategic focus on complex medicines, biologics, oncology products and vaccines. iv. Training of specialised personnel (assessors, inspectors, analysts). v. Strengthened collaborations in emergency use authorisation, pharmacovigilance (PV) plan and medicines donations. vi. Enhanced enforcement, market surveillance and inter-agency collaboration (ZRP, local authorities, PCZ, HPA etc.)
Technological	Digitalisation and AI (IRMIS, ZIMDIS enhancements, e-portals, AI screening)	i. Improved registration and licensing timelines, data integrity and regulatory decision-making. ii. Data-driven KPIs and reporting required by IRBM and WHO GBT. iii. New skills set for existing personnel
	Cybersecurity and data protection requirements Rapid advances in biotechnology and medical devices	iv. Strengthened ICT governance, SOPs and business continuity, protecting regulatory data v. Compliance with Data Protection Act vi. New skills set for existing personnel

FACTOR	ISSUE	IMPACT
Legal	Existing MASCA Act and proposed Medical Products & Allied Substances Control Bill Alignment with WHO GBT, ISO 9001, ISO 17025, WHO PQ, PIC/S, ICH, SADC and AMA frameworks Alignment with public procurement, corporate governance and data protection requirements	i. Expanded scope to medical devices and allied substances strengthens public health protection. ii. Clearer legal basis for enforcement and PMS across the full value chain. iii. Improved MCAZ rating (ML4), credibility and eligibility for reliance. iv. Improved compliance to requirements. v. Promoted transparency, accountability and robust controls consistent with Integrated Results Based Management (IRBM).
Ecological	Climate change and natural disasters Environmental impact of pharmaceuticals waste Growing Environmental Social and Governance (ESG) expectations from Government	i. Investment in resilient infrastructure (backup power, cold-chain monitoring, Disaster Recovery sites). ii. Appropriate disposal of pharmaceutical waste iii. Compliance with ESG-linked policies. iv. Acquired additional resources to meet environmental and governance standards.
Global	Regional and international harmonisation (ZAZIBONA, AVAREF, SADC, AMA, WHO) Competition from other strong NRAs in the region and beyond	i. Shorter timelines for critical medicines through reliance and work-sharing. ii. Increased efficiency from increased skills set. iii. Brain drain risk as experienced staff are attracted to better-paying regulators and international agencies.

SWOT ANALYSIS

STRENGTHS (Internal)	IMPACT TO MCAZ	WEAKNESSES (Internal)	IMPACT TO MCAZ	STRATEGY
1. Accreditations, certifications, and Prequalification (ISO 17025, ISO 9001, WHO Prequalification, WHO GBT ML 3).	1. Attestation to the Authority's competencies 2. Attracting new customers 3. Provides confidence to the Authority's customers. 4. Aids in reliance and recognition mechanisms	Working in silos	Limits information sharing leading to duplication of work and wastage of resources	1. Data compilation and presentation: Data driven decision making. 2. Admit inadequacies and gaps in the system, seek for guidance when required
2. Experienced and dedicated staff.	1. Retention of accolades 2. Top quality service provision to clients	Slow adoption in fully utilising technology (AI)	1. Increases workload 2. Compromises quality of work outputs	Training of employees on AI
3. Visible and well respected MCAZ brand.	1. Growth in industry (50% from 2021 to 2025) 2. Increase in number of medicines registered 3. Improvement in stakeholder engagements 4. Improvements in transparency and accountability	Poor Work-life balance.	Reduced productivity and efficiency	Improving efficiency of the automated systems
4. Effective financial management.	Well-resourced entity with sufficient cash flows			
5. Leadership and influence (Chairmanship of key WHO committees)	The ability to shape international policy on medicines regulation			

OPPORTUNITIES (External)	IMPACT TO MCAZ	THREATS (External)	IMPACT TO MCAZ
1. Government Support for Local Production. 2. Strategic Regional & International Influence & Alliance – e.g. Global harmonisation, African Regulatory networks, international partnerships.	Ease of proposal approvals from the parent ministry Helps MCAZ shape policies and align with ongoing global changes.	Regulatory fee reforms.	Failure to implement some programs due to budget deficit
3. Increased public interest in the quality of cancer drugs and other complex medicines. 4. Changing Disease Patterns.	Increased regulatory oversight	Emerging Competition from new and accredited medicines regulatory authorities.	Loss of human resources to other NRAs
5. Health-conscious public	Increased visibility Increased stakeholder engagement	Informal Markets- unregulated and illicit markets.	Tarnishing MCAZ reputation and brand

12. MCAZ Programmes and Outcomes:

Prog. Ref	Programme Name	Programme Preliminary Outcome/s	Weight	Responsible Departments	Contributing MDAs/ Other Partners	Type of Contribution	Sector Intermediate Outcome	National Tertiary Outcome	SDG Ref
1	Governance and Administration	1. Improved Governance and Administration	40	HR, FIN, DG's Office, PR, ICT, QU, LCAU, IAU, ICT, PAU	Ministry of Health and Childcare (MoHCC), Office of the President- Corporate Governance Unit (OPC-CGU), Ministry of Labour and Social Services, Ministry of Finance, Economic Development and Investment Promotion (MoFEDIP), Attorney General, Ministry of Information, Procurement Regulatory Authority of Zimbabwe (PRAZ), Ministry of Industry and Commerce (MOIC) Postal & Telecommunications Regulatory Authority of Zimbabwe (POTRAZ), Standards Association of Zimbabwe (SAZ),	Health Development Partners, NGOs, Institute of Personnel Management of Zimbabwe (IPMZ), Southern African Development Community Accreditation Service (SADCAS)	53, 65, 66, 70	27A, 31	3
2	Medicines and Medical Devices Control	Improved Access to	30	EVR, LED	Ministry of Health and Childcare (MoHCC),	Policy support	53, 65, 66, 70	27A, 31	3

		Essential Medicines							
		Improved regulatory Competence	15	LED PVCT, EVR	Ministry of Health and Childcare (MoHCC),	Policy support	53, 65, 66, 70		
		Improved quality of medicines available to the public	15	LSD, LED, PVCT, EVR	Ministry of Health and Childcare (MoHCC),	Policy support	53, 65, 66, 70		

13 CLIENT NEEDS/PROBLEMS ANALYSIS:

Extent Scale:

Extent	Interpretation/Meaning
High	High: the problem is severe and has a significant impact on operations, requires immediate attention.
Medium	The problem is of moderate seriousness that is it does not cause an immediate threat.
Low	The problem is minor and has limited impact on operations and can be addressed in the regular course of business.

Clients	Needs/Problems	Extent
1. Applicants for Marketing authorisation	Needs: 1. Efficiency and timeliness for registration of medicines. 2. Clarity and transparency. 3. Professionalism, integrity, and courtesy. Problems: 1. No clear guidelines for registration of medicines 2. Registration takes long. Causes: 1. Lack of timely revision of guidelines 2. Lack of automated systems and adequate staff resulting in pressure on the limited resources.	High
2. Manufacturers	Needs: 1. Supportive Regulatory environment 2. Ease of doing business 3. Collaboration- One stop shop with complementary regulations to reduce administrative burden. 4. Local industry facilitation and reduction in fees for local manufacturers. 5. Shorter registration timelines and quicker feedback. 6. Reduction in retention fees. 7. Streamline and automate licence amendments. 8. Better Pharmacovigilance practices. Problems: 1. Registration turnaround time. Causes: 1. Lack of automated systems and adequate staff resulting in pressure on the limited resources.	High
3. Wholesalers/Distributors	Needs: 1. Predictability in registrations, licensing, and amendments timelines. 2. Efficiency. 3. Sufficient and clear guidance 4. Ready online availability of all information 5. Reduced costs.	Medium

Clients	Needs/Problems	Extent
	6. Continued stakeholder engagements and feedback on inspections. 7. Clear guidelines to minimise clarification seeking and query letters. Problems: 1. Turnaround time of registration. Causes: 1. Lack of automated systems	
4. Retailers	Needs: 1. Timely delivery of application requests 2. Reduction in verification fees. 3. Reduction of persons' licenses fees. 4. Clear communication. 5. Adaptability to a changing environment. 6. Inclusion of Private sector in policy making to ensure relevance and practicality. Problems: 1. Sale of medicines in illegal markets Causes: 1. Inadequate human resources to ensure effective enforcement.	High
5. Industrial Clinics	Needs: 1. Timely processing of applications. 2. Communication and guidance. 3. Flexibility. Problems: 1. Operating outside the scope of their licenses. 2. Failure to renew licences on time. Causes: 1. Inadequate human resources to ensure effective enforcement.	High
6. Persons (Dispensers)	Needs: 1. Less cumbersome requirements for the acquisition of unregistered essential/lifesaving medicines. 2. More suppliers so that costs can be lower. Problems: 1. Sale of medicines in illegal markets Causes: 2. Inadequate human resources to ensure effective enforcement.	High

14. STAKEHOLDERS ANALYSIS

Direct Stakeholders	Demands/ Expectations	Extent
1. Ministry of Health and Child Care (MoHCC)	Demands 1. Compliance with National Laws and international standards 2. Efficient Regulation 3. Transparency in decision-making Expectations 1. Support for policy implementation. 2. Regular reporting and accountability	High
2. Board	Demands 1. Compliance Expectations 1. Timely intervention (responsiveness) 2. Improve timelines.	High
3. Office of the President and Cabinet (OPC)	Demands 1. Compliance with National Laws 2. Efficient Regulation 3. Transparency in decision-making	High
4. Government Agencies (ZIMRA, NSSA, PRAZ, AG, OAG, POTRAZ etc)	Demands 1. Compliance with National Laws	High
2. Financial Institutions	Expectations 1. Flexibility 2. Efficiency 3. Ease of doing business	Medium
3. Suppliers	Expectations 1. Efficiency 2. Timely provision of services and payments	Medium
4. Associations	Expectations 1. Efficiency 2. Timely provision of services	High
5. Councils	Expectations 1. Cooperation 2. Collaboration 3. Communication	High

Direct Stakeholders	Demands/ Expectations	Extent
6. Media	Expectations 1. More information on the work that the authority is doing in terms of safeguarding public health. 2. Transparency 3. Cooperation during public enquiries 4. Accountability	High
7. Academia	Expectations 1. Support for clinical trials and research proposals 2. Access to regulatory data for studies 3. Consider a PVCT fee schedule appropriate for locally designed and funded clinical research projects. 4. Harmonization of clinical research regulations, specifically liaising with POTRAZ to avoid duplication of the regulatory framework. 5. Vigilance on counterfeiting. 6. Efficiency in dossier review for new molecules. 7. Capacity building programs	Low
8. International, Regional, and National Bodies (e.g. SAZ, SADCAS, WHO, Development Partners)	Demands 1. Compliance with standards and guidelines 2. Data sharing Expectations 1. Participation in harmonization initiatives 2. Timely rereporting of adverse events	Low
9. Public (man on the empty chair)	Expectations 1. Equitable access to safe health care products 2. Efficient complaint resolution mechanisms 3. Transparency and accountability 4. Engagement 5. Continuous improvement – service delivery	High

15. STRATEGIES, ASSUMPTIONS, RISKS AND MITIGATIONS

Period	Strategies	Assumptions	Risks	Mitigations
Programme: GOVERNANCE AND ADMINISTRATION				
Outcome: Improved Governance and Administration				
Budget Year (2026)	Enhance employee engagement	Employee participation.	Failure to close identified gaps.	Continuous engagement
	Implement secure, data driven AI technologies that are compliant to the data protection Act in organisational processes	Training of all employees on AI	Inadequate funds for training and implementation	Develop inhouse training programs. Use of accessible AI tools
	Strengthen stakeholder engagement and responsiveness	Stakeholders are willing to participate in consultations and feedback processes.	Stakeholder fatigue. Miscommunication or misinformation due to digital connectivity.	Develop an annual stakeholder engagement plan Publish stakeholder feedback reports and regulatory updates quarterly. Strengthen communications capacity and messaging coordination. Enhance digital communication platforms for transparency.

Period	Strategies	Assumptions	Risks	Mitigations
Programme: Medicines & Medical Devices Control				
Outcome: Improved Access to Essential medicines				
Budget Year (2026)	Implement facilitative initiatives for promotion of local production of medical products	Local production remains a priority to the GoZ Appetite for entrance into the local industry remains high	Increases in the cost of production. Prohibitive tariff structures for imported starting materials and equipment.	Develop facilitative policies for technology transfer

Period	Strategies	Assumptions	Risks	Mitigations
Programme: Medicines & Medical Devices Control				
Outcome: Improved Access to Essential medicines				
				Lobbying on behalf of the local industry Prioritise regional and continental submissions

Period	Strategies	Assumptions	Risks	Mitigations
Programme: Medicines & Medical Devices Control				
Outcome: Improved regulatory competence				
Budget Year (2026)	Strengthen implementation and maintain WHO GBT compliance	Retention of skilled and competent staff	Changes in the WHO Benchmarking Tool	To ensure that MCAZ is involved in the change process.
	Establish MCAZ as a continental centre of regulatory excellence	Retention of skilled and competent staff Ability to work with Academia	Unavailability of resources Competition from other NRAs	Lobby to the GoZ for resources Engage partners for resource provision. Expedite execution of the strategy

Period	Strategies	Assumptions	Risks	Mitigations
Programme: Medicines & Medical Devices Control				
Outcome: Improved quality of medicines available to the public				
Budget Year (2026)	Develop a robust screening process for imported medicines at ports of entry	Government expectation to improve quality of medicines available to the public Adequate collaborations from other stakeholders at ports of entry	Change of government policies and competing priorities Inadequate number of devices for use during screening Smuggling of medical products via other ports of entry	Continuously engage the policy makers Prioritise budget for the devices Improve coverage of trainings offered to stakeholders Enhance public awareness programs

SECTION B: PERFORMANCE FRAMEWORK FOR MCAZ

16. Programme Performance Framework

16.a Preliminary Outcome Performance Framework

Ref	Outcome Description	KPI:	Measurement Criterion (time; \$; rate; etc)	Baseline		TARGETS									
						2026		2027		2028		2029		2030	
				YEAR	Value	T	ALV	T	ALV	T	ALV	T	ALV	T	ALV
1. Governance and Administration	Improved Governance and Administration	Client satisfaction level	%	2025	80	80	± 5%	81	± 5%	81	± 5%	82	± 5%	82	± 5%
		Employee Satisfaction level	%	2025	77.06	77.5	± 5%	77.5	± 5%	78	± 5%	78.5	± 5%	79	± 5%
		Compliance level	%	2025	100	100	0	100	0	100	0	100	0	100	0
2. Medicines and Medical Devices	Improved Access to Essential medicines	Registered Essential Medicines	%	2025	89	95	± 5%	95	± 5%	95	± 5%	95	± 5%	95	± 5%
		Registered Local Medicines	%	-	-	60	±5%	65	± 5%	70	± 5%	75	± 5%	80	± 5%
	Improved regulatory Competence	WHO GBT Compliance Level	%	2025	99.8	100%	0	100%	0	100%	0	100%	0	100%	0
	Improved quality of medicines available to the public	Quality of imported medicines	%	-	-	NMT5	±0	5	±0%	5	±0%	5	±0%	5	±0%

T = Target; ALV = Allowable Variance

17. Outputs Performance Framework

No. & Prog. ref	Outputs	Measure ment	5-year target	Baseline		Targets											
						2026			2027			2028		2029		2030	
				Value	Year	T	A	AV	T	A	ALV	T	ALV	T	ALV	T	ALV
Programme: Governance and Administration																	
OUC 1 Improved Governance and Administration																	
OP 1.1	Institutional support provided: Vacant Posts Filled (HR)	%	95	90	2025	95		+/-5%	95		+/-5%	95	+/-5%	95	+/-5%	95	+/-5%
OP 1.2	Institutional support provided: Gadgets procured (ICT)	No.	25	40	2025	5		+/-1	5		0	5	0	5	0	5	0
OP 1.3	Sector legislation drafted (LCAU)	No.	25	5	2025	5		+/-1	5		0	5	0	5	0	5	0
OP 1.4	Staff Development Programmes Conducted (All HoUs/HoDs)	No.	50	93	2025	95		0	100		0	105	0	110	0	115	0
OP 1.5	Board Meetings conducted (DG/ LCAU)	No.	20	4	2025	4		0	4		0	4	0	4	0	4	0
OP 1.6	Internal Audits Conducted (QU/IAU)	No.	105	21	2025	21		0	21		0	21	0	21	0	21	0
OP 1.7	ICT Systems Developed (ICT)	No.	20	12	2025	5		+/-1	5		+/-1	5	+/-1	5	+/-1	5	+/-1

No. & Prog. ref	Outputs	Measure ment	5-year target	Baseline		Targets											
						2026			2027			2028		2029		2030	
				Value	Year	T	A	AV	T	A	ALV	T	ALV	T	ALV	T	ALV
OP 1.8	Revenue Collected (PVCT, LSD, LED, EVR)	Amt ZWG	954M	190.8M	2025	190.8		+/- 10%	190.8		+/- 10%	190.8	+/- 10%	190.8	+/- 10%	190.8	+/- 19.08
OP 1.9	Educational Awareness programmes conducted (PR)	No.	100	20	2025	20		+/-2	20		+/-2	20	+/-2	20	+/-2	20	+/-2
OP 1.10	Sector Annual report produced (PR)	No.	5	1	2025	1		0	1		0	1	0	1	0	1	0
Programme: MEDICINES AND MEDICAL DEVICES																	
OUC 2 Improved Access to Essential Medicines																	
OP 2.1	Medicines and medical devices registered. (LSD)	No.	2500	505	2025	503		+/-50	503		+/- 50	503	+/- 50	503	+/- 50	503	+/-50
OP 2.2	Sector performance report produced (quarterly) (LED, PVCT, EVR, LSD)	No.	25	-	2025	4		0	4		0	4	0	4	0	4	0
OP 2.3	Sector research projects conducted (LED, EVR, PVCT)	No.	15	-	2025	3		0	3		0	3	0	3	0	3	0
OUC 3 Improved regulatory Competence																	
OP 3.1	Licences and permits processed	No.	17500	3500	2025	3500		+/-10	3500		+/- 10	3500	+/- 10	3500	+/- 10	3500	+/- 350

No. & Prog. ref	Outputs	Measure ment	5-year target	Baseline		Targets											
						2026			2027			2028		2029		2030	
				Value	Year	T	A	AV	T	A	ALV	T	ALV	T	ALV	T	ALV
	within GBT guidelines. (LED)																
OP 3.2	Licensing frameworks reviewed (LED)	No.	10	2	2025	8		0	2		0	8	0	2	0	8	0
OP 3.3	Inspections reports produced within GBT guidelines. (LED)	No.	5500	1100	2025	1100		+/-10	1100		+/-10	1100	+/-10	1100	+/-10	1100	+/-110
OP 3.4	Clinical trials recommended within GBT guidelines. (LED/PVCT)	No.	35	7	2025	7		+/-1	7		+/-1	7	+/-1	7	+/-1	7	+/-1
OUC 4 Improved quality of medicines available to the public																	
OP 4.1	Medicines and Medical Devices Analysed vs total received (LSD)	%	100%	95%	2025	95%		+/-5%	95%		+/-5%	95%	+/-5%	95%	+/-5%	95%	+/-10%
OP 4.2	Regulatory support equipment procured (LED)	No.	5	-	2025	5		+/-1	-		-	-	-	-	-	-	-

T = Target A = Actual AV = Actual Variance

ALV = Allowable Variance

18. MCAZ Budget

Programme	Preliminary Outcome	Programme Outputs	Budget Last Year (ZWG)	Budget Current Year (ZWG)	Budget Year 1 (ZWG)	Budget Year 2 (ZWG)	Budget Year 3 (ZWG)	Budget Year 4 (ZWG)	Budget Year 5 (ZWG)
Programme 1	Improved Governance and Administration	Institutional support: Vacant Posts Filled (HR)	94,423,051	131,700,181	111,751,666	117,339,249	123,206,212	129,366,522	135,834,848
		Institutional support: Gadgets (ICT)		530,000	556,500	584,325	613,451.25	644,218.31	676,492.23
		Sector legislation drafted (LCAU)	3,460,915	7,330,998					
		Staff Development Programmes Conducted (All HoUs/HoDs)	9,165,850	10,632,526	19,962,450	20,960,573	22,008,601	23,109,031	24,264,483
		Board Meetings conducted. (DG/LCAU)	4,801,071	8,184,752	2,486,243	2,610,555	2,741,083	2,878,137	3,022,044
		Internal Audits Conducted (IAU)	0.00	0.00	1,764,900	1,853,145	1,945,802	2,043,092	2,145,247
		ICT Systems Developed (ICT)	3,598,459	3,777,269	10,268,371	10,781,790	11,320,879	11,886,923	12,481,269
		Revenue Collected (EVR/PV CT/LSD/LED/FIN)	10,643,414	15,906,947	5,406,000	5,676,300	5,960,115	6,258,121	6,571,027
		Educational Awareness	0.00	0.00	3,293,950	3,458,648	3,631,580	3,813,159	4,003,817

		programmes conducted. (PR)							
		Sector Annual report produced (PR)	212,000	265,000	278,250	292,162.50	306,770.63	322,109.16	338,214.61
		Statutory reports produced	573,498	693,550					
		Internal QMS audits conducted (QU)	622,515	1,303,416					
		ML4 IDPs addressed	0.00	0.00					
Total Programme 2 Budget									
Programme 2	Improved Access to Essential Medicines	Medicines and medical devices registered. (EVR/MDU)	0.00	0.00	7,153,107	7,510,762	7,886,300	8,280,615	8,694,646
		Sector performance report produced (quarterly and annual) (LED, PVCT, EVR, LSD)	0.00	0.00					
		Sector research projects (LED, EVR, PVCT)	0.00	0.00					

		Schedule of GMP inspections conducted	5,168,761	8,970,298					
		Clinical trials assessed	0.00	0.00					
		Applications for licenses and permits processed	2,332,501	5,355,813					
		Applications for registration of medicines and medical devices processed	0.00	0.00					
	Improved regulatory Competence	Licenses and permits processed within GBT guidelines (LED)			302,857	318,000	333,900	350,595	368,125
		Licensing frameworks reviewed (LED)	0.00	0.00					
		Inspections reports produced within GBT guidelines (LED)			17,656,420	18,539,241	19,466,203	20,439,513	21,461,489
		Clinical trials recommended within GBT guidelines (PVCT)			302,857	318,000	333,900	350,595	368,125

	Improved quality of medicines available to the public	Medicines and medical devices analysed vs total received	2,570,120	3,324,456	302,857	318,000	333,900	350,595	368,125
		Regulatory support equipment procured (PAU)	0.00	-					
TOTAL MDA BUDGET			137,360,155	197,180,206	180,651,678	189,684,262	199,168,475	209,126,899	219,583,244

19. Human Resources for the Strategic Period.

No.	Category	Programme 1	Programme 2	Programme 3	Programme 4	MDA Total Personnel Requirements by Category
1	Top Management	2	5	-	-	7
2	Middle Management	6	10	-	-	16
3	Supervisory Management	8	20	-	-	28
4	Operational and Support staff	33	72	-	-	105
5	Total	49	107	-	-	156

20. Other Resources and Projects

I. Equipment and ICTs

Materials/ Equipment /ICT	2026		2027		2028		2029		2030	
	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost
e.g. Motor Vehicle										
Laptops										
Motorised graders										

II. Space Requirements (where applicable)

Location	2026		2027		2028		2029		2030	
	Quantity (m ²)	Cost	Quantity (m ²)	Cost	Quantity (m ²)	Cost	Quantity (m ²)	Cost	Quantity (m ²)	Cost
State land for CeCORE Project	10h									

III. Projects for the Period

Project Name	2026		2027		2028		2029		2030	
	% completion	Cost	% completion	Cost	% completion	Cost	% completion	Cost	% completion	Cost
AI tools for Assessors	100%	ZWG 7.5M	-	-	-	-	-	-	-	-

and clinical trials										
Trace for clinical trials	100%	ZWG 6.4M	-	-	-	-	-	-	-	-
Afrivigilance AU3S	20%	ZWG 5.3M	40%	ZWG 5.3M	60%	ZWG 5.3M	80%	ZWG 5.3M	100%	ZWG 5.3M
Global Fund Quality Assurance program	100%	ZWG10.6M	-	-	-	-	-	-	-	-