MEDICINES CONTROL AUTHORITY OF ZIMBABWE

5 YEAR STRATEGIC PLAN

[2022-2026]

Glossary of Acronyms and Definitions

The following definitions apply throughout this document, unless the context requires otherwise. The use of singular words imports the plural, and masculine words import both feminine and neuter, and words importing natural persons shall include juristic persons (whether corporate or incorporate and vice versa):

ACRONYMS

The following acronyms are used in the document:

ACRONYM	MEANING
ADMIN	Administration
APIs	Active Pharmaceutical Ingredients
CGMP	Current Good Manufacturing Practice
CSC	Client Service Charter
DDA	Dangerous Drugs Act
DG	Director General
eCTD	Electronic common technical document
EDLIZ	Essential Drugs (medicines) List of Zimbabwe
EMA	Environmental Management Authority
EUAL	Emergency Use Authorisation Listing
FIN	Finance
GoZ	Government of Zimbabwe
HoD	Head of Division
HoU	Head of Unit
HPA	Health Professions Authority
ICT	Information Communication Technology
IMF	International Monetary Fund
ISO	International Standards Organization
IVD	In-vitro Diagnostic Kits
KRA	Key Result Areas
MASCA	Medicines and Allied Substances Control Act
MCAZ	Medicines Control Authority of Zimbabwe
M&E	Monitoring and Evaluation
MoFED	Ministry of Finance and Economic Development
MoHCC	Ministry of Health and Child Care
NDS1	National Development Strategy 1 (2021-2025)
NHS	National Health Strategy
NRA	National Regulatory Authorities
OPC-CGU	Office of the President and Cabinet – Corporate Governance Unit
PCZ	Pharmacists Council of Zimbabwe
PESTEG	Political Economic Social Technological Ecological and Governance
PRAZ	Procurement Regulatory Authority of Zimbabwe
PQ	Prequalification
PV	Pharmacovigilance
PVCT	Pharmacovigilance and Clinical Trials
RBZ	Reserve Bank of Zimbabwe
RCORE	Regional Centre for Regulatory Excellence
SADC	Southern Africa Development Community
SADCAS	Southern African Development Community Accreditation Service
SDG	Sustainable Development Goals
SI	Statutory Instrument
SOP	Standard Operating Procedures
SPB	State Procurement Board
STG	Standard Treatment Guidelines
SWOT	Strengths Weaknesses Opportunity Threats

ToR	Terms of Reference
WHO	World Health Organisation
WoGEPMS	Whole of Government Electronic Performance Management System
ZIDA	Zimbabwe Investment Development Authority
ZIMRA	Zimbabwe Revenue Authority
ZIZABONA	Zimbabwe Zambia Botswana Namibia

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1. INTRODUCTION AND BACKGROUND

The Medicines Control Authority of Zimbabwe (MCAZ) is a state owned enterprise established by an Act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15.03]. MCAZ was enacted by the Government of Zimbabwe to serve a specific purpose through the Ministry of Health and Child Care, and holds the overall responsibility for ensuring good quality and safe medicines and related products throughout the Pharmaceutical value chain.

On 16 November 2020, the Government of Zimbabwe launched the National Development Strategy 1 (NDS1) which charts policies, institutional reforms and national priorities that Government will be focusing on from 2021-2025.NDS1 is a key component of the Second Republic's plan and drive to achieve Vision 2030, ***Zimbabwe to emerge a prosperous and empowered upper middle income society by 2030***, through a bold transformative development agenda and has succeeded the Transitional Stabilisation Programme (TSP) which ran from October 2018 to the end of 2020.This national strategy provides direction and guidance for all planning across the various sectors of the economy, and for MCAZ specifically the health sector.

The NDS 1 priorities to which MCAZ directly has a part to play are Health and Well-being, Good Governance, Moving the Economy up the Value Chain and Structural Transformation (Pharmaceutical value chain) and Human Capital Development. MCAZ plays a pivotal role ensuring access to good quality, safe medicines, medical supplies and products.

The Ministry of Health and Child Care (MoHCC) in its Strategic Plan (2021 -2023), also emphasises the need for improved access to essential medicines and commodities, the harmonisation of quantification, procurement, warehousing and distribution through the introduction of electronic Logistic Management Information System (e-LMIS) which will include critical private sector functions and the promotion of local manufacturing of medicines and medical products. MCAZ has paid particular attention to its responsibility, with the establishment of a Small Business Support (SBS) Unit in 2021, to provide local manufacturing support and facilitative assistance, under the Key Programme of Bio-Medical Engineering, Bio-Medical Science, Pharmaceutical and Bio-Pharmaceutical Production. This is in line with the Ministry thrust towards increased local medicines manufacturing to imported medicines ratio from 20:80 towards 80:20.

In line with the various issues highlighted at a national and sector level, MCAZ has developed a five year strategic spanning (2022-2026) which takes cognisant of, and supports the national agenda as set in NDS1 and in line with Ministry of Health and Child Care (MoHCC) vision *"to provide, administer, coordinate, promote and advocate for the provision of equitable, appropriate, accessible, affordable and*

acceptable quality health services and care to Zimbabweans while maximising the use of locally available resources in line with the Primary Health Care approach.''

This Results-Based Strategic Plan seeks to communicate the MCAZ vision, mission, key result areas, impacts, outcomes, strategies, major programmes, outputs and direction to its employees, clients, stakeholders and partners. It also establishes a road map of the strategic results, programmes, projects and activities that the MCAZ will focus on in the short to medium term. The initiatives from this strategic plan will be evaluated on the achievement of the anticipated results in terms of the MCAZ budgets, performance contracts, annual work and performance monitoring plans in the plan period.

This document captures the work done by the Medicines Control Authority of Zimbabwe in October and November 2021 in crafting its five year strategic plan (2022-2026). Intense discussions and interrogations were done to ensure not only alignment to national priorities and MCAZ mandate, but to validate targets, and the appropriate strategies to achieve defined outcomes.

2. NATIONAL & MINISTRY VISION AND PRIORITIES

i) National Level Contribution:

a. National Vision: "Towards a Prosperous Empowered Upper Middle-Income Society by 2030"

At the National Level, the realisation of Vision 2030 will be through the implementation of the following Strategic Programmes as outlined in The Zimbabwe National Development Strategy for the period 2021-2025(NDS1) supported by appropriate National Budgets

b. National Priorities the Authority is contributing to:

According to NDS 1, 14 priorities have been set; 4 of these are expected to impact MCAZ directly. The specific priorities, related Key Results Areas and Outcomes that MCAZ is contributing to are highlighted below:

	Description of National Priority Area
NPA1	Economic Growth and Stability
NPA 2	Food Security and Nutrition Security
NPA 3	Governance
NPA 4	Moving the Economy up the Value Chain and Structural Transformation
NPA 5	Human Capital Development
NPA 6	Environmental Protection, Climate Resilience and Natural Resource Management
NPA 7	Housing Delivery
NPA 8	Digital Economy
NPA 9	Health and Well-being
NPA 10	Infrastructure and Utilities
NPA 11	Image Building and International Engagement and Re-engagement
NPA 12	Social Protection
NPA 13	Youth, Sport and Culture and
NPA 14	Devolution.

c. National Key Result Areas the Authority is contributing to:

	Description of the National Key Result Area
NKRA 1	Nutrition Security
NKRA 2	Public Service Delivery
NKRA 3	Innovation and knowledge driven economy
NKRA 4	Public health and well being
NKRA 5	Provision of Infrastructure and services
NKRA 6	Quality and affordable social protection
NKRA 7	Equitable regional development

d. National Outcomes the Authority is contributing to:

	Description of National Outcome
NOUC 1	Improved Nutrition status

NOUC 2	Enhanced Service Delivery
NOUC 3	Specialised Workforce
NOUC 4	Improved Quality of life
NOUC 5	Improved infrastructure and access to services
NOUC 6	Improved access to inclusive social protection
NOUC 7	Improved inclusive governance and socio-economic development

ii) Ministry Level Contribution:

Ministry Name: Ministry of Health and Child Care

In pursuance of the National Priorities and in line with the National Health Strategy the MoHCC has defined its Key Result Areas for 2021 as shown below. For MCAZ specifically, MKRA 3 and MKRA 4 apply.

a. Ministry Key Results Areas:

	Description of Ministry Key Result Area	Weight (%)	NKRA Ref
MKRA 1	Public Health	40	1, 2, 4,6
MKRA 2	Curative Services	30	2,3,4,6
MKRA 3	Bio-Medical Engineering, Bio- Medical Science, Pharmaceuticals, Bio-Pharmaceutical Production	20	2,3,4,5
MKRA 4	Policy and Administration	10	2,4,5,6,7

b. Ministry Programme Outcomes

The Outcomes for the MoHCC are listed in the table below. The Outcomes that MCAZ is contributing to specifically are highlighted below:

	Description of Ministry Outcome
MOUC 1	Increased domestic funding for health
MOUC 2	Improved human resource performance in health sector
MOUC 3	Improved enabling environment for health service delivery (governance)
MOUC 4	Increased access to water, sanitation and health environment
MOUC 5	Reduced morbidity and mortality due to communicable and Non-Communicable Diseases
MOUC 6	Improved Reproductive, maternal, new-born, child and adolescent health and Nutrition
MOUC 7	Improved public health surveillance and disaster preparedness and response
MOUC 8	Improved access to primary, Secondary, Tertiary, Quaternary and Quinary health care services
MOUC 9	Improved access to availability of essential medicines
MOUC 10	Improved infrastructure facilities and critical equipment for Health service Delivery

3. MCAZ VISION (where are we going)

"To be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally."

Key focus for MCAZ for 2022 and over the next five years of its vision is stated below:

Key focus 2022

"To attain WHO GBT level 3 by 31 December 2022."

Key focus 2026

"The authority to be fully automated by 31 December 2026."

4. MCAZ MISSION (why do we exist)

"To ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health."

5. VALUES

Values are critical in guiding behaviours, and these are defined to ensure a common understanding. Organisational values drive the way we influence, how we interact with each other, and how we work together to achieve results. Our values as an organisation form the foundation of workplace behaviours and are not descriptions of the work we do or strategies we employ to achieve our mission.

Our values are the unseen drivers of our behaviour, based on our deeply held beliefs that drive decision-making. The collective behaviours of all employees become the organisational culture – "***the way we do things around here".*** As part of the strategic process, MCAZ defined the following values as key enablers and reflecting the behaviours that are important to them to row the strategic boat in the right direction and the right way. These are listed below and their supporting definitions:

- **Customer Focus:** Being reliable, responsive to needs, communicating and creating a conducive working environment.

- **Integrity:** Being ethical, professional, objective, honest and adhering to moral values.
- **Continuous Improvement:** Being proactive, dynamic, and adaptive in all we do.
- **Accountability:** Taking full responsibility for our actions.
- **Innovation:** Being innovative in our problem solving.
- **Teamwork:** Being collaborative, working together as one in pursuit of defined outcomes.

6. TERMS OF REFERENCE

The terms of reference provide guidelines to how MCAZ operates. These are: -

a. **Medicines and Allied Substances Control Act [Chapter 15:03]**
b. **Dangerous Drugs Act (Chapter 15:02)**

7. MCAZ OVERALL FUNCTIONS

MCAZ's core functions are derived from the terms of reference and provide clarity on the activities that the organisation must undertake as detailed below:

a. Control of clinical trials.
b. Registration of medicines and medical devices.
c. Licensing and controlling premises and persons handling medicines.
d. Safety monitoring of medicines and medical devices.
e. Import/export control.
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
i. Provision of Medicines Information and promotion of rational use of medicines.
j. Monitoring of medicines utilisation.

8. DEPARTMENTS AND CORE FUNCTIONS

MCAZ is comprised of various departments who work to fulfil and support the core functions. The departments and their respective functions are detailed in the table below:

DEPARTMENT/UNIT	FUNCTIONS
EVALUATION AND REGISTRATION DIVISION (EVR)	• Registration of human and veterinary medicines. • Approval of complimentary medicines. • Inspection of veterinary medicines general dealer. • Publication of the drug register.
PHARMACOVIGILANCE AND CLINICAL TRIALS (PVCT)	• Pharmacovigilance (PV) (safety monitoring of medicines, vaccines & medical devices) including active PV programs & projects • Data analysis of drug safety data, publications & WHO shared databases, Vigiflow, Vigilyze and Cemflow. • Communication of drug safety information in a way that improves therapeutics & patient safety. • Drug information bulletin publications. • Training of PV & GCP to relevant stakeholders internal & external. • Monitoring product defects & recalls. • Regulation of clinical trials of medicines, vaccines & medical devices including Good Clinical Practice (GCP) inspections. • Post-registration processes such as: (i) Application for amendments to registered medicines (ii) Applications for reinstatements of registered medicines (iii) Annual retention of registered medicines (iv) Registered medicines cancellations or withdrawals (v) Medicines safety reviews • Harmonisation and keeping abreast with global standards.
LICENSING AND ENFORCEMENT(LED)	• Conducting planned routine & new premises inspections for monthly Licensing & Advertising Committee meetings. • Conducting Market Surveillance and product defect investigations. • Attending to all import and export issues. • Attending to all narcotics issues. • Attending to all enforcement issues. • Assessing and processing applications for importation of unregistered medicines. • Recording minutes and executing decisions of the Licensing & Advertising Committee.

DEPARTMENT/UNIT	FUNCTIONS
QUALITY OFFICE (QU)	• Responsible for development & implementation of the Quality Management Systems: - ISO 17025 Standard - ISIO 9001 standard - cGMP & WHO guidelines in the laboratories - Good Laboratory Practices • Complaints Handling System • Service to the Customer • QMS Audits • QMS trainings • Responsible for accreditation, certification and Pre-Qualification processes • Responsible for Samples Handling • Responsible for document control & formatting.
CHEMISTRY DIVISION	• Overall function is to ensure quality of medicines in the nation through testing. • Samples analysed are for purposes of - Registration of medicines - Post-market surveillance - Pre-distribution analysis - Quality checks after adverse drug reaction on the market.
MEDICAL DEVICES AND MICROBIOLOGY UNIT	• Medical Devices: - Regulation and Quality Conformity Assessment of male condoms in accordance with SI 183 of 2005 - Regulation and Quality Conformity Assessment of medical gloves in accordance with SI 1 of 2006 - Factory inspections (cGMP) of condom and glove manufacturing facilities. • Microbiology: - Quality Conformity Assessment of medicines and allied substances - Quality Conformity Assessment of complementary medicines - Evaluation of vaccine Summary lot protocols.
THE LEGAL UNIT	• To competently implement all relevant statutes. This entails the constant review of legislation to ensure that it suites the changing needs of the industry. Where gaps are identified, to draft the necessary amendments to the legislation and, with the approval of the Minister of Health and Child Care, have the regulations gazetted.

DEPARTMENT/UNIT	FUNCTIONS
ICT	• 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 its vision and mission.
INTERNAL AUDIT UNIT	• 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	• 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. • To facilitate strategic human resource planning at all levels and the development of appropriate activities to attract highly competent talent. • To continuously develop and facilitate performance management methods and processes throughout the organization and communicating outcomes for further HR planning. • To identify and facilitate relevant training and developmental opportunities in terms of the overall learning and growth strategy of the organization. • To champion a culture that encourages and rewards individual growth. • To facilitate the design and implementation of reward systems that maximise staff retention and contribution. • To promote a culture of a harmonious industrial relations climate.
FINANCE	• Cash Flows - To control the cash flow position throughout the Authority to understand the sources and uses of cash, and maintain the reliability of the streams of funds for the Authority • Accounts Receivable and Payable - The finance department also makes sure that creditors are paid in time. And also, to ensure that debtors pay within their approved debtor days. • Investments - The Finance department is responsible for managing the financial operations functional responsibilities. • Accounting/Reporting - The most important to running the business are the reports prepared for the Authority, for it is those reports that are used to appreciate their Authority's financial past and make decisions about its financial future.

DEPARTMENT/UNIT	FUNCTIONS
PROJECTS AND PUBLIC RELATIONS	• Planning, development and implementation of the Authority's projects and public relations strategies. • Undertakes research and produces presentations and press releases. • Organizes events, press conferences, exhibitions and press tours. • Involved in projects planning -related activities and monitoring budget execution. • 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 in order to improve the Authority's systems. The Unit also evaluates, investigates and resolves customer complaints to ensure that the Authority maintains a good relationship with its customers.
PROCUREMENT AND ADMINISTRATION	• Ensuring sustainable procurement on all matters through effective planning, effective sourcing, effective negotiations, good supplier relationship management, strict adherence to specifications, internal procedures, controls, adherence to stipulated turnaround times and time management in compliance with relevant statutes such as the Public Procurement and Disposal of Public Assets (PPDPA) Act and Regulations. • Planning for asset disposals and ensure obsolete assets are disposed of in line with the Public Procurement and Disposal of the Public Assets (PPDPA) Act, • Maintaining a robust paper and electronic Registry and filing system. Ensure a well-coordinated filing system in the Records Rooms and functional Reference File Index system in all correspondences • Ensuring regular maintenance and servicing of motor vehicles, equipment and buildings

9. ENVIROMENTAL SCAN

a. Current Situation - 2021 Performance Review

A review of the Authority's successes and challenges in the Key Result Areas as at 30 September 2021, the final year of the 3-year planning period 2019-2021 was conducted. The following are what were identified:

KEY RESULT AREA	SUCCESSES	CHALLENGES
1. Sustainable Resource Base	1. Operational Revenue collected was ZWL$117.5M and USD2M. The consolidated Revenue collected was USD3.4M vs a target of USD3.5M 2. Revenue mobilised: - 2021-2023 Global Fund budget approved. US$1,026,424.50 earmarked for 2021. - UNICEF US$80k initial budget request approved. Additional budget request of $100,000.00 submitted to UNICEF. - External samples analyzed to date $122,402 3. 100% required infrastructure attained. - Implementation of the back-up solar project is 99% complete, with licensing of the Solar system in progress and officers to be trained on the solar system. 4. Increased inflow of medical gloves for - testing (100% increase from last year).	1. USD 12, 283 received as indirect costs (MCAZ income) for year 2 of the EDCTP project. 2. Reduced revenue for Desk reviews of factories. 3. Economic volatility. 4. Covid-19 disruptions resulting in delayed payments for GMP inspections.
2.Competent and Motivated People	1. 250% upward review of basic salary back-dated to January 2021. 2. Regular employee engagement. 3. Some Divisions conducted competency assessment of their staff e.g. Chemistry, LED, PVCT, Quality, MMD and the concerned staff were advanced to the next higher grade after meeting the requisite competencies.	1. Employees' satisfaction 70% vs target of 75%. An employee satisfaction survey will be conducted at the end of 2021 to establish the new satisfaction rate. 2. Competency gap at 3% vs target of 2%. 3. Loss of critical skills and high turnover continues to be a challenge. 4. Challenges with work from home – internet connectivity, time allocation, supervision, equipment
3. Effective Regulatory Process	1. Increase in number of local applications submitted, with 95% annual target achieved. 2. Baseline 7 registrations in 2020. 50% increase on 7 products is 10.5 products. So far 10 products registered towards a target of 10.5% 3. MoHCC engaged on pending legislation and MCAZ advised on submission format aligned to National agenda to accelerate process. Draft submissions have been made.	1. Formal assessment by WHO done from the 16th -27th August 2021. Overall MCAZ is at ML1 against the target of WHO GBT Maturity Level 3. 2. PVCT- Adhered to 90% timelines some delay in approval of a COVID-19 vaccines trial in pregnancy. 3. Enabling legislation still pending approval.
4. Effective Automated Systems	1. No intrusion and data loss has been recorded. 0%.	1. Planned processes automatedat 84.6% vs target of 90%. 2. Operational efficiency of automated systems at 81% vs target of 90%.

KEY RESULT AREA	SUCCESSES	CHALLENGES
5. Positive and Constructive Stakeholder Relations	1. Customer satisfaction survey carried out as planned and reported. 2. Most of the gaps noted in the Customer Satisfaction survey have been addressed. 3. 2021 Stakeholder engagement plan developed. 4. Exploited virtual platforms for increased customer engagement. 5. Increased engagement with media houses	1. Customer satisfaction is low at 39.95% vs target 70%. 2. Implementation of Stakeholder engagement plan is currently at 95% owing to inability to conduct planned physical public awareness activities due to Covid-19 restrictions and lockdowns. 3. Transferability of the SERVQUAL survey methodology to an organization like MCAZ. 4. Increased call for MCAZ involvement in matters to do with drugs and substance abuse.
6. Good Governance	1. Compliance with all relevant and appropriate legislation and governance practices. 2. Microbiology lab commissioned and in operation 3. Medical devices lab maintained its ISO 17025 Accreditation. 4. ISO 9001 certification retained 5. ISO 17020 accreditation 6. Two short courses offered to the region.	1. Lack of cleaning and gowning material for the cleanroom. 2. Absence of Sterility testing equipment (Steritest)

From the performance review above, all units were adversely affected by the Covid-19 pandemic in different ways. The Covid-19 pandemic was an overarching challenge with some units not being able to execute all events and activities as planned and in the form that is usually done. This led to the unavoidable pressure to adapt quickly to working differently in the virtual space, as well as Covid-19 vaccines testing and approvals.

An analysis and review of the organisation's performance in 2021, and the related successes and challenges also provided input for the determination of the organisation's current strengths and weaknesses which are discussed later in this document.

b. PESTEG Analysis

The PESTEG analysis identified those factors (political, economic, social, technological, environmental and legal/ governance), in the macro-environment that affect and are expected to affect the operations of the MCAZ going forward. Outlined in the table below is the analysis of the various factors.

FACTOR	KEY TRENDS AND ASSUMPTIONS
POLITICAL	1. Greater focus to capacitate MCAZ by the government. 2. Regional harmonization- AMA and SADC Harmonisation project. 3. Economic sanctions a barrier to access some multilateral funds. 4. Mandate overlap of multiple agencies (NBA, DTM/TMPC, ZIDA).
ECONOMIC	1. Government support for local Pharma and complementary medicines industry 2. Donor dependence. 3. Increased appetite for local investment (e.g., ZIDA). 4. Loss of revenue due to corruption in the supply chain 5. Skills flight- migration of highly qualified and skilled staff. 6. NDS1 – from consumerism to production 7. Reduced customer levies due to multiple regulators (one stop shop), ease of doing business. 8. Currency restrictions – bond notes (fees pegged in volatile ZWL-viability), RTGs, restrictions in remittances, lack of flexibility with the USD accounts and security of currency in place.
SOCIAL	1. Increased demand for complementary (and traditional) medicines. 2. Improved health seeking behavior. 3. Increase in incidences of substance abuse. 4. Smuggling and illegal sourcing of drugs and medicines which are comparatively cheaper potentially unsafe medicines. 5. Non-regulated goods in transit. 6. Covid-19 pandemic- lockdown and work from home, uncertainty, PPEs and test kits quality issues. 7. Below average quality of life.
TECHNOLOGICAL	1. Increased drive for use of ICT in the country. 2. RFID and cloud computing. 3. Data piracy/theft, Cyber-crimes (Cyber disinformation. 4. Potential for improved customer satisfaction due to availability of more convenient online services, Import systems. 5. Rapid change in technology and acceleration of digitalization. 6. New technology not yet regulated (nanotechnology, gene therapy).
ECOLOGICAL	1. Systems Strengthening for Emergency Preparedness 2. Antimicrobial resistance (Antibiotics, Feed additives, Antimicrobial APIs, Discharge of antimicrobial residues into the environment (land, water, air). 3. Waste Management and disposal (EMA Waste disposal guidelines)
LEGAL AND GOVERNANCE	1. Greater focus on corruption and transparency in Government. 2. Increased demand for centre of Excellence in regulatory affairs. 3. Increased insistence on compliance 4. Delays in approval of legislation. 5. Unregulated cosmetics. 6. Non-cGMP compliant local manufacturers. 7. Regulation and capping of salaries. 8. Expansion of regulatory scope – Medical Devices (including IVDs), PPEs, API, Blood and Blood Products. 9. MASCA review necessitated by WHO GBT assessment. 10. Available network of potential regulatory partners *(BfARM Germany, VMD UK, Egypt, China, NMRC).*

c. SWOT Analysis

As a culmination of the successes and challenges and PESTEG analysis above, a SWOT analysis to evaluate the MCAZ's internal situation Strengths and Weaknesses, as well as the Opportunities and Threats emanating from the external environment, was undertaken; this is detailed below along with the key issues identified from the analysis:

STRENGTHS- Strengths are the qualities that enable us to accomplish MCAZ's mission. These are the basis on which continued success can be made and continued/sustained. Strengths can be either tangible or intangible
1. Core medical products regulator. 2. Standardized systems and statutes. 3. Skilled and experienced personnel. 4. Quality management system in place with documented SOPs. 5. Performance management system in place linked to strategy. 6. Number of committees with stakeholder representation. 7. Strong self-accounting system. 8. Accreditation, and WHO Prequalification status 9. Independent decision making. (Authority board has final say-autonomous). 10. Robust core business infrastructure. 11. Good relationship with the Ministry. 12. Good governance structure including committed board and committee members. 13. Donor confidence. 14. Ability to develop regulatory capacity e.g. RCORE. (training of staff and other regulators) 15. Ability to influence statutes 16. Ability to influence global and regional regulatory affairs. 17. Majority of staff is vaccinated and PPE availed to staff 18. Adaptive culture to change e.g. work from home, virtual meetings and virtual inspections. 19. Salaries consistently paid.

WEAKNESSES - Weaknesses are the qualities that could prevent MCAZ from accomplishing its mission and achieving our full potential.
1. Poor remuneration 2. Lack of tools of trade 3. Inadequate retention of human resources. 4. Inadequate categorisation of skills (HR prioritising due to budgets, LED inspectors inadequate in terms of numbers). 5. Customer Service inconsistencies (external). 6. Slow progress in bringing new staff up to speed (steep learning curve due to the nature of the job, for example a new member of staff being trained to become a GMP inspector or dossier assessor).

WEAKNESSES - Weaknesses are the qualities that could prevent MCAZ from accomplishing its mission and achieving our full potential.

7. Inadequate coverage of regulatory activities due to inadequate legislative framework and resources.
8. Bureaucratic decision making due to legal operating framework
9. Centralization of services in Harare
10. Inadequate resources (financial, HR and materials e.g. laptops and vehicles).
11. Document management systems not up to standard.-not fully automated
12. Lack of fully validated automated ICT systems.
13. Poor connectivity to support virtual activities
14. Ineffective teamwork- working in silos.
15. Failure to fully exploit technology.
16. Slow responsiveness to the environment (Geo- economic and political issues).
17. Long Turnaround times
18. High staff turnover

OPPURTUNITIES- These arise when MCAZ can take benefit of conditions in its environment to plan and execute strategies that enable it to provide better service delivery.

1. Greater focus on corruption and transparency in Government.
2. Greater focus to capacitate MCAZ by the government
3. Increased demand for complementary (and traditional) medicines.
4. Available network of potential regulatory partners *(BfARM Germany, VMD UK, Egypt, China, NMRC).*
5. Increased drive for use of ICT in the country.
6. Potential for improved customer satisfaction due to availability of more convenient online services, Import systems (Automation of all key business processes).
7. Increased insistence on compliance.
8. Regional harmonization- AMA and SADC Harmonisation project.
9. Increased demand for centre of Excellence in regulatory affairs.
10. Unregulated cosmetics.
11. Increased appetite for local investment (e.g., ZIDA).
12. Refurbished Microbiology.
13. Antimicrobial resistance (Antibiotics, Feed additives, Antimicrobial APIs, Discharge of antimicrobial residues into the environment (land, water, air).
14. Government support for local Pharma and complementary medicines industry.
15. NDS1 – from consumerism to production.
16. Expansion of regulatory scope – Medical Devices (including IVDs), PPEs, API, Blood and Blood Products.
17. MASCA review necessitated by WHO GBT assessment.
18. Systems Strengthening for Emergency Preparedness.

THREATS- Threats arise from conditions in the external environment that jeopardize the reliability and service delivery of MCAZ.

1. All fees pegged in volatile ZWL-viability?
2. Economic sanctions.
3. Non-cGMP compliant local manufacturers

THREATS- Threats arise from conditions in the external environment that jeopardize the reliability and service delivery of MCAZ.
4. Donor dependence. 5. Reduced customer levies due to multiple regulators (one stop shop), ease of doing business. 6. Poor perception by society regarding effectiveness of delivery. 7. Increase in incidences of substance abuse. 8. Smuggling in of drugs and medicines. 9. Non-regulated goods in transit. 10. Loss of revenue due to corruption in the supply chain 11. Rapid change in technology. 12. New technology not yet regulated (nano technology, gene therapy). 13. Delays in approval of legislation. 14. Regulation and capping of salaries. 15. Currency restrictions – bond notes, ZWL, RTGs, restrictions in remittances, lack of flexibility with the USD accounts and security of currency in place. 16. Data piracy/theft, Cyber-crimes(Cyber disinformation 17. Covid-19 pandemic- lockdown and work from home, uncertainty, PPEs and test kits quality issues. 18. Migration of highly qualified and skilled staff. 19. Mandate overlap of multiple agencies (NBA, DTM/TMPC, ZIDA).

d. Key Strategic Issues

Considering the SWOT analysis, a number of key strategic issues were identified as being critical for defining the strategic direction of MCAZ over the next five years. The focal priority areas were aimed at aligning with the national agenda on health as spelt out in the National Development Strategy 1 as well as the evolving and changing environmental dynamics and challenges presented by Covid-19. These are listed below:

- Human Capital
- Service Delivery
- Governance
- Regulatory Processes
- Legislative Framework
- Resources
- Technology
- Organisational Development (Culture)

10. PROGRAMMES AND OUTCOMES

The NDS1 priorities, National Health Strategy, MoHCC Key Result Areas, together with the key issues from the SWOT Analysis were then used to assist in defining the Key Programmes for MCAZ as outlined in the table below.MCAZ Programmes reflect that it plays a complementary role in achieving ministry and ultimately national outcomes, these programmes also speak to and support the sustainability development goal (SDG), "**Ensure healthy lives and promote well-being for all at all ages"**.

Programme	Programme Name	Programme Outcome/s	Weight %	Responsible Department	Contributing AGENCYs/Other Partners	Type of Contribution	Ministry Outcome Ref.	National Outcome Ref	SDG ref
1.	**Medicines and Medical Devices Control**	Increased Customer Satisfaction	25%	DG's Office, PR, EVR,LED PVCT, Finance, PAU,ICT, HR	MoHCC, Ministry of Information, Attorney General	Policy Technical Advisory Support	3,7	2,3,4,6	3
		Increased Facilitative Regulatory Processes	20%	QU/All units /divisions					
		Improved Enabling Legislative framework	5%	Legal & Corporate Affairs, DG's Office, Finance					
2.	**Institutional Capacity**	Improved Effective Talent Management	15%	HC, Finance, DG's Office, HOD's	MoHCC, Ministry of Labour and Social Service, IPMZ, Ministry of Information, PRAZ MOFED, Health Development Partners, NGO's, MOIC, MOFAIT, ZIDA, DPS	Policy Technical Advisory Policy Financial Intersectoral Support	2,3	2.3.4	3
		Increased Operational Efficiency	15%	IT/DG's Office Finance					
		Adequate Resources	10%	PVCT,LED MMD unit, Chemistry Lab, DG's Office					
		Improved Values Based Culture	5%	DG's Office, HR, Finance					
3.	**Governance**	Good Corporate Governance	5%	Board, DG, Legal &Corporate Affairs	OPC-CGU, MoHCC, MoFED	Policy, Technical, Advisory	3, 7	2,3	3

11. POLICIES

No.	External	Prog Ref	No.	Internal	Prog Ref
1.	WHO Guidelines	1,3	1.	Human Resource Policy Manual	2
2.	Public Financial Management Act	2	2.	Finance and Administration Policy Manual	2,3

No.	External	Prog Ref	No.	Internal	Prog Ref
3.	Public Entities Corporate Governance Act[Chapter 10:31]	2,3	3.	ICT Security Policy Manual	2,3
4.	Public Procurement and Disposal of Public Assets Act [Chapter 22:23]	2	4.	Enterprise Risk Management Framework	3
5.	Procurement Regulations	2	5.	Human Resource Policy Manual	2
6.	Dangerous Drugs Act[Chapter 15:02].	1	6.	Finance and Administration Policy Manual	2,3
7.	ISO /IEC 4074 Standard for Natural Latex Rubber Condoms- Requirements and Test Methods	3			
8.	Medicines and Allied Substances Control Act (MASCA)(Chapter 15:03)	1			
9.	Southern African Development Community Accreditation Service (SADCAS)	3			
10.	Labour Act (National Employment Code of Conduct) Regulations 2006 SI 15 of 2006	2			
11.	MASCA Regulations SI 150 of 1991	1,3			
12.	MASCA Condom Regulation SI 183 of 2005	1,3			
13.	MASCA Gloves Regulation SI 1 of 2006	1			
14.	International Financial Reporting Standards	2			

12. CLIENTS' NEEDS AND PROBLEM ANALYSIS

External Clients	Needs/Problems	Characteristics/Extent and Priorities
1. Applicants	**Needs:** - Timely registration. - Timely, clear and scientifically sound, efficient and effectivecommunication, Clearup-to-dateguidance, access to information (online status updates), electronic submissions, courtesy, integrity, friendly environment, clear costing. Easy and efficientpayment processes. **Problems** - No clear guidelines, registration takes long, information not accessible.	- Poor availability of registered medicines.
2. Manufacturers	**Needs**: - Supportive Regulatory Authority; timely resolution of regulatory problems; guidance on best practice; timely reports after GMP inspections; preferential evaluations of applications for registration (local manufacturers); protection from foreign manufacturers (local manufacturers).Ease of doing business: One-Stop Shop, collaboration and complementarity of regulations. - Expedition of the registration of local medicines. - Expedition of approval/disapproval of variations. - MCAZ to partner with Manufacturing. - Facilitate technological transfer. - Relaxation of DMF. - Establishment of a Bioequivalence (BE) Study Centre and BE waivers. **Problems** - Old infrastructure; old products; little investment in R&D; poor capitalisation of operations, forex shortages for raw materials inputs.	- Further deterioration/demise of local industry as fewer and fewer manufacturers survive the economic turmoil and the overwhelming pressure from foreign manufacturers.

External Clients	Needs/Problems	Characteristics/Extent and Priorities
3. Distributors	**Needs:** - Faster registration of medicines; faster processing of import permits and licences; faster processing of applications for amendments; lower permit renewal fees; faster resolution of regulatory problems; less restrictions to trade. Faster authorisation of Section 75 applications. **Problems** - Most proprietors are laypersons when it comes to knowledge pertaining to the use and handling of medicines.	- Increase of incidences in the improper handling of medicines, importation of unregistered medicines, smuggling into Zimbabwe of unregistered medicines; avoidance of import permits; utilization of "runners" to speed up access to unregistered medicines.
4. Retailers	**Needs:** - Timely processing of applications. - Communication and guidance. - Flexibility in certain situations. - Policy issues relating to pricing and competition. - Inclusion of private sector in policy making. - Access to financing. - Research and Re-education into the production of galenical medicines. **Problems:** - Failure to provide adequate supervision for their premises. - Selling expired and unregistered medicines. - Buying medicines from unlicensed sources. - Duplication of processes (Licenses, License Fees).	- Lack of confidence in MCAZ as well as frustrations. - Patients being exposed to unqualified and unprofessional personnel. - Patients being exposed to medicines of unknown safety, quality and efficacy. - Collaboration with the Schools of Pharmacy. - Focus on Science of Pharmacy (distribution, supply, production) - Collaboration from and among between the entire sector (retailers, manufacturing, wholesalers
5. Industrial Clinics	**Needs:** - Timely processing of applications. - Communication and guidance. - Flexibility. **Problems** - Operating outside the scope of their licenses. - Failure to renew licences on time.	- Frustration and lack of confidence in MCAZ. - Patients being exposed to unqualified and unprofessional personnel.
6. Persons (Dispensers)	**Needs:**	- Exposure of the public to unapproved unregistered medicines; erroneous advice from unqualified

External Clients	Needs/Problems	Characteristics/Extent and Priorities
	- Less restrictive access to medicines required by patients. Less cumbersome requirements for acquisition of unregistered essential/life-saving medicines; more suppliers so that costs can be lower. **Problems** - Poor supervision of licensed premises; poor adherence to good dispensing practices; poor observation of regulatory requirements with respect to dispensing; sale of expired medicines; sale of unregistered medicines without authorisation.	persons; exposure of the public to expired medicines.
7. Hospitals and clinics	**Needs:** - Timely processing of applications. - Communication and guidance. - Flexibility in certain situations. **Problems** - Failure to provide adequate supervision for their premises. - Selling expired and unregistered medicines. - Buying medicines from unlicensed sources.	- Lack of confidence in MCAZ as well as frustrations. - Patients being exposed to unqualified and unprofessional personnel. - Patients being exposed to medicines of unknown safety, quality and efficacy.
8. Wholesalers/ Distributors	**Needs:** - Responsiveness to market needs - Enforcement (counterfeit products in the market). - Responsiveness to Non-Communicable Diseases (NCD) products. - Reduction of timelines with regard to registration - Data and information sharing. - Information on pending registration - Importation of devices. **Problems:** - Responsiveness of MCAZ - Cost of compliance is high as well as registration	- Wholesalers to become Warehouses of Manufacturers.
9. Academia	- Merging of retailers and wholesalers - Support in delivery of programmes	- MCAZ heavily involved in the training health sciences students.

External Clients	Needs/Problems	Characteristics/Extent and Priorities
	- Partnerships with the sector such as existing partnership with VARICHEM and Pharmaceutical Zimbabwe. - Appreciation of the importance of Education 5.0.	- The University of Zimbabwe has introduced 4 Masters Programmes (Heritage Based Pharmacy, Pharmaceutical Science, Pharmaceutical Toxicology and Regulatory Affairs) geared to enhance innovation in Pharmacy. - In a national first, MCAZ helped a traditional healer obtain product registration.
10. Researchers	**TBA**	-
11. Cannabis Producers	**TBA**	-
Internal Clients	**Demands/expectations**	**Characteristics/Extent/Priorities**
1. Staff	• Equal access to all employment benefits. • Unrealistic and or unaffordable remuneration. • Remuneration based on cost of living and not to productivity. - Training and development. - Promotion and advancement. - Health and safe working environment. - Guaranteed job security. - Equal opportunities. - Fair labour practices. - Sustained cushion from inflation (ca. 600%). - Improvement of conditions of services. - Engagement to provide service excellence. • Nostro personal and housing loans.	• The impact of staff demands will be negative as the organization will not be sustainable and lose its credibility due to unfettered access and release of confidential information to the public by all levels of staff. • Staff problems lead to an ungovernable workplace, incessant labour disputes on matters of right and matters of interest, lack of loyalty and sense of ownership, and failure to achieve the bigger picture of the organization in the medium to long term (vision and mission). - Indiscipline. - Failure to meet performance targets agreed on. - Confrontational, winner-take all mind-sets. - Vocal and outspoken as an end in itself. - Inability to interpret labour and employment laws. - Perceived favouritism. - Mob psychology tendencies.
2. Management (Inter Departmental)	- Accurate, effective & timeous communication. - Submission of agenda items on time. - Timely submissions of requests	• Frustration of staff • Committee members contributions compromised • Meeting preparation inadequate.

External Clients	Needs/Problems	Characteristics/Extent and Priorities
	- Timeous response/feedback to requests(reports, requisitions) - E-mail contributions must be timeous. - Effective project collaboration. - Good interpersonal relationships	• External reports – information could be insufficient and inaccurate • Loss of project funds. • Factions/ bias • Delay in submission of required information to execute internal business processes. • Delay in release of agendas to committee members • Delay in compilation of external reports. • Poor quality reports • Management meetings value compromised. • Internal bickering
3. Board	• Provided with clear Terms of Reference. • Provision of a properly constructed induction program. • Expect that Board decisions and recommendations are aptly executed. • Receive accurate, timely, adequate high-quality information to enable it to make sound decisions, monitor, effectively and provide advice to promote the success of the organisation. • Decent remuneration. • Expect to be able to give strategic direction for the organisation. • Monitors organisation performance against its strategic, operating and capital plans and financial budgets and assesses whether the objectives are being met. • The Board expects management to identify the principal risks facing the organisation, implements systems to manage these risks, and regularly reports on them to the Board. • The Board expects management to put in place appropriate policies and internal control systems in place to facilitate effective communication processes, to satisfy continuous disclosure requirements and ensure that financial results and other material events are reported on a timely basis. • Adequate time in the form of meetings to discuss business of the organisation.	• Lack of knowledge of duty expectations. • Failure to contribute effectively- Inability to give sound advice and recommendations. • None or delayed implementation of Board decisions and recommendation-leading to business failure- Poor relationship with management. • Inability to make effective or sound decisions or advice • Failure to attract Competent, experienced and knowledgeable Board members. • Failure to influence the strategic direction of the organisation. • Strategic failure. • Failure to determine whether the organisation has achieved an appropriate balance between risk and reward. • Poor decisions or advice given. • Rushed or poorly formulated policies and decisions passed. • Poor working relationship with management.

External Clients	Needs/Problems	Characteristics/Extent and Priorities
	• Competent, loyal and reliable management team.	
4. Committees	• Meet MASCA chapter 15:03 Act & statutory requirements. • Approve or disapprove or recommend decisions. • Rectify decisions with Full Authority. • Consider appeals or applicant representations. • Meet terms of references, roles & responsibilities. • Declare conflict of interest. • Meet confidentiality requirements. • Monitor relevant Division strategic /work plans & targets in line with DG work plan. • Advisory role to MCAZ & relevant Division/Unit • Competent Committee members. • Promote stakeholders' interest as per the Committee appointment e.g. representative from NatPharm, DPS-MoHCC etc. • Good Corporate governance, ethics & professional conduct.	• Poor attendances & lack of quorum sometimes. • Delayed decision-making process & timelines not met. • MASCA Mandate not met therefore: • Public exposure to substandard and harmful medicines thus impacting on public health and Prevalence of illegal drug manufacture leading to substance abuse, drug addict and growth of opportunistic infections. (HIV). Exposure of public to experimented drugs (treated as guinea pigs).No integrity in the distribution channels and unrestricted access to drugs leading to drug abuse and antibacterial resistance • Difficult to find Relevant competent Committee members • Poor remuneration. • Bureaucratic decision process & referral of some items between Committees & maybe duplication of work sometimes therefore increase timelines for approvals.

13. STAKEHOLDERS ANALYSIS

External Stakeholders	Demands/expectations	Characteristics/Extent/Priorities
1. Ministry of Health and Child Care.	• Fulfill the Mandate. • Ensure Quality of Medicines and Medical devices. • Ensure Safety of medicines. • Ensure Efficacy of medicines. • Provide Reports.	• Public exposure to substandard and harmful medicines thus negatively impacting on public health. • Prevalence of illegal drug manufacture leading to substance abuse, drug addict and growth of opportunistic infections.(HIV)

External Stakeholders	Demands/expectations	Characteristics/Extent/Priorities
	• Administer the DDA & the Conventions. • Regulation of Clinical trials. • Regulation of premises and persons. • Increased enforcement to curb leakage of medicines from public to private sector; prevent sale of Substandard Falsified medicines, illegal imports. • Support for local production. • Expansion of sources of supply to increase competition and lower prices. • Review of National Medicines Policy of 1980s where applicable.	• Exposure of public to experimented drugs (treated as guinea pigs). • Lack of integrity in the distribution channels and un restricted access to drugs leading to drug abuse and antibacterial resistance.
2. NatPharm	• Quick and efficient registration of medicines/medical devices. • Access to information.	• Ordering and Stocking of unregistered products by development partners.
3. National AIDS Council	• Registration of ARVs and medical devices. • Ensure safe, effective and quality of medicines and medical devices.	• Procurement of unregistered ARVs. • Spread of HIV virus by use of substandard medicines and devices by the public.
4. Public	• Available and affordable safe, efficacious and good quality medicines. • Quality service delivery. • Readily accessible information.	• Exposure to alternative, substandard, harmful medicines which pose a risk to public health. • Loss of credibility. • Soiled brand name.
5. Development Partners	• Partners are upholding the mission of the development partner and applying funds for the intended activities • Partners are keeping proper books of accounts • Accuracy of the financial records • Funds are utilized within stipulated timelines • Review and feedback on how programs can be expanded and improved	• Poor risk rating resulting in possibility of withdrawal of funds and being blacklisted. • Poor risk rating resulting in possibility of losing future grants • Poor risk rating resulting in possibility of losing credibility as a partner • Grant is forfeited
6. Professional Associations	• Sound, harmonized policies • Timely responses to issues • Collaboration • Guidance and Communication	• Professional subjected to multiple similar licensing • Frustration and lack of confidence in MCAZ • Lack of proper guidance for professions • Non-compliant professionals

External Stakeholders	Demands/expectations	Characteristics/Extent/Priorities
(PSZ, ZIMA, ZVA, HPA)	• Responsiveness and flexibility	• Professionals opting to break the law to meet patient needs
7. Trade Associations (PMA, EDA, AHIC, RPA)	• Timely processing of applications • Information on any development or changes • Flexibility and responsiveness to situations	• Delays to the end user of the medicines • Associates failing to comply with the current requirements • Lack of confidence in MCAZ
8. Suppliers	• To receive formal orders from MCAZ • To be paid for their services in time • Good relationship with MCAZ • Service level agreements	• If the suppliers do not receive written orders, they do not take MCAZ orders seriously. • If not paid in time, they do not treat MCAZ as their first-class customer. • If there is no good relation, suppliers' rate MCAZ as a very risk client and hence give it second class treatment. • If there is no service level agreement, suppliers do not really know how to satisfy MCAZ and are compelled to treat MCAZ like any other customer.
9. Professional Councils (ZVC,PCO,MC, TMPCZ)	• Sound harmonized policies and collaboration. • Timely response of issues. • Guidance and communication • Responsiveness	• Duplication of licenses • Frustration and lack of cooperation with MCAZ. • Lack of proper guidance for professionals
10. Other Gvt Ministries and Agencies (MoFED, Auditor General, MoHACH, EMA, SERA, PRAZ, CGU, ZIDA)	• Keeping of proper books of accounts. • Available and affordable safe, efficacious and good quality medicines. • Consider environment impact of medicines • Access to information and tech support • Separation of Audit Committee and Risk Committee	• Improve accounting of public funds • Destruction of the ecosystem. • Decline in animal health • Currently Audit and Risk Committee are one committee (2021 AGM feedback)

14. STRATEGIES, ASSUMPTIONS AND RISKS

Strategies: Game plan to achieve the targets

Assumptions: Positive factors that can assist in the achievement of the targets

Risks: Factors that militate against the achievement of results

Risk Mitigation: Interventions to reduce the gravity or intensity of the damage

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2022)	• Optimize automated systems. (i.e. Customer facing applications that have been deployed).	- Available resource capacity (human and financial). - Retention of competent technical staff. - Availability of funds.	- Failure to retain key personnel implementing systems. - Uavailability of funds for ongoing system maintenance.	- HR strategy for HR retention - Resource mobilization. .
	• Engage service providers (Universities) to develop ZIMDIS portal for payments that is integrated to all MCAZ systems.	- Competency and suitability of service providers. - Adequacy of resources. - System can be integrated with other existent systems.	- Iincompetent service providers - Delay in funds disbursed. - Incompatibility of the system.	- Clear User Requirement Specifications. - Involvement of technocrats in the procurement process. - Extensive due diligence in the selection process. - Resource mobilization.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2022)	• Engage service providers (Universities) to develop Stand-alone customer management system that is integrated to all MCAZ systems.	- Ability of University to develop systems. - Availability of Universities to develop systems. - Cooperation. - Financial resources.	- Slow response by Universities. - Apathy. - Late disbursement of funds. - Competing programs	- Early engagement. - Resource mobilisation. - Clear User Requirement Specifications. - Extensive due diligence in the selection process.
	• Implement strategies to close the gaps identified in the customer satisfaction survey as a gap closing tool that compel action on the part of the Authority. • (Introduce process timeline accountability policies)	- Gaps are representative of the customer base. - Have the capacity (human and financial) to close the gaps. - Automation of key business processes can close some of the gaps. - Retention of competent staff. - Availability of resources to continue with customer service excellence trainings. - No strict lockdowns to delay processes	- Insufficient time to implement change. - Staff attrition. - Inadequate human resources. - Lack of staff buy-in. - Redundancy in processes. - Processes not properly defined.	- Staff engagement and buy in. - Optimize automated processes developed. - Clear definition of processes.
	• Empowered and dedicated Customer Service function (Contact Desk).	- Competent personnel. - Authority buy-in. - Adequate of resources.	- Resistance to change. - Lack of resources. - Incompetent personnel. - Authority and staff does not buy-in. - Inadequate resources.	- Training development - Orientation - Advocating - Engagement of key stakeholders.
	• Conduct Customer Satisfaction survey to determine progress in	- Funds will be available. - Customers will respond.	- Lack of Cooperation from customers. - Lack of funds.	- Review SERVQAL type of survey and consider tailored regulatory survey.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2022	addressing customer satisfaction gaps		- PESTEG Environment likely to distort results.	
	• Customer journey mapping for key processes. – Identify pain points for all customers.	- Funds will be available. - Customers will respond. -	- Lack of Cooperation from customers. - Lack of funds. - PESTEG Environment likely to distort results.	- Review SERVQAL type of survey and consider tailored regulatory survey.
	• Conduct survey to determine baselines for all mapped key processes (Customer effort score (CES) survey).	- Funds will be available. - Customers will respond. -	- Lack of Cooperation from customers. - Lack of funds. - PESTEG Environment likely to distort results.	- Review SERVQAL type of survey and consider tailored regulatory survey.
	• Implement strategies to address customer pain points and improve Customer Effort Score ((Internal and External).	- Availability of resources (Financial and Human). -	- Lack of resources. - Poor customer engagement.	- Re-evaluate PR approach i.e., PR team members, IEC materials, Brand Strategy etc.
	• To develop the Stakeholder (Customer) Engagement Plan.	- Availability of resources (Financial and Human). -	- Lack of resources.	- Resource mobilization.
	• To implement the Stakeholder (Customer) Engagement Plan- Implement measures that improves Customer Effort Score.	- Availability of resources (Financial and Human).	- Lack of resources. - Poor customer engagement.	- Re-evaluate PR approach i.e., PR team members, IEC materials, Brand Strategy etc.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2023-2024)	• Optimize automated systems (i.e. Customer facing applications that have been deployed). • Rollout ZIMDIS portal for payments.	- Authority will retain the technical competencies to implement automated systems. - Availability of funds.	- Failure to retain key personnel implementing systems. - Uavailability of funds for ongoing system maintenance.	- HR strategy for HR retention. - Resource mobilization.
	• Implement process timelines accountability policies that compel action on the part of the Authority. • Note – After optimization of automated systems.	- Systems are optimized - Competent personnel - Efficient systems	- Loss of competent personnel. - Policy abuse.	- Adherence to policy. - Training and awareness. - System redundancy.
	• Implement strategies to close the gaps identified in the customer satisfaction survey as a gap closing tool.	- Gaps are representative of the customer base. - Have the capacity (human and financial) to close the gaps. - Automation of key business processes can close some of the gaps. - Retention of competent staff. - Availability of resources to continue with customer service excellence trainings	- Insufficient time to implement change. - Staff attrition. - Inadequate human resources. - Lack of staff buy-in.	- Optimize automated processes developed.
	• To develop the Stakeholder (Customer) Engagement Plan.	- Availability of resources (Financial and Human).	- Lack of resources.	- Resource mobilization.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2023-2024)	• To implement the Stakeholder (Customer) Engagement Plan.	- Availability of resources (Financial and Human).	- Lack of resources. - Poor ccustomer engagement.	- Re-evaluate PR approach i.e., PR team members, IEC materials, Brand Strategy etc.
Budget Year (2025-2026)	• Optimize automated systems (i.e. Customer facing applications that have been deployed). • Rollout ZIMDIS portal for payments.	- Authority will retain the technical competencies to implement automated systems. - Availability of fund	- Failure to retain key personnel. Implementing systems. - Uavailability of funds for ongoing system maintenance.	- HR strategy for HR retention. - Resource mobilization.
	• Implement process timelines accountability policies that compel action on the part of the Authority. • Implement strategies to close the gaps identified in the customer satisfaction survey as a gap closing tool.	- Systems are optimized. - Competent personnel. - Efficient systems. - Gaps are representative of the customer base. - Have the capacity (human and financial) to close the gaps. - Automation of key business processes can close some of the gaps. - Retention of competent staff. - Availability of resources to continue with customer service excellence trainings.	- Loss of competent personnel. - Policy abuse. - Insufficient time to implement change. - Staff attrition. - Inadequate human resources. - Lack of staff buy-in.	- Adherence to policy. - Training and awareness. - System redundancy. - Optimize automated processes developed.
	• Empowered and dedicated Customer	- Competent personnel. - Authority buy-in.	- Incompetent personnel	- Training development. - Orientation.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1:MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 1: INCREASED CUSTOMER SATISFACTION				
Budget Year (2025-2026)	Service function (Contact desk).	- Adequate resources.	- Authority and staff does not buy-in - Late disbursement of resources.	-Advocating
	• Conduct Customer Satisfaction survey to determine progress in addressing customer satisfaction gaps.	- Funds will be available. - Customers will respond.	- Lack of Cooperation from customers. - Lack of funds. - PESTEG Environment likely to distort results.	- Review SERVQAL type of survey and consider tailored regulatory survey.
	• To develop the Stakeholder (Customer) Engagement Plan.	- Availability of resources (Financial and Human).	- Lack of resources.	- Resource mobilization.
	• To implement the Stakeholder (Customer) Engagement Plan.	- Availability of resources (Financial and Human).	- Lack of resources. - Poor ccustomer engagement.	- Re-evaluate PR approach i.e., PR team members, IEC materials, Brand Strategy etc.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 2: INCREASED FACILITATIVE REGULATORY PROCESSES				
Budget Year (2022)	• Launch and formalise Small Business Support Unit (SBS)	• Executive Management support.	- Conflicting interests of the staff (Impartiality) - Political pressure.	- Use of separate teams for consultancy and regulatory work - Documented communication policy for the SBS

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 2: INCREASED FACILITATIVE REGULATORY PROCESSES				
Budget Year (2022)	• Reengineering of processes using risk-based approach. (identify and categorize processes for re-engineering)	- Capacity to re-engineer the measurement process. - Availability of resources.	- Inability to monitor and evaluate. - Inadequacy of resources.	- Training. - Use of external expert.
	• Development of risk-based framework to guide the re-engineering process.	- Availability of expertise to develop the framework.	- Non –availability of expertise	- Engage and external expert.
	• Develop and implement facilitative policies and processes that will encourage more local participation in the medical and pharmaceutical industry.	- Ability to conduct the assessment to determine the level of regulation of the local industry. - Resources available.	- Lack of ability to carry out assessment.	- Develop a plan, proposal and budget to enable the Authority to resource mobilise
	• To identify regulatory processes to be streamlined and integrated.	• Ability to identify regulatory processes that requires streamlining and integrated	- Failure to identify processes for streaming and integration.	- Review of criteria for streamlining and integration
	• Streamlining and integration of identified regulatory processes.	• Capacity to streamline and integration of regulatory processes.	- In ability to streamline and integrate regulatory processes.	- Training. - Use of external expert.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 2: INCREASED FACILITATIVE REGULATORY PROCESSES				
Budget Year (2023-2024)	• Review of streamlined and integrated processes for continuous improvement.	- Ability to review the streamlining and integration of regulatory processes for continuous improvement.	- Inability to review the streamlining and integration of regulatory processes for continuous improvement. - Inability to identify the need for continuous improvement.	- Training. - Use of external expert.
	• Re-engineering of processes for integration.	- Capacity to re-engineer processes for integration.	- Inability to re-engineer processes for integration.	- Training. - Use of external expert.
	• Monitoring and evaluation of the re-engineering process.	- Capacity to monitor and evaluate. - Availability of resources.	- Inability to monitor and evaluate. - Inadequacy of resources.	- Training. - Use of external expert. - Resource planning and mobilisation.
Budget Year (2025-2026)	• Review of streamlined and integrated processes for continuous improvement.	- Ability to review the streamlining and integration of regulatory processes for continuous improvement.	- Inability to review the streamlining and integration of regulatory processes for continuous improvement. - Inability to identify the need for continuous improvement.	- Training. - Use of external expert.
	• Re-engineering of processes for integration.	- Capacity to re-engineer processes for integration.	- Inability to re-engineer processes for integration.	- Training. - Use of external expert.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 2: INCREASED FACILITATIVE REGULATORY PROCESSES				
	• Monitoring and evaluation of the re-engineering process.	- Capacity to monitor and evaluate. - Availability of resources.	- Inability to monitor and evaluate. - Inadequacy of resources.	- Use of external expert. - Resource planning and mobilisation. Training.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 3 : IMPROVED ENABLING LEGISLATIVE FRAMEWORK				
Budget Year (2022)	• To advocate for the approval of the updated MASC Bill to incorporating GBT CAPA IDPs and Model Law	- The Bill will be updated within timelines.	- Failure to meet timelines due to Covid restrictions/lockdowns. - Delays in approval of the Bill. - Apathy.	- Continuous engagement until Bill is approved. - Hold progress update meetings. - Influence principals to approve the Bill.
	• To advocate for approval of Statutory Instruments addressing IDPS arising from the WHO GBT assessment	- The Statutory Instruments will be developed within timelines.	- Delays in approval of the SIs. - Competing priority issues.	- Influence principals to approve the Sis. - Continuous engagement.
	• Advocating stakeholders for support for the approval of the following drafts of legislation: 1. Import and Export of Medical Devices. 2. General Regulations. 3. Veterinary Medicines Regulations.	- Stakeholders willing to be push. - Positive response to advocating	- Delays in approval.	- Influence principals to approve the SI's. - Continuous engagement.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 3 : IMPROVED ENABLING LEGISLATIVE FRAMEWORK				
Budget Year (2022)	4. Blood and Blood components Regulations. 5. Hand sanitisers Regulations. 6. Medical Personal Protective Equipment Regulations. 7. Active Pharmaceuticals (API) Regulations. 8. In-vitro diagnostics (IVDs) Regulations. 9. Cosmetics Regulations. 10. Medicated Feeds Regulations			

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 3 : IMPROVED ENABLING LEGISLATIVE FRAMEWORK				
Budget Year (2023-2026)	• To advocate for the approval of the updated MASC Bill to incorporating GBT CAPA IDPs and Model Law.	- The Bill will be updated within timelines.	- Failure to meet timelines due to Covid-19 restrictions/lockdowns. - Delays in approval of the Bill. - Apathy.	- Continuous engagement until Bill is approved. - Hold progress update meetings. - Influence principals to approve the Bill.
	• To advocate for approval of Statutory Instruments	- The Statutory Instruments will be developed within timelines.	- Delays in approval of the SIs. - Competing priority issues.	- Influence principals to approve the SIs. - Continuous engagement.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 1 : MEDICINES AND MEDICAL DEVICES CONTROL				
OUTCOME 3 : IMPROVED ENABLING LEGISLATIVE FRAMEWORK				
	addressing IDPS arising from the WHO GBT. assessment.			
Budget Year (2023-2026)	• Advocating stakeholders for support for the approval of the following drafts of legislation: 1. Import & Export of Medical Devices. 2. General Regulations. 3. Veterinary Medicines Regulations. 4. Blood and Blood components Regulations. 5. Hand sanitisers Regulations. 6. Medical Personal Protective Equipment Regulations. 7. Active Pharmaceuticals (API) Regulations. 8. In-vitro diagnostics (IVDs) Regulations. 9. Cosmetics Regulations. 10. Medicated Feeds Regulations	- Stakeholders willing to be push. - Positive response to advocating	- Delays in approval.	- Influence principals to approve the SIs. - Continuous engagement.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2 : INSTITUTIONAL CAPACITY				
OUTCOME 4 :IMPROVED EFFECTIVE TALENT MANAGEMENT				
Budget Year (2022)	• Develop and implement a policy on competitive remuneration, engagement, and retention of Authority staff. • Pay based on benchmarking of salaries	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.
	• Develop and implement a policy integrating talent management with technology development resulting in efficient utilisation of Human Capital.	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.
Budget Year (2023-2024)	• Conduct employee engagement survey.	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.
	• Conduct Divisional Competency assessment with components of technological development that fosters full utilisation of human capital.	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.
Budget Year (2025-2026)	• Conduct employee engagement survey.	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.
	• Conduct Divisional Competency assessment with components of technological development that fosters full utilisation of human capital.	- Competent staff to articulate the right policy fit for purpose.	- Failure to develop and implement a sound policy.	- Divisional engagement.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2 :INSTITUTIONAL CAPACITY				
OUTCOME 5:IMPROVED VALUE BASED CULTURE				
Budget Year (2022)	• Develop and Implement value-based culture programme.	- Management and Staff understand and espouse the organisational values.	- Fatigue. - Resistance to change.	- Reasonable pacing. - Change management.
	• To include MCAZ culture assessment component in the service delivery customer satisfaction survey (Internal and External).	- Positive engagement of customers.	- Failure to get honest responses due to the nature of our business (Regulator)	- Accept risk.
Budget Year (2023-2024)	• Implement value based culture programme.	- Management and Staff understand and espouse the organisational values.	- Fatigue - Resistance to change	- Reasonable pacing - change management
Budget Year (2025-2026)	• Implement value based culture programme.	- Management and Staff understand and espouse the organisational values.	- Fatigue - Resistance to change	- Reasonable pacing - change management

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2 :INSTITUTIONAL CAPACITY				
OUTCOME 6: ADEQUATE AND EFFICIENT USE OF RESOURCES				
Budget Year (2022)	• Review local fees to enable MCAZ to support Programme Based Budgeting.	- The Minister approves the Fees.	- Industry might Industry might complain/protest.	- Intervention of Stakeholder Engagement.
	• Review utilisation of current funding and implementing divisions to reengineer processes to fully utilise donor funds. (Chemistry lab)	- Chemistry Lab processes have been reengineered enough to support the strategy.	- The budget might not be approved in time.	- MCAZ will request for pre-approval.
	• Optimise use of existent donor funds strategy. Develop resource mobilisation strategy.	- There is more donor appetite.	- Current staff's competencies may not be adequate.	- Train the staff or recruit more competent staff.
	• Invest MCAZ income into the Money and Capital Markets	- There will be lucrative products in the markets.	- There will meaningful savings for investments.	- Use operational income savings for savings.
	• Develop and implement strategy for non-statutory revenue.	- Staffs are competent.	- Strategy may not be implementable.	- Advocating and engagement to relevant stakeholders.
	• Prepare Microbiology Lab for Pre-Qualification	- Staffs are competent.	- Failure to procure requirements in time.	- To engage the sponsors.
	• Prepare costing of fees for pending legislation	- Develop clear process flows.	- Poor process flows.	- Interdivisional and stakeholder coordination.
Budget Year	• Review local fees to enable MCAZ to support Programme Based Budgeting.	- The Minister approves the Fees.	- Industry might Industry might complain/protest.	- Intervention of Stakeholder Engagement.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2 :INSTITUTIONAL CAPACITY				
OUTCOME 6: ADEQUATE AND EFFICIENT USE OF RESOURCES				
(2023-2024)	• Invest MCAZ income into the Money and Capital Markets.	- There will be lucrative products in the markets -	- There will meaningful savings for investments.	- Use operational income savings for savings.
	• Micro Biology Lab for Pre-Qualification.	- Staffs are competent.	- Failure to procure requirements in time.	- To engage the sponsors.
	• Implementation of new legislation.	- Parliament approves the legislation.	- None approval of the legislation.	- Continuous lobbing.
Budget Year (2025-2026)	• Review local fees to enable MCAZ to support Programme Based Budgeting.	- The Minister approves the Fees.	- Industry might Industry might complain/protest.	- Intervention of Stakeholder Engagement.
	• Invest MCAZ income into the Money and Capital Markets.	- There will be lucrative products in the markets	- There will meaningful savings for investments.	- Use operational income savings for savings.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2:INSTITUTIONAL CAPACITY				
OUTCOME 7:INCREASED OPERATIONAL EFFICIENCY				
Budget Year (2022)	• To develop and implement an Authority policy that prioritizes ICT expenditure.	- Authority buy in. - Availability of resources	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
	• To develop and implement an Authority policy for prioritization of ICT projects.	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
Budget Year (2022)	• To develop and implement an Authority policy that	- Authority buy in. - Availability of resources.	- Inadequate financial resources.	- Advocating.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2:INSTITUTIONAL CAPACITY				
OUTCOME 7:INCREASED OPERATIONAL EFFICIENCY				
	promotes adoption of newly implemented ICT solutions.		- Authority has other priorities.	
	• To optimize prioritised automated systems.	- Authority buy in. - Authority will retain the technical competencies to implement automated systems. - Availability of funds.	- No buy in. - Failure to retain key personnel implementing systems. - Uavailability of funds for ongoing system maintenance. - Change management.	- HR strategy for HR retention. - Resource mobilization.
	• To develop and implement a policy that ensures system redundancy.	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
Budget Year (2023-2024)	• To develop and implement an Authority policy that prioritizes ICT expenditure.	- Authority buys in. - Availability of resources	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
	• To develop and implement an Authority policy for prioritization of ICT projects	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
Budget Year (2023-2024)	• To develop and implement an Authority policy that promotes adoption of newly implemented ICT solutions	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating. - Training and advocating.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2:INSTITUTIONAL CAPACITY				
OUTCOME 7:INCREASED OPERATIONAL EFFICIENCY				
Budget Year (2025-2026)	• To develop and implement an Authority policy that prioritizes ICT expenditure.	- Authority buys in. - Availability of resources	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
	• To develop and implement an Authority policy for prioritization of ICT projects.	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating.
	• To develop and implement an Authority policy that promotes adoption of newly implemented ICT solutions.	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating. - Training and advocating.
	• To optimize prioritised automated systems.	- Authority buy in. - Authority will retain the technical competencies to implement automated systems. - Availability of funds.	- No buy in. - Failure to retain key personnel implementing systems. - Unavailability of funds for ongoing system maintenance. - Change management.	- HR strategy for HR retention. - Resource mobilization.
	• To develop and implement a policy that ensures system redundancy.	- Authority buy in. - Availability of resources.	- Inadequate financial resources. - Authority has other priorities.	- Advocating.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2:INSTITUTIONAL CAPACITY				
OUTCOME 8:GOOD CORPORATE GOVERNANCE				
Budget Year (2022)	• Engage OPC, CGU for Board and Management on Corporate Governance training.	- Availability of key stakeholders - Cooperation.	- Clashing schedules. - Apathy	- Early engagement.
	• Integration of all key processes that are eligible.	- Processes are mapped to identify the interfaces.	- Resistance to break silos.	- Training.
	• Integrate QMS (ISO 9001, 17025, 17020, WHO PQ, GBT).	- All standards and guidelines can be integrated.	- Continued changes to guidelines.	- Keep abreast of changes in guidelines.
	• To attain WHO GBT Maturity level 3.	- Availability of human resources to work on the identified IDPs.	- Failure to meet timelines for ML3 due to delays in approval of legislation.	- Advocating with the Ministry.
	• Institutionalise Quality Management.	- Accreditation audits to be conducted as per schedule.	- Failure to maintain accreditation.	- To ensure all requirements are implemented as required.
	• To attain WHO PQ for the Micro lab.	- Availability of a consultant.	- Delays and inefficiencies due to donor procurement process.	- Authorization to pre-finance the project.
	• To implement ICT Governance framework.	- Availability of skills. - Financial.	- Apathy. - Unavailability of financial support.	- Engagement. - Look for alternative resources.
Budget Year (2023-2024) Budget Year	• Integration of all key processes that are eligible.	- Processes are mapped to identify the interfaces.	- Resistance to break silos.	- Training.
	• Integrate QMS (ISO 9001, 17025, 17020, WHO PQ, GBT).	- All standards and guidelines can be integrated.	- Continued changes to guidelines.	- Keep abreast of changes in guidelines.
	• Integration of QMS.	- All standards and guidelines can be integrated.	- Failure to meet timelines.	- Retreats.

Period	Strategies	Assumptions	Risks	Risk Mitigation
PROGRAMME 2:INSTITUTIONAL CAPACITY				
OUTCOME 8:GOOD CORPORATE GOVERNANCE				
(2023-2024)	• To attain WHO GBT Maturity level 3.	- Availability of human resources to work on the identified IDPs -	- Failure to meet timelines for ML3 due to delays in approval of legislation.	- Advocating with the Ministry.
	• Institutionalise Quality Management.	- Accreditation audits to be conducted as per schedule.	- Failure to maintain accreditation.	- To ensure all requirements are implemented as required.
	• To maintain WHO PQ for the Micro lab.	- Availability of a consultant.	- Delays and inefficiencies due to donor procurement process.	- Authorization to pre-finance the project.
Budget Year (2025-2026)	• Integration of all key processes those are eligible.	- Processes are mapped to identify the interfaces.	- Resistance to break silos.	- Training.
	• Integrate QMS (ISO 9001, 17025, 17020, WHO PQ, GBT).	- All standards and guidelines can be integrated.	- Continued changes to guidelines.	- Keep abreast of changes in guidelines.
	• Integration of QMS.	- All standards and guidelines can be integrated.	- Failure to meet timelines.	- Retreats.
	• To attain WHO GBT Maturity level 3.	- Availability of human resources to work on the identified IDPs	- Failure to meet timelines for ML3 due to delays in approval of legislation.	- Advocating with the Ministry.
	• To maintain WHO PQ for the Micro lab.	- Availability of a consultant.	- Delays and inefficiencies due to donor procurement process.	- Authorization to pre-finance the project.

15. MCAZ PERFORMANCE FRAMEWORK

a. OUTCOMES PERFORMANCE FRAMEWORK

Ref	Programme	Outcome Description	Key Performance Indicator (KPI)	Measure Criterion (time; $; rate; etc.)	Baseline 2021	TARGETS									
						2022		2023		2024		2025		2026	
					Value	T	ALV	T	ALV	T	ALV	T	ALV	T	ALV
1.	Medicines and Medical Devices Control	Increased Customer Satisfaction	%Adherence to timelines.	%	80%	90	± 5	95	± 5	99	± 1	99	± 1	99	± 1
			Customer Journey (Customer Effort Score – to get to result/end).	Score	3.27	3-4	± 0.5	3-4	± 0.5	3-4	± 0.5	5-7	± 0.5	5-7	± 0.5
			Customer Effort Score – to get to result/end (Internal Customer journey).	%	15	50	± 5	85	± 5	95	± 5	95	± 5	95	± 5
		Increased Facilitative Regulatory Processes	Number of identified reengineered processes.(% done)	%	TBA	TBA	± 5	85	± 5	85	± 5	95	± 5	95	± 5
			% of streamlined and integrated processes.	%	NIL	100	± 5	100	± 5	100	± 5	100	± 5	100	± 5
		Improved Enabling Legislative framework	% of submitted legislation approved	%	NIL	90	± 10	10	± 10	30	± 10	50	± 10	70	± 10
2.	Institutional Capacity	Improved Effective Talent Management	Remuneration (Quartile)	% of Q	25% Q1	80% of Q2	± 5	90% of Q2	± 5	80% of Q3	± 5	80% of Q3	± 5	80% of Q3	± 5
			Engagement	%	26	30	± 3	35	± 3	40	± 3	45	± 3	50	± 3
			Retention	%	92	92	± 5	95	± 5	95	± 5	95	± 5	95	± 5
			Competency	%	TBA	85	± 5	90	± 5	93	± 5	95	± 5	95	± 5
.		Improved Value based culture	% of Organisational alignment to desired Culture/ Values	%	20	40	± 5	55	± 5	65	± 5	80	± 5	95	± 5
		Adequate and efficient use of resources	Adequacy ($9m)	%	41	59	± 5	63	± 5	65	± 5	65	± 5	65	± 5
			Non-Statutory Revenue: Total Revenue	%	5	6	± 20	7	± 20	8	± 20	9	± 20	10	± 20

Ref	Programme	Outcome Description	Key Performance Indicator (KPI)	Measure Criterion (time; $; rate; etc.)	Baseline 2021	TARGETS									
						2022		2023		2024		2025		2026	
					Value	T	ALV	T	ALV	T	ALV	T	ALV	T	ALV
		Increased Operational Efficiency	% Automation	%	84.6	90	± 5	93	± 5	96	± 5	99	± 1	100	- 1
			System Availability	%	TBA	TBA	± 5	85	± 5	88	± 5	91	± 5	95	± 5
			Improvement (Automated timelines vs. manual timelines (Manual-Automated/manual time)	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3.	**Governance**	**Good Corporate Governance**	Standardized, integrated operational processes (Small Business Support Unit & QF52	%	85	100	- 5	100	- 5	100	-5	100	- 5	100	-5
			Level of integration of quality management systems (ISO 9001, 17025, 17020 WHO PQ, GBT, SADCAS Accreditation)	%	25	50	± 5	75	± 5	85	± 5	90	± 5	100	- 5
			% Compliance to WHO GBT	ML	ML1	ML3	-	ML4	-	ML4	-	ML4	-	ML4	-
			% Compliance to WHO PQ(Micro Lab)	%	75	100	-2	100	-2	100	-2	100	-2	100	-2
			% Compliance to ISO 9001, 17025, 17020 Standards, WHO PQ, GBT, SADCAS Accreditation	%	75	100	-2	100	-2	100	-2	100	-2	100	-2
			Compliance to the Corporate Governance Framework	%	TBA	90	± 5	95	± 5	97	± 3	98	± 2	100	-2

T = Target **ALV = Allowable Variance**

b. OUTPUTS PERFORMANCE FRAMEWORK

Prog Ref Code	Outputs	5 yr. target	Baseline 2021 Value	Targets															
				2022			2023			2024			2025			2026				
				T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	
PROGRAMME 1 : **MEDICINES AND MEDICAL DEVICES CONTROL**																			
OUC 1 :**INCREASED CUSTOMER SATISFACTION**																			
OP 1.1	Optimised systems.	5	-	5	-	-1	5	-	-1	5	-	-1	5	-	-1	5	-	-1	
OP 1.2	ZIMDIS portal for payments.	100 %	-	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	
OP 1.3	Customer Management System.	1	-	1	-	0		-			-			-			-		
OP 1.4	Gap closing Strategies implemented.	70%	-	70%	-	± 5%	70%	-	± 5%	70%	-	± 5%	70%	-	± 5%	70%	-	± 5%	
OP 1.5	Customer Service Function.	1	0	1	-	0	1	-	0	1	-	0	1	-	0	1	-	0	
OP 1.6	Customer satisfaction.	5 to 7	-	3 to 4	-	± 0.5%	3 to 4	-	± 0.5%	3 to 4	-	± 0.5%	5 to 7	-	± 0.5%	5 to 7	-	± 0.5%	
OP 1.7	Journey Maps.	100 %		TBA	-	-		-			-			-			-		
OP 1.8	Baseline CES score.	1	-	1	-	0		-			-			-			-		
OP 1.9	CES	5 to 7	-	3 to 4	-	± 0.5%	3 to 4	-	± 0.5%	3 to 4	-	± 0.5%	5 to 7	-	± 0.5%	5 to 7	-	± 0.5%	
OP 1.10	SEP developed	1		1	-	0	1	-	0	1	-	0	1	-	0	1	-	0	
OP 1.11	Implemented Strategies (SEP)	100 %		100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	
OP 1.12	Accountability Policy	1	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	
OUC 2: INCREASED FACILITATIVE REGULATORY PROCESSES																			
OP2.1	Reengineered functional SBS unit	1	1	1	-	0	-	-	-	-	-	-	-	-	-	-	-	-	

Prog Ref Code	Outputs	5 yr. target	Baseline 2021 Value	Targets													
				2022			2023			2024			2025			2026		
				T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV
PROGRAMME 1 : **MEDICINES AND MEDICAL DEVICES CONTROL**																		
OP2.2	Number of Identified and categorised processes	TBA	-	25%	-	± 5%	TBA	-	-	TBA	-	-	TBA	-		TBA	-	
OP2.3	Approved risk based framework for re-engineering of processes	1	-	1	-	0	-	-	-	-	-	-	-	-	-	-	-	-
OP2.4	Developed policies and processes (% of identified policies & processes)	100 %	-	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%
OP2.5	Number of processes identified for streamlining &integration	TBA	TBA	TBA	-	-	100%	-	- 5%	100%	-	-5%	100%	-	- 5%	100%	-	-5%
OP2.6	% streamlined and integrated processes	100 %	-	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%
OP2.7	Measurement tools and criteria finalized and approved.	100 %	-	-	-	-	90%	-	-5%	90%	-	-5%	100%	-	-5%	100%	-	-5%
OUC 3: IMPROVED ENABLING LEGISLATIVE FRAMEWORK																		
OP3.1	Final draft Bill incorporating WHO GBT and Model law requirements	100 %	-	100%	-	-5%	100%	-	-5%	100%	-	-5%	100%	-	-5%	100%	-	-5%
OP3.2	Approved Statutory Instruments addressing the WHO GBT IDPs	70%	-	90%	-	± 5%	10%	-	- 5%	30%	-	± 5%	50%	-	± 5%	70%	-	± 5%
OP3.3	Approved legislation	90%	-	90%	-	± 10%	40%	-	± 10%	40%	-	± 10%	50%	-	± 10%	50%	-	± 10%

Prog Ref Code	Outputs	5 year target	Baseline 2021 Value	Targets															
				2022			2023			2024			2025			2026				
				T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV		
PROGRAMME: INSTITUTIONAL CAPACITY																			
OUC 4 : IMPROVED EFFECTIVE TALENT MANAGEMENT																			
OP4.1	Policy document (Remuneration)	1	NIL	1	-	0	-	-	-	-	-	-	-	-	-	-	-	-	-
OP4.2	Policy document(Talent Management and technology-HC efficient utilisation)	1	NIL	1	-	0	-	-	-	-	-	-	-	-	-	-	-	-	-
OP4.3	Employee Engagement report	2	-	-	-	-	1(35%)	-	-	1(35%)	-	-	1(50%)	-	-	1(50 %)	-	-	
OP4.4	Divisional Competency report	2	-	-	-	-	1(90%)	-	-	1(90%)	-	-	1(95%)	-	-	1(95 %)	-	-	
OUC 5: IMPROVED VALUE BASED CULTURE																			
OP 5.1	Entrenched value-based culture (Programmes)	95%	NIL	65%	-	± 5%	65%	-	± 5%	65%	-	± 5%	95%	-	± 5%	95%	-	± 5%	
OP 5.2	Survey report (Culture component)	1	NIL	1	-	0	-	-	-	-	-	-	-			-	-		
OP 5.3	Improved value based culture	95%	-	40%	-	± 5%	55%	-	± 5%	65%	-	± 5%	80%	-	± 5%	95%	-	± 5%	
OUC 6: ADEQUATE AND EFFICIENT USE OF RESOURCES																			
OP 6.1	US$875k local revenue increase	US$ 875 k	-	US$1.5 m local	-	± 5%	US$1.5 m local	-	± 5%	US$1.5 m local	-	± 5%	US$1.5 m local	-	± 5%	US$1. 5m local	-	± 5%	
OP 6.2	US$150k revenue increase	US$ 150 k	-	US$150k	-	± 5%	-	-	-	-	-	-		-	-	-	-	-	
OP 6.3	US$1.1m		-	US$1.1 m	-	± 5%	-	-	-	-	-	-		-			-		

Prog Ref Code	Outputs	5 year target	Baseline 2021 Value	Targets															
				2022			2023			2024			2025			2026				
				T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	
OP 6.4	US$50k investment Minimum of US$50k portfolio	450 K	-	Minimum of US$50k	-	± 5%	US$100k	-	-	US$100k	-	± 5%	US$100k	-	± 5%	US$100k	-	± 5%	
OP 6.5	Strategy document	1	-	US$10k	-	± 5%	-	-	-	-	-	-	-	-	-	-	-	-	
OP 6.6	100% Preparedness Document	100 %	-	100%	-	± 5%	-	-	-	-	-	-	-	-	-	-	-	-	
OP 6.7	Proposed Fee schedule	1	-	1	-	0	-	-	-	-	-	-	-	-	-	-	-	-	
OP 6.8	Prequalified Status	1	-	-		-	100%	-	-	-	-	-	-	-	-	-	-		
OP 6.9	New legislation implemented.	100 %	-	-	-	-	-	-	-	100%	-	-	-	-	-	-	-	-	
OUC 7: **INCREASED OPERATIONAL EFFICIENCY**																			
OP 7.1	Policy -Prioritise ICT expenditure	1	NIL	1	-	0	1	-	0	1	-	0	1	-	0	1	-	0	
OP 7.2	Policy -Prioritise ICT projects	1	NIL	1	-	0										1	-	0	
OP 7.3	Policy -Adoption of ICT solutions	1	NIL	1	-	0	1	-	0	1	-	0	1	-	-	1	-	-	
OP 7.4	Optimised systems	100 %(5)	-	100%	-	0	100%	-	0	100%	-	0	100%	-	0	100%	-	0	
OP 7.5	Policy –System redundancy	3	NIL	1	-	0	-	-	-	1	-	-	-	-	-	1	-	0	

Prog Ref Code	Outputs	5 year target	Baseline 2021	Targets														
				2022			2023			2024			2025			2026		
			Value	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV	T	A	ALV
PROGRAMME 3: GOVERNANCE																		
OUC 8 :**GOOD CORPORATE GOVERNANCE**																		
OP 8.1	Board and Management trained	100 %	-	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%
OP 8.2	Standardized and integrated processes	100 %	85%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%	100%	-	± 5%
OP 8.3	Integrated System (QMS)	100 %	25%	50%	-	± 5%	70%	-	± 5%	70%	-	- 5%	100%	-	- 5%	100%	-	- 5%
OP 8.4	GBT ML3	GBT ML4	GBT ML1	GBT ML3	-	- -	GBT ML4	- -	- -	GBT ML4	- -	- -	GBT ML4	- -	- -	GBT ML4	- -	- -
OP 8.5	Accredited and certified quality systems(Accredited Labs)	100 %	-	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	100%	-	± 5%	100%	-	- 5%
OP 8.6	WHO PQ for Micro Lab	100 %	-	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%	100%	-	- 5%
OP 8.7	ICT Governance framework	100 %	-	90%	-	± 5%	95%	-	± 5%	97%	-	± 3%	98%	-	± 2%	100%	-	-2%

c. PROGRAMME BUDGET FRAMEWORK (TBC Finance)

Programme	Outcomes	Programme Outputs	Budget Current Year2021 (USD)	Budget Year2022 (USD)	Budget Year 2023 (USD)	Budget Year 2024 (USD)	Budget Year 2025 (USD	Budget Year 2026 (USD
1.Medicines and medical devices Control	**1. INCREASED CUSTOMER SATISFACTION**							
		Optimised systems.	-	15 000	15 000		15 000	-
		ZIMDIS portal for payments.		10 000	10 000		10 000	-
		Customer Management System.		50 000				
		Gap closing Strategies implemented.		10 000	10 000		10 000	-
		Customer Service Function.			D1/D2 Position			
		Customer satisfaction.						
		Journey Maps.						
		Baseline CES score.						
		CES			10 000	-	10 000	-
		SEP developed	-	-				-
		Implemented Strategies (SEP)			60 000	-	60 000	
		Accountability Policy	-	-	-	-	10 000	-
	2. INCREASED FACILITATIVE REGULATORY PROCESSES							
		Reengineered functional SBS unit	-	TBA	-	-	-	-
		Number of Identified and categorised processes	-	-	-	-	-	-
		Approved risk based framework for re-engineering of processes	-	-	-	-	-	-
		Developed policies and processes (% of identified policies & processes)	-	-	-	-	-	-

Programme	Outcomes	Programme Outputs	Budget Current Year2021 (USD)	Budget Year2022 (USD)	Budget Year 2023 (USD)	Budget Year 2024 (USD)	Budget Year 2025 (USD	Budget Year 2026 (USD
1.Medicines and medical devices Control		Number of processes identified for streamlining &integration	-	-	-	-	-	-
		% streamlined and integrated processes	-	-	-	-	-	-
		Measurement tools and criteria finalized and approved.	-	-	2000	-	2000	-
		% Measured regulatory processes	-	-	-	-	-	-
		% of effectiveness of measured regulatory processes	-	-	-	-	-	-
		% of monitoring and evaluation reports	-	-	-	-	-	-
	3. IMPROVED ENABLING LEGISLATIVE FRAMEWORK							
		Final draft Bill incorporating WHO GBT and Model law requirements	-	5 000	3 000	-	2 000	-
		Approved Statutory Instruments addressing the WHO GBT IDPs	-	3 000	2 500	-	2 000	-
		Approved legislation		10 000	6 000	-	5000	-
Total Programme Budget								
2: Institutional Capacity	**4.IMPROVED EFFECTIVE TALENT MANAGEMENT**							
		Policy document (Remuneration)	-	-	-	-	-	-
		Policy document(Talent Management and technology-HC efficient utilisation)	-	-	-	-	-	-
		Employee Engagement report	-	-	2000	-	2000	-

Programme	Outcomes	Programme Outputs	Budget Current Year2021 (USD)	Budget Year2022 (USD)	Budget Year 2023 (USD)	Budget Year 2024 (USD)	Budget Year 2025 (USD	Budget Year 2026 (USD
2: Institutional Capacity		Divisional Competency report	-	-	2000	-	2000	-
	5.**IMPROVED VALUE BASED CULTURE**							
		Entrenched value-based culture	-	-	-	-	-	-
		Survey report (Culture component)	-	-	-	-	-	
		Improved value based culture	-	-	-	-	-	-
	6. **ADEQUATE AND EFFICIENT USE OF RESOURCES**							
		US$875k local revenue increase						
		US$150k revenue increase						
		US$1.1m						
		US$50k investment Minimum of US$50k portfolio						
		Strategy document						
		100% Preparedness Document						
		Proposed Fee schedule						
		New legislation implemented						
	7. IN**CREASED OPERATIONAL EFFICIENCY**							
		Policy -Prioritise ICT expenditure	-	-	-	-	-	-
		Policy -Prioritise ICT projects	-	-	-	50 000	-	-
		Policy -Adoption of ICT solutions	-	-	-	-	-	-
		Optimised systems	-	25 000	10 000	25 000	-	25 000
		Policy –System redundancy	-	-	-	20 000	-	

Programme	Outcomes	Programme Outputs	Budget Current Year2021 (USD)	Budget Year2022 (USD)	Budget Year 2023 (USD)	Budget Year 2024 (USD)	Budget Year 2025 (USD	Budget Year 2026 (USD
								-
Total Programme Budget								
Programme 3: Governance	**8. GOOD CORPORATE GOVERNANCE**							
		Board and Management trained		TBA				
		Standardized and integrated processes		TBA				
		Integrated System		TBA				
		GBT ML3		TBA				
		Accredited and certified quality systems		TBA				
		WHO PQ for Micro Lab		TBA				
		ICT Governance framework		TBA				
Total Programme Budget								
OVERALL TOTAL PROGRAMMES BUDGET								
Other resources requirements								
TOTAL								
TOTAL AGENCY BUDGET								

16. RESOURCE REQUIREMENTS

i) Human Resources for the Strategic Period (TBC Human Capital)

The following have been identified as the human resources requirements by category for each programme:

No.	Category	2021			Required Establishment					Programme Total Personnel Requirements By Category
		Current Establishment	Filled Position	Vacant Positions	2022	2023	2024	2025	2026	
PROGRAMME 1: MEDICINES AND MEDICAL DEVICES CONTROL										
1	Top Management	7	6	1	7					
2	Middle Management	15	11	5	15					
3	Supervisory Management	22	16	6	22					
4	Operational , Support staff	111	95	16	111					
5	**PROGRAMME TOTAL**	**155**	**127**	**28**	**155**					
PROGRAMME 2: : INSTITUTIONAL CAPACITY										
1	Top Management	7	6	1	7					
2	Middle Management	15	11	5	15					
3	Supervisory Management	22	16	6	22					
4	Operational , Support staff	111	95	16	111					
5	**PROGRAMME TOTAL**	**155**	**127**	**28**	**155**					
PROGRAMME 3: GOVERNANCE										
1	Top Management	7	6	1	7					
2	Middle Management	15	11	5	15					
3	Supervisory Management	22	16	6	22					
4	Operational, Support staff	111	95	16	111					
5	**PROGRAMME TOTAL**	**155**	**127**	**28**	**155**					
MCAZ TOTAL REQUIREMENTS										

ii) OTHER RESOURCE REQUIREMENTS (TBC)

Other resource requirements needed (Materials, Equipment and ICTs) for the planning period have been specified below according to Programmes and are listed hereunder:

Materials/ Equipment /ICT	2022		2023		2024		2025		2026	
	Quantity	Cost USD	Quantity	Cost USD	Quantity	Cost USD	Quantity	Cost USD	Quantity	Cost USD
PROGRAMME 1: MEDICINES AND MEDICAL DEVICES CONTROL										
Total Programme Cost										
PROGRAMME 2: : INSTITUTIONAL CAPACITY										
Total KRA Cost										
PROGRAMME 3: GOVERNANCE										
Total KRA Cost										
MCAZ TOTAL COST										

17. GLOBAL CORPORATE RESOURCE REQUIREMENTS

In order to efficiently achieve the defined goals certain resources are required. Listed below are the requirements that were identified at a global level for all programmes presented in summary.

HUMAN RESOURCES	MATERIAL AND EQUIPMENT
• Customer Contact centre personnel. • Small Business Support unit personnel.	• Laptops • Team building • Leadership development programme. • External courses, seminars, workshops for staff development.
SPACE REQUIREMENTS	**ICT REQUIREMENTS**
-	• ZIMDIS portal for payments • System Redundancy (System Backup) • Customer Management System. • Document Management System • Internet access • Microsoft Access

18. CONCLUSION

2022 marks the beginning of a new 5 year journey for MCAZ towards its vision "***To be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally".***

It is important to realise that planning and formulating a strategic plan is only the first step. Implementation, performance monitoring and evaluation are critical and will determine whether MCAZ will achieve the desired outcomes in its three Programme areas.
"The important decisions, the decisions that really matter, are strategic . . . [But] more important and more difficult is to make effective the course of action decided upon."– *Peter Drucker.*

Bold transformative steps in the journey will be required, fuelled by an emphasis on living the values. What will set the organisation apart, and truly be a game changer is the change of mind sets and how things are done moving forward. Indeed a good foundation has been laid for

success, and will go a long way in ensuring that MCAZ lives and performs its mandate, whilst recognising its reason for existence ***"To ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health"***

APPENDIX

ENVIRONMENTAL ANALYSIS

i. Political and Geo Political Analysis

There is good political support in the Health sector, with the leadership of the sector at the highest level in Government led by the Vice President. The Zimbabwe Government has a strong commitment to the regional and sub-regional integration initiatives. Engagement and re-engagement policy, with the possibility of Sino-Zimbabwe and UK-Zimbabwe collaboration in regulatory harmonisation. There is also support for regional harmonisation- SADC Regulatory Harmonisation in the area of Joint SADC review of veterinary medicines supported by VMD UK and BMGF, as well as strengthening SADC joint review of Medicines. The WHO report for Maturity Level 3 outcome report, may be used as a good basis to engage the AG to approve MASC Bill and draft regulations that are pending as these play a pivotal role in assuring alignment to Vision 2030, NDS1 and the Pharma Strategy for the nation. There is growth potential in the local Pharma sector, as witnessed by a flurry of greenfield projects, with 3 so far, as well as resuscitation of previously closed or idle plants like the CAPS closure in Prospect and over the counter products for pain, fever and coughs. An increase in local production of medicines will result in increased access to medicines locally at more affordable prices to end users. As local applicants advocate for waiver of some key requirements, faster approvals and discounted fees, this may have the down side of creating more work for MCAZ at a lower cost.

There are also some potential threats caused by inconsistent changes in policy like Enforcement of statutory instrument on importation of essential medicines (negatively – fewer samples to test) Pharma strategy allows for local producer, if there are at least 3 local companies, product can be removed from open general list.- but they fail to provide. A decline in revenue due to local production, therefore this may lead to increased subsidies.

ii. Economic Analysis

The economic environment continues to be challenging not only globally but locally as well due to the Covid-19 pandemic. The economy continues to be beset with foreign currency and liquidity challenges that have led to a surge in the prices of goods and services. Economic outlook for 2022 is a projected growth of 5.4%, anchored by mining, manufacturing and electricity generation, Containment of inflation through non-monetization of budget deficit and reduction SADC macroeconomic convergence benchmark, reducing supply of money and SADC inflation containment - commitment to sustainable budget deficit 1.5%. Government priorities include:

- ***Inclusive Growth*** and ***Macro-Economic stability*.**
- Developing and Supporting Productive Value Chains (***local manufacturing***).
- Optimising Value in our Natural Resources (***complementary medicines***).
- Infrastructure, ICT s and Digital Economy.
- Social Protection, Human Capital Development and Well- being (***SDG3 Health availability of Quality Safe Effective medicines***)
- Effective Institution Building & Governance (***Compliance with Corporate Governance***)
- Engagement and Re-engagement/Arrears clearance and debt restructuring and ***Collaboration Opportunities.***

There are however downside risks caused by the disruption of global supply chains, increased ***Covid-19 cases*** local and global-lockdowns, shorter working hours, shortage of goods and services, price hikes, currency instability and discrepancies between the official bank rate and the illegal parallel market rates as some service providers seem to use varying rates. Monetary policy pronouncements and changes in policy statements also have an impact on the economy.

iii. Demographic, Social and Cultural Trends

The demographic landscape is characterised by a wide base of youth, with increasing life expectancy due to successful prevention and management of HIV/AIDS. Triple burden of diseases: Communicable (Infectious), Non-Communicable (non-infectious) and Injuries (accidents, natural

disasters) in which MCAZ support access to Quality Safe Effective and affordable cancer medication. MCAZ strives to ensure affordable; medicines as a safety net. There is high turnover of senior staff (critical skills flight), and a mismatch of education, skills and salaries offered, as well as entry requirements and job profiles. The young workforce is against organisational remuneration and retention policies. African traditional medicines present an opportunity. TMPC Practitioners eager to commercialise African Traditional Medicines. Some manufacturers and distributors of African Traditional Medicines (ATM) that used to serve localized niche markets eager to regularize and this presents opportunities for MCAZ, and supports local Pharma industry. Other trends that present opportunities are society seeking readily available natural products (zumbani, ginger, onion) and home remedies for prevention of Covid-19 and treatment of flu-like symptoms, Zimbabwe medicinal trees reportedly being harvested and exported for use outside the country, a general interest in preventive natural medicines. There is also a rich fact-checked body of knowledge on Trees of Southern Africa with medicinal value published by Zimbabwean researchers in reputable journals from early 50s to date.

There is still a real threat of drug abuse e.g. the abuse of Mutoriro and Kambwa, effects of self-treatment during Covid-19 pandemic (resistance to antibiotics) and smuggling of pharmaceutical products into the country through borders.

iv. Technological Trends

The fast rate of developments in the field of technology has opened opportunities to consolidate social engagement through various social media channels such as Twitter and Facebook to increase information dissemination and solicitation of public views on impending policy changes. The COVID-19 pandemic and new way of working accelerated the digitalisation of MCAZ with Virtual conferencing equipment installations and innovation in Virtual GMP and GCP inspections. Competence in Virtual Inspections will be pivotal in the expansion of space equipped with technologies and present opportunities to enhance operational efficiency and enhanced global reach and interaction. Laboratory Management Systems- reduce repetition of entries of same information, transcriptional errors; eliminate process black box, increase workflow management and throughput. Electronic Submission of Dossiers- reduce costs filing physical dossiers, increase remote access by assessors, and reduce the risk misfiling and mislaid documents. ZIMDIS Drug Registration System- Need to optimize the system for improved service delivery and customer

satisfaction. Cloud based Submission- dynamic dossier that contains current information that is updated in real time, audit trail based on block chain technology, zero storage space needed, true opportunity for Reliance as MCAZ regulator may be authorized to review the exact report reviewed by EU or USFDA regulator. Keeping abreast with technological advancements – this requires more resources to be invested.

v. ***Natural Environment***

The ecological environment deals with all the living and non-living things around and within the environment in which we live and work. The effects of global warming are being felt the world over e.g. the increasing frequency of natural disasters such as droughts and floods. These effects will create a bigger power generation deficit, lower food production leading to lost revenue from exports and unplanned expenditure on food imports thereby deepening the underperformance of the economy. Use of renewable energy, which MCAZ has taken the opportunity to do by Optimising Solar Energy at its offices. There is need to prepare for climate change and heat waves through controlled offices and storeroom environments. Cases of antimicrobial resistance (Antibiotics, Feed additives, Antimicrobial APIs) and the discharge of antimicrobial residues into the environment (land, water, air) are also increasing. Patients developing life threatening infections after minor elective surgical operations- Circumcision, C-section, and a re-emergence of difficult to treat versions of diseases: Gonorrhea, Candidiasis, Methicillin resistant staphylocus. MCAZ has an important role to play to:

- **Compile data** to generate evidence of names, types, quantities of Antimicrobials used in humans and animals.
- When assigning **Categories for distribution** follow WHO (Critically Important Antibiotics CIA) and OIE Guidelines (Veterinary Critically Important Antibiotic) of good stewardship of antimicrobials.
- **Mapping the distribution channels** for Human Allopathic and Veterinary Medicines to identify points where Substandard Falsified medicines (SF) enter the system.
- **Enforcement blitz** to raid illegal traders of antimicrobials.

There is need for Emergency preparedness for diseases like Covid-19, as global pandemics disrupt normalcy to life and operations.

vi. Governance-Rules and Regulations

Governance and legal issues have an impact on MCAZ operations. TMPC Regulations for use of African Traditional Medicines in the practice setting- possible overlap MCAZ-TMPC Mandate and may have an impact revenue. There is need for Guidelines on conducting Research on African Traditional Medicines (*need for synergy DTM-MCAZ PVCT).*SI on import ban of medicines produced by local companies- may require PMA ring fencing more products than they can produce. SIs on charging goods in official tender ZWL- AGs Office insisting MCAZ fees be denominated in ZWL not USD, this will affect revenue. Procurement regulations in favour of locally produced goods- fleet replacement with imported vehicles not approved and this may have a negative impact on operations. Public tendering for extension of 106 Baines Story Building- exorbitant quotations due to the procurement process and regulations (PRAZ). EMA – new laws and charges on importation and transportation of chemicals may affect prices of medicines. *Triple Helix approach – Ministry of Health, Industry and Commerce, Education* may be required.

vii. Uncertainties

These are factors or behaviours that have potential to have a large impact on business, though the manner in which they may occur is not yet clear. There is risk of resurgence of Covid-19 morbidity and mortality. Virtual space and meetings remains uncertain as to whether physical training programmes will resume in full. Virtual trainings are good, but numerous distractions as long as the officer is at the workplace (telephone calls, dispatch, approvals, and authorizations). Political interventions on Condom Total Market approach – National condom programming strategy may impact MCAZ business for condom testing. The refurbished MCAZ microbiology lab towards WHO PQ – Changes in workflow in quality testing of pharmaceuticals. These all-present uncertainties to the Authority, with potential negative impacts.

List of Participants

Participants for 2021

Name	Position
Authority Members	
1. Dr M. Chiware	Authority Chairperson
2. Dr C. Duri	Authority Member
3. Dr S. Mutambu	Authority Member
4. Dr C. Mutisi	Authority Member
5. Mr P. Mwendera	Authority Member
6. Dr C. Pasi	Authority Member
7. Dr E. Waniwa	Authority Member
8. Mr D.N. Vuragu	Authority Member
9. Air Cmdre P.G.S. Zimondi	Authority Member
Management	
10. Mr R. Rukwata	Acting Director-General
11. Dr W. Wekwete	Head – Evaluations and Registration Division
12. Mr E. Kulube	Head – Finance
13. Mr C. Shamuyarira	Acting Head – Chemistry Division
14. Mrs P.P. Nyambayo	Head – Pharmacovigilance & Clinical Trials Division
15. Mr E. Munhenga	Head – Human Resources
16. Mrs R. Gwata	Finance Manager
17. Mr A. Nyathi	Procurement Officer
18. Ms R. Tugwete	Internal Auditor
19. Mrs A. Chikowore	Quality Manager
20. Mr T. Nyovhi	ICT Manager
21. Mr T.A. Gonho	Medical Devices & Microbiology Unit Manager
22. Mr S. Mutyavaviri	Senior Regulatory Officer – GMP Inspector
23. Mrs P. Murandu	Regulatory Officer – Legal
24. Ms A. Verenga	Chief Regulatory Officer – Enforcement
25. Mr M. Mutasa	Senior Analyst – Chemistry Division
26. Ms G.R. Matimba	Senior Regulatory Officer – Evaluations & Registration
27. Mr K. Dzawo	Senior Analyst – Chemistry Division
28. Mrs T. Sithole	Projects & PR Manager
29. Mrs C. Samatanga	Chief Regulatory Officer – Enforcement
30. Mrs N. Seve	Senior Analyst – Chemistry Division
31. Mrs T. Maunga	Senior Quality Officer
32. Mr F.B. Masekela	Senior Regulatory Officer – Evaluations & Registration
33. Dr Z. A. Makoni	Senior Regulatory Officer

34. Mr S. Gwatidzo	Projects and PR Officer
35. Mrs L.J. Mamvura	Senior Analyst – Chemistry Division
36. Mr A. Maqolo	Senior Analyst – MMDU
37. Mr W. Dengu	Senior Regulatory Officer – GMP Inspector
38. Mr T. Nyamandi	Senior Regulatory Officer – PVCT
39. Mr L. Chirinda	Senior Regulatory Officer – PVCT
40. Ms T.G. Muvirimi	Senior Regulatory Officer – Evaluations & Registration
41. Ms L. Mudyiwenyama	Senior Regulatory Officer – Evaluations & Registration
42. Ms P. Kadare	Senior Regulatory Officer – LED
43. Mr B. Bondamakara	ICT – Systems Developer
FACILITATORS	
44. E.D. Zinyengere	Team Consulting
45. T.T. Chikondo	Team Consulting
46. V.T. Mapiye	Team Consulting