



QUALITY UNIT

POLICY TITLE: GOOD REGULATORY PRACTICES			
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1.0 INTRODUCTION

This policy establishes the framework for the consistent development, implementation, and regular updating of documented policies, procedures, and mechanisms, with written criteria, for the promotion and application of Good Regulatory Practices (GRPs) to ensure efficient and effective oversight of medical products and allied substances.

2.0 SCOPE

The policy applies to all Medicines Control Authority of Zimbabwe (MCAZ) Units/Divisions. It describes the Good Regulatory Practices to be adopted in the regulation of medical products and allied substances. It specifies the requirements for establishing sound and effective oversight of medical products, as an important part of health system performance and sustainability. This policy covers the promotion, establishment, and application of GRP principles in all regulatory functions and areas.

The framework of best practices for regulation under which GRP falls and which the Authority has taken into account includes the following aspects;

- i. Good reliance practices.
- ii. Benchmarking and performance measurement.
- iii. QMS for regulatory authorities.
- iv. Global competency framework.
- v. Good regulatory model.
- vi. Models for regulatory systems.
- vii. Good governance practices.
- viii. Good review practices.
- ix. Good guidance practices.

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3.0 TERMS AND DEFINITIONS

3.1 Process

Series of inter-related steps involved in an activity or examination that uses resources and manages to transform inputs into outputs.

3.2 Laws

These are legal enactments that define the mandate of the Regulatory Authority. They include regulations which are high-level documents for the Authority that state the conditions to be met and the requirements defined by law.

3.3 Guidelines

Documents that provide further details and instructions on how the regulated stakeholders can comply with laws and regulations. They may also provide details of the processes of enforcement of the respective legislation.

3.4 GRP Enablers

Components of the environment that facilitate successful implementation of Good Regulatory Practices.

3.5 Quality Management System

A program developed to support efficient, effective, appropriate and high quality outputs for the Authority.

3.6 Medical Product

For MCAZ the term includes medicines and medical devices.

3.7 Allied Substances

Any substance, which is prohibited, controlled or restricted in terms of Section 38 of the Medicines and Allied Substances Control Act (Chapter 15:03)

3.8 Medicines Regulatory Authority

Is a public institution or governmental body or bodies authorized by law to exercise independent regulatory oversight over the development, production, marketing and surveillance of medical products.

3.9 Regulatory Framework

The collection of laws, regulations, guidelines, guidance documents and other regulatory instruments through which a government and a regulatory authority control particular aspects of a specific activity.

3.10 Regulatory System

The combination of institutions, processes and the regulatory framework with which a government controls particular aspects of an activity.

3.11 Reliance

The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessment by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and

accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

3.12 Impartiality

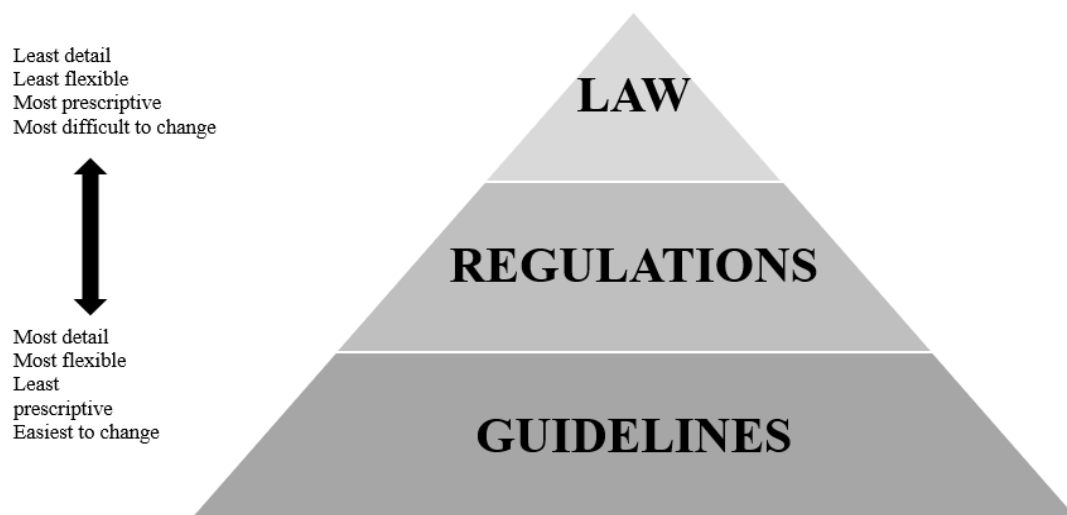
Presence of objectivity. This includes freedom from bias, freedom from conflict of interest, lack of prejudice, neutrality etc.

3.13 Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment (RIA) is a systematic, evidence-based process used by governments and regulatory authorities to evaluate the positive and negative effects of proposed and existing regulations and regulatory alternatives.

4.0 MCAZ REGULATORY FRAMEWORK

The MCAZ regulatory framework shall be guided by Medicines and Allied Substances Control Act (Chapter 15:03) MASCA and consists of the regulations, guidelines and other regulatory instruments which the Ministry of Health and Child Care (MOHCC) and the Authority deem necessary.



Adopted from the WHO guideline on GRP in the Regulation of Medical Products (TRS 1033 Annex 11)

5.0 LAW

- 5.1 The Medicines Control Authority of Zimbabwe (MCAZ), is a statutory body established by an Act of Parliament, The Medicines and Allied Substances Control Act (Chapter 15:03) (MASCA).
- 5.2 The mandate of the Authority is to ensure access to safe effective and good quality medical products and allied substances for the protection of public and animal health. The Authority achieves this by;
 - i. Evaluation and registration of medical devices, medicines and allied substances.
 - ii. Control of manufacture, distribution and storage of medicines and medical devices.
 - iii. Control of import and export of medicines and medical devices.
 - iv. Licensing of premises and persons.

- v. Inspections and post-market surveillance.
- vi. Quality conformity testing of medicines and medical devices.
- vii. Administration of the Dangerous Drugs Act (Chapter 15:02) on behalf of the Ministry of Health and Child Care.
- viii. Pharmacovigilance and clinical trials

6.0 REGULATIONS

MCAZ shall be guided by the regulations as listed below in the execution of its mandate;

- i. Medicines and Allied Substances Control General Regulations 1991 SI 150 of 1991
- ii. Medicines and Allied Substances Control (Homeopathic Remedies) (Repeal) Regulations, 2015, SI 96 of 2015
- iii. Dangerous Drugs Regulations, 1975 RGN No. 1111 of 1975
- iv. Dangerous Drugs (Amendment) Regulations, 2015 SI 133 OF 2015
- v. Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008
- vi. Medicines and Allied Substances Control (Import and Export of Precursors and Certain Chemical Substances) Regulations, 2008
- vii. Medicines and Allied Substances Control (General) (Amendment) Regulations, 2016(No.29), SI 99 of 2016
- viii. Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 (Amendment)
- ix. Medicines and Allied Substances Control (Complementary Medicines) (Amendment) Regulations 2018, (No. 1)
- x. Dangerous Drugs (Amendment) Regulations, 2019, Statutory Instrument 232 of 2019
- xi. Medicines and Allied Substances Control (Import and Export of Medicines) (Amendment) Regulations. 2013 (No.3) SI 48 of 2013
- xii. Medicines and Allied Substances Control (Import and Export of Medicines) (Amendment) Regulations. 2010 (No. 3)
- xiii. Medicines and Allied Substances Control (Import and Export of Precursors and Certain Chemical Substances) Regulations, 2010 (No.2)

7.0 GUIDELINES

The Authority has various Guidelines within Units/ Divisions which provide further details on how the regulated stakeholders can comply with the requirements of the law and regulations.

8.0 COMPONENTS OF MCAZ REGULATORY SYSTEM

The regulatory framework includes MASCA, ISO 9001:2015, ISO 17025:2017, WHO GPPQCL and WHO Global Benchmarking Tool. The regulatory outputs emanate from MCAZ Units/ Divisions as listed below:

- i. Chemistry Division.
- ii. Microbiology and Medical Devices Unit.
- iii. Evaluations and Registration Division.
- iv. Licensing and Enforcement Division.

- v. Pharmacovigilance & Clinical Trials Division.
- vi. Quality Unit.
- vii. Human Resources Unit.
- viii. Internal Audit Unit.
- ix. Legal and Corporate Affairs Unit.
- x. Procurement and Administration Unit.
- xi. Finance Unit.
- xii. Information Communication and Technology.
- xiii. Public Relations Unit /Customer Service Function.

9.0 ENABLERS OF GOOD REGULATORY PRACTICES AT MCAZ

For application and implementation of GRP at MCAZ, several enablers have been adopted. These include;

- i. **Political and Government-wide support.**
MCAZ is fully supported by the Ministry of Health and Child-Care which gazettes the enabling legislation. The Ministry also set policies that assist MCAZ on how to regulate medicines, medical devices, and allied substances. They approve the fees schedule for MCAZ services. Furthermore, they approve the gazetted inspectors.
- ii. **Effective organization and good governance supported by leadership.**
MCAZ is governed by Public Entities Corporate Governance Act (PECOGA) which provides a uniform mechanism for regulating the conditions of service of members of public entities and their senior employees. The MCAZ Quality Policy Statement also highlights leadership commitment to ensuring that the regulatory activities are conducted effectively.
- iii. **Inter- and intra-organizational communication, collaboration and co-ordination.**
MCAZ uses various modes of communication with its different stakeholders for cascading information related to the regulatory activities. These include circulars, newspaper, radio broadcasting, website etc. MCAZ works with other NRAs through mechanisms such as reliance, recognition, joint reviews and co-regulation to ensure efficient and effectiveness in its regulatory functions as guided by the Reliance policy QPM 09.
- iv. **A robust, well-functioning Quality Management System.**
The Authority has a Quality Management System in place as guided by its ISO 9001:2015 certification by the Standards Association of Zimbabwe. The Laboratories are ISO 17025:2017 accredited and the Chemistry Laboratory is also WHO pre-qualified.
- v. **Sufficient, sustainable financial resources.**
The Authority is a self-sufficient and autonomous corporation relying financially on the fees it levies to the public to conduct business. The Authority does not get fiscus support thus it sustains its operations.

- vi. **Competent human resources.**
The Authority has competent and qualified employees who operate under the different Units and Divisions.
- vii. **Organizational ethics and values.**
The Authority employees conduct themselves as guided by the HR-COE-01 MCAZ Code of Ethics.
- viii. **Science- and data-driven decision-making processes.**
Regulatory decisions at MCAZ have scientific backing and are guided by principles adopted from the standards, WHO guidelines and any other relevant documents of external origin.

10.0 PRINCIPLES OF GOOD REGULATORY PRACTICES

The Authority is guided by the principles of Good Regulatory Practices which facilitate the achievement of its regulatory objectives.

10.1 Legality

MCAZ operates in terms of the Medicines and Allied Substances Control Act (MASCA) and its regulations. Regulatory systems and the decisions taken by the Authority must have a sound legal basis. This is achieved by the attendance of the Authority's internal lawyers at some committee meetings where regulatory decisions are made where they give legal guidance. The principle of legality requires that a regulatory system be structured such that all regulatory actions and decisions are based on clear legal authority, thus respecting the rule of law. A regulatory body exists to achieve objectives deemed by the government to be in the public interest. It must operate within and in accordance with the powers conferred by the legal framework.

10.2 Consistency

Regulation of medical products must be performed in the context of and in ways coherent with the national legal framework, general government policies and public health policy objectives. MCAZ is a centralized National Regulatory Authority for medical products and allied substances in Zimbabwe. The Authority has a well-functioning Quality Management System that covers all regulatory activities which is critical for regulatory consistency. There is clear, non-conflicting mandates which enable effectiveness and co-ordination.

10.3 Independence

The appointment of Board, Committee members and Senior management at MCAZ is done in terms of MASCA and the Public Entities Corporate Governance Act (Chapter 10:31) and MCAZ further complies to all requirements of PECOGA. As a matter of procedure, Board and Committee members are required to declare any interests they may have at every meeting. If they have any interests in any matter, then they will have to recuse themselves when that matter is under consideration. This will ensure that the Board or Committee makes independent decisions.

MCAZ subscribes to Axcentium Ethics Line Tips Off Anonymous which addresses and ensures that an anti-corruption program is in place and implemented. The Authority has a Code of Conduct which guides employees, Authority Members and external experts in conducting their regulatory activities independently.

MCAZ is funded through fees and the fee structure incorporates a cost recovery mechanism.

10.4 Impartiality

MCAZ leadership has made a statement of impartiality which is adhered to by all staff. This is supported by a procedure for Impartiality MR 4.27. The Authority ensures that all staff complete Conflict of Interest forms before commencement of duty and on an on-going basis when deemed necessary. MCAZ decisions are transparent, and these are taken through legislative committees. (DG/Legal to assist see Good Regulatory Practices guidance GRP WHO TRS 1033 Annex 11 section 8.4 key elements)

10.5 Proportionality

The outcomes of the regulatory activities have graded hierarchical weight depending on the nature or gravity of the deficiency, violation, or risk. Decision trees are utilized to ensure proportionality. The Authority's regulatory activities are conducted on a risk-based approach to ensure resources are allocated where the need for conformance is greater.

10.6 Flexibility

MCAZ exhibits flexibility in responding to changes in the regulated environment. The system has inbuilt flexibilities for its regulatory activities as guided by MASCA and any other relevant guidance documents. This includes Section 75 of MASCA to cater for emergencies (e.g, authorization to import unregistered medicines). The Authority has a guideline which promotes responsiveness in times of public health emergencies. The guideline for Emergency Authorization of Medical Products (allopathic medicines, complementary medicines, biological medicinal products and medical devices) is used during a declared public health emergency. The Authority's legal framework is updated as and when there are advances in science and technology. MCAZ is actively involved in international harmonization and convergence programs such as ZaZiBoNa.

10.7 Clarity

The MCAZ legal framework is clearly documented in such a way that there is no ambiguity or misinterpretations. The Authority conducts Consultative Stakeholder meetings for proposed changes in its legal framework. The Authority subscribes to Good Review Practices and a guideline is in place.

10.8 Efficiency

MCAZ's regulatory interventions are designed to achieve intended public health outcomes and desired regulatory impacts. The Authority shall measure and evaluate the results of its decisions and processes against its stated objectives to ensure they are fit-for-purpose and deliver value. Regulatory and Key Performance Indicators shall be identified by all Unit and Divisions and measured quarterly in accordance with the procedure MR 4.19 and recorded on QF 53 for analysis and evaluation of performance. The RPIs/KPIs shall include performance indicators identified for GRP enablers and principles. GRP implementation evidence shall be documented on the QMS Report Form (QF 25). All outcomes of regulatory activities are tabled at Authority Committees. MCAZ through reliance and recognition, ensures efficient utilization of resources by avoiding duplication of work and providing opportunities to strengthen the regulatory system. ZaZiBoNa, for example allows for joint review of assessments by member states which facilitates registration of several products at the same time. Refer to the Reliance Policy QPM 09.

10.9 Transparency

The Authority is transparent which is essential for building public trust and enabling international cooperation. The Authority has a policy on Information Disclosure and Communication (QPM 04) which promotes effective communication with internal and external stakeholders. Information relating to Authority processes, procedures and decisions is availed to stakeholders by way of publications, through the website and social media platforms. MCAZ communicates and actively collects feedback from stakeholder engagements which include the quarterly Human Liaison Meetings, Annual stakeholder's forum as well as external customer satisfaction surveys. The LCAU ensures that all affected and potentially interested parties have an equal opportunity to be informed of new or amended regulations by publishing stakeholder meeting invitations on the MCAZ website. This discourages discriminatory, corrupt, and abusive practices. The authority uploads unambiguous regulations and guidelines on its website for the benefit of its stakeholders.

11.0 GRP Implementation and Evidence

To demonstrate implementation of GRPs, MCAZ maintains and provides evidence of GRP application including but not limited to:

- 11.1 Policies and Regulations: All documented policies, procedures, guidelines, and legal instruments explicitly outlining the application of GRP principles (legality, impartiality, consistency, proportionality, flexibility, effectiveness, efficiency, clarity, transparency) in the oversight of medical products and allied substances.
- 11.2 Application Examples: Records demonstrating the practical application of GRP principles, such as:
 - i. Decision-making records illustrating proportionality, impartiality, and transparency.
 - ii. Minutes of meetings where GRP principles guided discussions or outcomes.
 - iii. Records of public consultations and their impact on regulatory instruments.
 - iv. Documentation of efforts to ensure consistency across different regulatory functions.
 - v. Evidence of responsiveness and flexibility during public health emergencies.
 - vi. Reports on efficiency gains due to process improvements.
 - vii. Communication Records: Internal and external communications demonstrating promotion of GRPs, including training materials, website content, and public awareness campaigns.
 - viii. Performance Reviews: Reports from internal audits, management reviews, and performance monitoring related to GRP implementation and outcomes.
- 11.3 Communication with external stakeholders shall be through the Medicines Information Bulletin which is publicized bi-annually.

12.0 Training

MCAZ shall promote awareness and understanding of GRP principles through:

- i. Mandatory initial and refresher training for all staff via the online training portal.
- ii. External communication of its GRP policy and GRP in Action to stakeholders via its website.

11.0 References

- i. https://extranet.who.int/pqweb/sites/default/files/documents/01_Regulatory_updates.pdf
- ii. https://www.paho.org/sites/default/files/20220601-oms_1.pdf
- iii. Good Regulatory Practices guidance GRP WHO TRS 1033 Annex 11
- iv. MR 4.3 Standard Operating Procedure for Document Control
- v. MR 4.27 Standard Operating Procedure for Safeguarding Impartiality and Operational Integrity at MCAZ
- vi. MR 4.18 Standard Operating Procedure for Risks and Opportunities Management
- vii. MR 4.14 Standard Operating Procedure for Internal QMS Audits
- viii. ISO 9001:2015 Quality Management Systems Requirements
- ix. MCAZ/EVR/GL-01 Guideline for Emergency Use Authorization of Medical Products
- x. LE 67 Standard Operating Procedure for Receiving and Processing Suspected Defective, Substandard and Falsified (SF) Medical Products and Re-calls
- xi. HR-COE-01 Rev 2_May 2023 MCAZ Code of Ethics
- xii. WHO Global Benchmarking Tool
- xiii. WHO Guidance on regulatory instrument lifecycle management

ACRONYMS

N .B. These acronyms shall only apply to MCAZ.

GRP	Good Regulatory Practices
CHEM	Chemistry Laboratory
CCT	Crisis Communication Team
EVR	Evaluations and Registrations
FU	Finance Unit
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HR	Human Resources
IAU	Internal Audit Unit
ICT	Information Communication Technology
ISO	International Organization for Standardization
LED	Licensing and Enforcement Division
LCAU	Legal and Corporate Affairs Unit
MCAZ	Medicines Control Authority of Zimbabwe
NC	Non-conformity
PAU	Procurement and Administration Unit
PVCT	Pharmacovigilance and Clinical Trials
QMS	Quality Management System
QPM	Quality Policy Manual
QU	Quality Unit
SADCAS	Southern African Development Community Accreditation Service
SAZ	Standards Association of Zimbabwe
SOP	Standard Operating Procedure
WHO	World Health Organization

HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	May 2023	System Improvement to incorporate GBT recommendations Added details into section 9.0 ENABLERS OF GOOD REGULATORY PRACTICES AT MCAZ For application and implementation of GRP at MCAZ, several enablers have been adopted. These include; i. Political and Government-wide support. MCAZ is fully supported by the Ministry of Health and Child Care which gazettes the enabling legislation. The Ministry also set policies that assist MCAZ on how to regulate medicines, medical devices, and allied substances. They approve the fees schedule for MCAZ services. Furthermore, they approve the gazetted inspectors. ii. Effective organization and good governance supported by leadership. MCAZ is governed by Public Entities Corporate Governance Act (PECOGA) which provides a uniform mechanism for regulating the conditions of service of members of public entities and their senior employees. The MCAZ Quality Policy Statement also highlights leadership commitment to ensuring that the regulatory activities are conducted effectively. iii. Inter- and intra-organizational communication, collaboration and co-ordination. MCAZ uses various modes of communication with its different stakeholders for cascading information related to the regulatory activities. These include circulars, newspaper, radio broadcasting, website etc. iv. A robust, well-functioning Quality Management System. The Authority's has a Quality Management System in place as guided by the by its ISO 9001:2015 certification by the Standards Association in Zimbabwe. The Laboratories are ISO 17025:2017 accredited and the Chemistry Laboratory is also WHO pre-qualified. v. Sufficient, sustainable financial resources.

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1	June 2023	System Improvement to ensure alignment of the policy with WHO GBT RS03.05 sub indicator on Good regulatory Practices 1.0 Introduction changed from This policy is a response to the need for guidance in meeting high-level principles of Good Regulatory Practices (GRP) at the Medicines Control Authority of Zimbabwe (MCAZ). The policy considers the principles of GRP as guided by the WHO guideline on GRP in the Regulation of Medical Products (TRS 1033 Annex 11). These were found to be applicable to MCAZ as they result in desired regulatory outcomes and impacts. 1.0 Introduction changed to This policy establishes the framework for the consistent development, implementation, and regular updating of documented policies, procedures, and mechanisms, with written criteria, for the promotion and application of Good Regulatory Practices (GRPs) across all functions and areas of the Medicines Control Authority of Zimbabwe (MCAZ), to ensure efficient and effective oversight of medical products and allied substances. 2.0 Scope changed from The policy applies to all MCAZ Units/ Divisions and describes the Good Regulatory Practices to be adopted. It specifies the

		requirements for providing a means of establishing sound and effective oversight of medical products and allied substances as an important part of health system performance and sustainability. GRP provides a set of principles and practices applied to development, implementation and review of regulatory instruments to fulfil the National Public Health Policy most efficiently. 2.0 Scope changed to The policy applies to all MCAZ Units/Divisions and describes the Good Regulatory Practices to be adopted in the regulation of medical products and allied substances. It specifies the requirements for establishing sound and effective oversight of medical products, as an important part of health system performance and sustainability. This policy covers the promotion, establishment, and application of GRP principles in all regulatory functions and areas. Added Definition 3.13 Regulatory Impact Assessment (RIA) A Regulatory Impact Assessment (RIA) is a systematic, evidence-based process used by governments and regulatory authorities to evaluate the positive and negative effects of proposed and existing regulations and regulatory alternatives. Section 9.0 (iii) Added.... MCAZ works with other NRAs through mechanisms such as reliance, recognition, joint reviews and co-regulation to ensure efficient and effectiveness in its regulatory functions as guided by the reliance policy QPM 09. Section 10.3 Independence Changed from The appointment of Board, Committee members and Senior management at MCAZ is done in terms of MASCA and the Public Entities Corporate Governance Act (Chapter 10:31) Section 10.3 Changed to The appointment of Board, Committee members and Senior management at MCAZ is done in terms of MASCA and the Public Entities Corporate Governance Act (Chapter 10:31) and MCAZ further complies to all requirements of PECOGA. Section 10.3 Changed from Deloitte Tips Off Anonymous to Axcentium Ethics Line Section 10.8 changed from MCAZ achieves the intended results within the required time and at reasonable effort and cost. All outcomes of regulatory activities are tabled at Authority Committees as part of the performance
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