

EVALUATIONS AND REGISTRATION DIVISION

RECOGNITION FRAMEWORK FOR MEDICINES SUBMITTED THROUGH THE EXPEDITED REVIEW PATHWAY FOR WORLD HEALTH ORGANISATION COLLABORATIVE REGISTRATION PROCEDURE, STRINGENT REGULATORY AUTHORITY COLLABORATIVE REGISTRATION PROCEDURE, AFRICAN MEDICINES AGENCY-LISTED AND ZAZIBONA RECOMMENDED PRODUCTS

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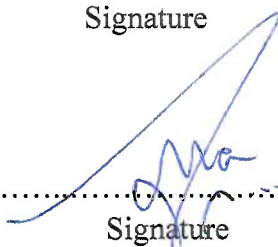

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Acronyms

AMA	African Medicines Agency
cGMP	current Good Manufacturing Practice
CRP	Collaborative Registration Procedure
CTD	Common Technical Document
GReIP	Good Reliance Practices
MCAZ	Medicines Control Authority of Zimbabwe
QIS	Quality Information Summary
SmPCs	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
SRA-CRP	Stringent Regulatory Authority Collaborative Registration Procedure
WHO	World Health Organisation
WHO-CRP	World Health Organisation Collaborative Registration Procedure

1.0 Introduction

The Medicines Control Authority of Zimbabwe (MCAZ) implements regulatory reliance as a strategic regulatory mechanism aimed at enhancing operational efficiency, minimising duplication of effort, and expediting equitable access to quality-assured medical products. In alignment with the World Health Organisation's Good Reliance Practices (GRoP), MCAZ adopted reliance on regulatory decisions issued by trusted entities, including the World Health Organisation (WHO), WHO listed National Regulatory Authorities (NRA) otherwise known as Stringent Regulatory Authorities (SRAs), the African Medicines Agency, and the ZAZIBONA Centralised Procedure.

This framework establishes the procedures for the recognition and registration of medical products in Zimbabwe that have received a positive recommendation from the aforementioned platforms. Such recognition is contingent upon the provision of unrestricted access to all relevant assessment reports and supporting documentation reviewed and approved by the reference authorities.

2.0 Definitions

- 2.1 **Collaborative Registration Procedure** – a process that enables faster registration of medicines through reliance on prior assessments.
- 2.2 **Good Reliance Practices Good Reliance Practices (GRoP):** Principles and operational practices recommended by the World Health Organization (WHO) to guide regulatory authorities in implementing reliance in a transparent, consistent, and efficient manner.
- 2.3 **Marketing Authorisation:** The official approval granted by MCAZ for a medicinal product to be marketed and distributed in Zimbabwe, based on evaluation of its quality, safety, efficacy and/or performance.
- 2.4 **Reference NRA:** A National Regulatory Authority whose regulatory decisions are considered reliable for reliance purposes.
- 2.5 **Reliance:** The act whereby a regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another authority or trusted institution.
- 2.6 **Stringent Regulatory Authority** – a regulatory authority recognised for its high standards in evaluating medical products.
- 2.7 **Stringent Regulatory Authority Collaborative Registration Procedure (SRA CRP)–** A reliance pathway that enables faster national registration of medicines that have already been approved by SRAs such as the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), etc.
- 2.8 **Stringent Regulatory Authority Collaborative Registration Procedure** – a reliance pathway for medicines approved by SRAs such as the FDA, EMA, etc.

- 2.9 **World Health Organisation Collaborative Registration Procedure** – a mechanism to facilitate accelerated national registration of medicines that have been prequalified by WHO.
- 2.10 **ZAZIBONA** – a collaborative medicines registration initiative among Southern African Development Community (SADC) countries to improve regulatory efficiency.

3.0 The framework

This framework applies to medical products that have received a positive recommendation through the WHO Collaborative Registration Procedure (WHO-CRP), SRA-CRP, the African Medicines Agency Expert Medical Products Technical Committee (AMA EMP-TC), and the ZAZIBONA Centralised Procedure. Such products may be submitted for registration in Zimbabwe via reliance mechanisms, including verification and abridged review pathways.

3.1 Required documentation

- 3.1.1 The following documentation must accompany an application where the manufacturer intends to market a product in Zimbabwe:
 - i. Signed and dated cover letter on company letterhead indicating that the information provided in support of the application is true and correct.
 - ii. Expression of interest comprising a list of products intended for submission under the expedited review pathway.
 - iii. Completed, signed, and dated administrative pages (pages 1 and 2) of the MC8 form.
 - iv. A completed Quality Information Summary (QIS) **drafted** by the manufacturer and **approved** by reference agency/ authority to confirm the current properties of the product as approved by the reference NRA intended to be supplied on the Zimbabwean market. This QIS where applicable should bear the official seal of the reference NRA, stamped, and signed by the reference NRA as confirmation of its endorsement.
 - v. An updated CTD dossier as approved by the reference NRA (which matches the endorsed QIS above), incorporating all approved variations made to the product since its initial registration. The full dossier should also be in line with the CTD Guidelines on submission of documentation for registration of medicines in Zimbabwe or comparable CTD guidelines.
 - vi. Labelling information in English and meeting the requirements of the Medicines and Allied Substances Control Act section 37 and the MCAZ Guideline on Product Information and Labelling. This

includes the carton and blister labels, package inserts, Summary of Product Characteristics (SmPCs), and patient information leaflets, where applicable.

- vii. A valid cGMP certificate issued by the reference NRA.
- viii. Additionally, MCAZ **may** require the manufacturing site to be inspected and deemed cGMP compliant by the Authority.
- ix. Two (2) product samples for registration purposes.
- x. Application fee in line with the MCAZ fee schedule.
- xi. A relevant signed indemnity form allowing the reference authority to share full assessment reports and supporting documentation with MCAZ.

3.2 Timelines

3.2.1 All applications submitted under the expedited review pathway shall be processed within a defined regulatory timeframe of ninety (90) calendar days, referred to as MCAZ time. This timeframe represents the period during which the MCAZ actively evaluates the application.

3.2.2 It is important to note that MCAZ time excludes any duration taken by the applicant to respond to queries, provide additional documentation, or address deficiencies identified during the review process. Applicants are therefore encouraged to ensure timely and complete responses to facilitate adherence to the expedited review timeline and enable prompt regulatory decision-making.

4.0 The role of the manufacturer

- 4.1 Drafting the cover letter on the company letterhead, indicating that the information provided in support of the application is true and correct.
- 4.2 Expression of interest comprising a list of products intended for submission under the expedited review pathway.
- 4.3 Completion of pages 1 and 2 (Administrative pages of the MC8 form).
- 4.4 A current CTD dossier as approved by the reference authority (which matches the CTD dossier assessed and approved by the reference authority/platform). The full dossier should also be in line with the CTD Guidelines on submission of documentation for registration of medicines in Zimbabwe or comparable CTD guidelines.
- 4.5 Compilation of the proposed labelling information in English, which is a requirement of the Medicines and Allied Substances Control Act, section 37. This includes the carton and blister labels, the package inserts, as well as the patient information leaflets, where applicable.
- 4.6 Pay the application fee to MCAZ. The current fees are as follows:

Application type	Application fee
New chemical entity	USD 4000
Generic	USD 4000
Line extension (additional strength)	USD 3000

4.7 Submission of all the documents related to the application.

5.0 The role of the reference authority

- 5.1 Provide full access to all reports assessed and approved by the reference authority.
- 5.2 Confirmation that the medical product in question has been given a positive recommendation for registration by reference NRAs on which reliance is being placed, and that the product is considered safe, efficacious, and of acceptable quality.
- 5.3 Provision of a current cGMP certificate to the manufacturer, who will include this cGMP certificate together with the application.

6.0 The role of MCAZ

- 6.1 Assessment of the information submitted by the manufacturer, including the reports provided by the reference authority.
- 6.2 Verification that the information in the reports matches the information in the submitted CTD dossier.
- 6.3 Assessment of quality, safety and efficacy data in modules 3, 4 and 5 as required.
- 6.4 Communication with the applicant to resolve outstanding issues in the submitted application.
- 6.5 Issuance of registration upon completion of the assessment and verification process.
- 6.6 Finalise the application within ninety (90) days (MCAZ time) of submission of a complete application.

In line with Good Reliance Practices (GReIP) and the MCAZ Reliance Policy, the Authority reserves the right to request additional data and/or conduct its own assessments, where deemed necessary.

7.0 Attachments/ Appendices

- 7.1 Attachment 1: MC8 Application for Registration of a Medicine Form
- 7.2 Attachment 2: EVRF 76 QIS form

8.0 History

DOCUMENT HISTORY		
Revision Number	Date Approved	N/A
N/A	N/A	