



EVALUATIONS AND REGISTRATION DIVISION

RELIANCE FRAMEWORK FOR MEDICINES APPROVED BY NATIONAL REGULATORY AUTHORITIES UNDER MEMORANDUM OF UNDERSTANDING WITH MCAZ

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Acronyms

cGMP	current Good Manufacturing Practice
CTD	Common Technical Document
GReIP	Good Reliance Practices
MCAZ	Medicines Control Authority of Zimbabwe
QIS	Quality Information Summary
SRA	Stringent Regulatory Authority
WHO	World Health Organization
SmPCs	Summary of Product Characteristics
MoU	Memorandum of Understanding

1.0 Introduction

The Medicines Control Authority of Zimbabwe (MCAZ) recognises the importance of regulatory reliance as a strategic tool to enhance efficiency, reduce duplication, and accelerate access to quality-assured medical products. In line with World Health Organization's (WHO's) Good Reliance Practices (GRelP), MCAZ relies on decisions made by other National Regulatory Authorities (NRAs) with which Zimbabwe has signed Memoranda of Understanding (MoUs) on regulatory cooperation.

This framework outlines the process for recognising medicines approved by reference NRAs for registration in Zimbabwe, provided they are manufactured in the respective countries and actively marketed there.

2.0 Definitions

- 2.1 Good Reliance Practices (GRelP):** 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.
- 2.2 Marketing Authorisation:** The official approval granted by MCAZ for a medical product to be marketed and distributed in Zimbabwe, based on evaluation of its quality, safety, efficacy and/or performance.
- 2.3 Reference NRA:** A National Regulatory Authority with which MCAZ has a formal MoU and whose regulatory decisions are considered reliable for reliance purposes.
- 2.4 Recognition:** A reliance pathway in which MCAZ fully accepts the regulatory decision of a reference NRA without conducting an independent assessment.
- 2.5 Reliance:** The act whereby the MCAZ takes into account and gives significant weight to regulatory decisions or assessments performed by another trusted NRA in reaching its own decisions.

3.0 The framework

This framework is applicable to medical products that have been authorised by NRAs in jurisdictions with which the MCAZ has established formal MoUs, provided such products are manufactured and currently marketed within the respective reference country, and are submitted for registration in Zimbabwe through reliance mechanisms including verification, abridged review, or recognition pathways.

3.1 Required documentation.

3.1.1 The following documents support an application approved by a reference NRA where the manufacturer intends to market the same 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. Completed, signed, and dated administrative pages (pages 1 and 2) of the MC8 form.
- iii. A completed Quality Information Summary (QIS) **drafted** by the manufacturer and **endorsed** by reference NRA 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.
- iv. A current Common Technical Document (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.
- v. Labelling information in English and meeting the requirements of the Medicines and Allied Substances Control Act section 37. This includes the carton and blister labels, the package inserts, Summary of Product Characteristics (SmPCs) as well as the patient information leaflets where applicable.
- vi. A valid current Good Manufacturing Practices (cGMP) certificate issued by the reference NRA.
- vii. Confirmation of cGMP compliance in the form of a GMP report from the reference NRA generated within 2 years of submission of the application.
- 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. Proof that the product is being actively marketed in the country it is registered by the reference NRA
- xi. Application fee in line with the MCAZ fee schedule.

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 of the cover letter on company letterhead indicating that the information provided in support of the application is true and correct.
- 4.2 Completion of pages 1 and 2 (Administrative pages of the MC8 form).
- 4.3 Completing the Quality Information Summary (QIS) and liaising with the reference NRA to have QIS signed.
- 4.4 Compilation of the current 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.
- 4.5 Compilation of the proposed labelling information in English which 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 3000
Generic	USD 2500
Line extension (additional strength)	USD 1500

- 4.7 Submission of all the documents related to the application.

5.0 The role of the reference NRA

- 5.1 Confirmation of the information on the QIS submitted to the NRA for endorsement, incorporating all approved variations made to the product since its initial registration.
- 5.2 Endorsing the QIS through sealing and signing the document.
- 5.3 Provision of a current cGMP certificate (based on an inspection within 2 years of the submission of the application) 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 QIS endorsed by the reference NRA.
- 6.2 Verification that the information in the QIS 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 (GReLP) 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 Medicines form
- 7.2 Attachment 2: EVRF 76 Quality Information Summary (QIS) form

8.0 History

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
0	June 2023	To consolidate and include all other MoUs signed with reference NRAs and to revise the framework in line with Good Reliance Practices (GRelP) and the MCAZ Reliance Policy. The following changes/amendments were done from Revision 00 to Revision 01 Title changed from “RECOGNITION FRAMEWORK FOR MEDICINES MANUFACTURED IN EGYPT AND APPROVED BY THE EGYPTIAN DRUG AUTHORITY (EDA)” To “RELIANCE FRAMEWORK FOR MEDICINES APPROVED BY NATIONAL REGULATORY AUTHORITIES UNDER MEMORANDUM OF UNDERSTANDING WITH MCAZ” Section 1.0 Introduction Change from “In March 2023, the Government of Zimbabwe and the Egyptian Government agreed to cooperate in pharmaceuticals. One of the key areas of cooperation is the aspect of medicines registration. Recognition and reliance are recognised as key to improving efficiency in the work conducted by regulatory Authorities. MCAZ will therefore recognise the products registered by EDA for the purpose of registration in Zimbabwe in with the Memorandum of Understanding signed between the 2 parties on the 12th of May 2023.” to “The MCAZ recognizes the importance of regulatory reliance as a strategic tool to enhance efficiency, reduce duplication, and accelerate access to quality-assured medical products. In line with WHO’s GRelP, MCAZ relies on decisions made by other NRAs with which Zimbabwe has signed MoUs on regulatory cooperation. This framework outlines the process for recognizing medicines approved by reference NRAs for registration in Zimbabwe, provided they are manufactured in the respective country and actively marketed there.”

		Section 2.0 Definitions (Additions) 2.1 Good Reliance Practices (GRoP): Principles and operational practices recommended by the WHO to guide regulatory authorities in implementing reliance in a transparent, consistent, and efficient manner. 2.2 Marketing Authorization: The official approval granted by MCAZ for a medicinal product to be marketed and distributed in Zimbabwe, based on evaluation of its quality, safety, and efficacy. 2.3 Reference NRA: A National Regulatory Authority with which MCAZ has a formal MoU and whose regulatory decisions are considered reliable for reliance purposes. 2.4 Recognition: A reliance pathway in which MCAZ fully accepts the regulatory decision of a reference NRA without conducting an independent assessment. 2.5 Reliance: The act whereby the MCAZ takes into account and gives significant weight to regulatory decisions or assessments performed by another trusted NRA in reaching its own decision. Section 2.0 Framework “The WHO SRA CRP process includes requirements that may be used for the purposes of reliance. These will be used as the basis of the recognition of approvals of the EDA-approved products by MCAZ. The framework is restricted to products manufactured in Egypt and is currently active on the Egyptian market. The following documents support an application approved by EDA where the manufacturer intends to market the same product in Zimbabwe: - Signed and dated cover letter on company letterhead indicating that the information provided in support of the application is true and correct. - Completed, signed, and dated administrative pages (pages 1 and 2) of the MC8 form. - A completed QIS drafted by the manufacturer and endorsed by EDA to confirm the current properties of the product as approved by EDA intended to be
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		supplied on the Zimbabwean market. This QIS should be sealed, stamped, and signed by EDA as confirmation of its endorsement. iv. A current CTD dossier as approved by EDA (which matches the endorsed QIS above) v. Labelling information in English and meeting the requirements of the Medicines and Allied Substances Control Act section 77. This includes the carton and blister labels; the package inserts as well as the patient information leaflets where applicable. vi. Confirmation of cGMP compliance in the form of a GMP report from EDA generated within 2 years of submission of the application. vii. Application fee in line with the MCAZ fee schedule” To Section 3.0 “This framework is applicable to medical products that have been authorized by NRAs in jurisdictions with which the MCAZ has established formal Memoranda of Understanding (MoUs), provided such products are manufactured and currently marketed within the respective reference country, and are submitted for registration in Zimbabwe through reliance mechanisms including verification, abridged review, or recognition pathways.” 3.1 Required documentation. 3.1.1 The following documents support an application approved by a reference NRA where the manufacturer intends to market the same 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. Completed, signed, and dated administrative pages (pages 1 and 2) of the MC8 form. iii. A completed QIS drafted by the manufacturer and endorsed by reference NRA to confirm the current properties of the product as approved by the reference NRA intended to be supplied on the Zimbabwean market. This QIS should be sealed, stamped, and signed by the reference NRA as confirmation of its endorsement. iv. A current CTD dossier as approved by the reference NRA (which matches the endorsed QIS above), incorporating all approved variations made to the
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		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. v. Labelling information in English and meeting the requirements of the Medicines and Allied Substances Control Act section 37. This includes the carton and blister labels, the package inserts, Summary of Product Characteristics (SmPCs) as well as the patient information leaflets where applicable. vi. A valid cGMP certificate issued by the reference NRA. vii. Confirmation of cGMP compliance in the form of a GMP report from the reference NRA generated within 2 years of submission of the application. viii. Additionally, the manufacturing site must be inspected by the MCAZ and deemed cGMP compliant. ix. Two (2) product samples for registration purposes. x. Proof that the product is being actively marketed in the country it is registered by the reference NRA xi. Application fee in line with the MCAZ fee schedule. 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.” Section 3.0 The role of the Manufacturer
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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 \$2500
Generic	USD \$3000
Line extension (additional strength)	USD \$1500

4.7 Submission of all the documents related to the application.

Section 4.0 The role of EDA (Deleted)

i. Confirmation of the information on the QIS submitted to EDA for endorsement.

ii. Endorsing the QIS through sealing and signing the document.

iii. Provision of a current cGMP certificate (based on an inspection within 2 years of the submission of the application) to the manufacturer who will include this cGMP certificate together with the application.

Section 5.0 The role of the reference NRA (New)

5.1 Confirmation of the information on the QIS submitted to the NRA for endorsement, incorporating all approved variations made to the product since its initial registration.

5.2 Endorsing the QIS through sealing and signing the document.

5.3 Provision of a current cGMP certificate (based on an inspection within 2 years of the submission of the application) to the manufacturer who will include this cGMP certificate together with the application.

Section 5.0. The role of MCAZ changed from

i. Assessment of the information submitted by the manufacturer including the QIS endorsed by EDA.

ii. Verification that the information in the QIS matches the information in the submitted CTD dossier.

		iii. Communication with the applicant to resolve outstanding issues in the submitted application. iv. Issuance of registration upon completion of the assessment and verification process. v. Finalise the application within 30 days (MCAZ time) of submission of a complete application. To section 6.0 6.1 Assessment of the information submitted by the manufacturer including the QIS endorsed by the reference NRA. 6.2 Verification that the information in the QIS 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 90 days (MCAZ time) of submission of a complete application. In line with Good Reliance Practices (GRelP) and the MCAZ Reliance Policy, the Authority reserves the right to request additional data and/or conduct its own assessments, where deemed necessary. Section 6.0 Acronyms <table> <tr> <td>i.</td><td>cGMP</td><td>current Good Manufacturing Practice</td></tr> <tr> <td>ii.</td><td>CRP</td><td>Collaborative Registration Procedure</td></tr> <tr> <td>iii.</td><td>CTD</td><td>Common Technical Document</td></tr> <tr> <td>iv.</td><td>EDA</td><td>Egyptian Drug Authority</td></tr> <tr> <td>v.</td><td>MCAZ</td><td>Medicines Control Authority of Zimbabwe</td></tr> <tr> <td>vi.</td><td>QIS</td><td>Quality Information Summary</td></tr> <tr> <td>vii.</td><td>SRA</td><td>Stringent Regulatory Authority</td></tr> <tr> <td>viii.</td><td>WHO</td><td>World Health Organization</td></tr> </table> Moved to the first part of the document	i.	cGMP	current Good Manufacturing Practice	ii.	CRP	Collaborative Registration Procedure	iii.	CTD	Common Technical Document	iv.	EDA	Egyptian Drug Authority	v.	MCAZ	Medicines Control Authority of Zimbabwe	vi.	QIS	Quality Information Summary	vii.	SRA	Stringent Regulatory Authority	viii.	WHO	World Health Organization
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