EVALUATION AND REGISTRATION DIVISION

RELIANCE FRAMEWORK FOR MEDICINES MANUFACTURED IN BELARUS AND APPROVED BY THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS

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Acronyms

cGMP	current Good Manufacturing Practice
CRP	Collaborative Registration Procedure
CTD	Common Technical Document
RUE-CETH	Republic Unitary Enterprise Centre for Expertise and Testing in Healthcare
MCAZ	Medicines Control Authority of Zimbabwe
QIS	Quality Information Summary
SRA	Stringent Regulatory Authority
WHO	World Health Organization

1.0 Introduction

In May 2024, the Medicines Control Authority of Zimbabwe (MCAZ) and Republic Unitary Enterprise Centre for Expertise and Testing in Healthcare (RUE CETH) signed an agreement to cooperate in medicines regulation. Among the key areas of cooperation are aspects of medicines registration and cGMP inspections. Reliance is recognised as key to improving efficiency in the work conducted by regulatory Authorities. Pursuant to article 2.2 of the MOU signed between Medicines Control Authority of Zimbabwe and Republic Unitary Enterprise Centre for Expertise and Testing in Healthcare , MCAZ will rely on the approval of products by the Ministry of Health of Belarus for the purpose of registration in Zimbabwe in line with the Memorandum of Understanding signed between the 2 parties on the 30th of May 2024.

2.0 The 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 reliance on approvals of the Ministry of Health Belarus approved products by MCAZ. The framework is restricted to products manufactured in Belarus and is currently active on the Belarus market. The following documents support an application approved by Ministry of Health of Belarus where the manufacturer intends to market the same product in Zimbabwe:

2.1 Signed and dated cover letter on company letterhead indicating that the information provided in support of the application is true and correct.

2.2 Completed, signed, and dated administrative pages (pages 1 and 2) of the MC8 form.

2.3 A completed Quality Information Summary (QIS) drafted by the manufacturer and endorsed by RUE CETH to confirm the current properties of the product as approved by Ministry of Health of Belarus intended to be supplied on the Zimbabwean market. This QIS should be sealed, stamped, and signed by RUE CETH as confirmation of its endorsement.

2.4 A current CTD dossier as accepted by RUE CETH (which matches the endorsed QIS above)

2.5 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.

2.6 Confirmation of current Good Manufacturing Practice (cGMP) compliance in the form of a GMP report from State Pharmaceutical Supervision in the sphere of Medicines Circulation (Gospharmnadzor) generated within 3 years of submission of the application.

2.7 Application fee in line with the MCAZ fee schedule

3.0 The role of the Manufacturer

3.1 Writing of the cover letter on company letterhead indicating that the information provided in support of the application is true and correct.

3.2 Completion of pages 1 and 2 (Administrative pages of the MC8 form)

3.3 Completing the Quality Information Summary (QIS) and liaising with RUE CETH to have QIS signed.

3.4 Compilation current CTD dossier as accepted by RUE CETH (which matches the endorsed QIS above)
3.5 Compilation of the proposed labelling information in English which requirement 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.
3.6 Pay the application fee to MCAZ. The current fees are as follows:

Application type	**Application fee**
Generic	USD $2500
New chemical entity	USD $3000
Line extension (additional strength)	USD $1500

3.7 Submission of all the documents related to the application.

4.0 The role of RUE CETH

4.1 Confirmation of the information on the QIS submitted to RUE CETH for endorsement.
4.2 Endorsing the QIS through sealing and signing the document.
4.3 Provision of a current cGMP report (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.

5.0 The role of MCAZ

5.1 Verification of the information submitted by the manufacturer including the QIS endorsed by RUE-CETH.
5.2 Verification that the information in the QIS matches the information in the submitted CTD dossier.
5.3 Communication with the applicant to resolve outstanding issues in the submitted application.
5.4 Issuance of import permit upon completion of the assessment and verification process.
5.5 Finalise the application within 30 days (MCAZ time) of submission of a complete application.

6.0 Attachments/ Appendices

6.1 Attachment 1: MC8 Application for Registration of a Medicines form
6.2 Attachment 2: EVRF 76 Quality Information Summary (QIS) form