MCAZ Medicines Control Authority of Zimbabwe

EVR-RF-01

# EVALUATIONS AND REGISTRATION DIVISION

# RECOGNITION FRAMEWORK FOR MEDICINES MANUFACTURED IN EGYPT AND APPROVED BY THE EGYPTIAN DRUG AUTHORITY (EDA)

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| Written by: | ..... Signature | 26/06/2023 ..... Date |
| Checked by HoD/HoU: | ..... Signature | 26/06/2023 ..... Date |
| Approved by QM: | ..... Signature | 05/07/2023 ..... Date |
| Authorised for use by: Director-General | pp ..... Signature | 06/07/2023 ..... Date |

## 1.0 Introduction

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 Egyptian Drug Authority (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.

## 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 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:

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 EDA to confirm the current properties of the product as approved by EDA intended to be 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

## 3.0 The role of the Manufacturer

i. Writing of the cover letter on company letterhead indicating that the information provided in support of the application is true and correct.
ii. Completion of pages 1 and 2 (Administrative pages of the MC8 form)
iii. Completing the Quality Information Summary (QIS) and liaising with EDA to have QIS signed.
iv. Compilation current CTD dossier as approved by EDA (which matches the endorsed QIS above)
v. 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.

vi. 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 |

vii. Submission of all the documents related to the application.

## 4.0 The role of EDA

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.

## 5.0 The role of MCAZ

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.

## 6.0 Acronyms

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| 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 |

## 7.0 Attachments/ Appendices

7.1 Attachment 1: MC8 Application for Registration of a Medicines form
7.2 Attachment 2: EVRF 73 Quality Information Summary (QIS) form