MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 26 OF 2025

ERRATUM TO CIRCULAR 25 OF 2025 ISSUED ON THE 21ST AUGUST 2025
Explanation: Circular 25 of 2025 was issued with minor errors.

DATE: 28th August 2025

TO: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: NOTIFICATION FOR PUBLICATION OF PUBLIC ASSESSMENT REPORTS (ZIMPARs)

The Medicines Control Authority of Zimbabwe (MCAZ), "The Authority", wishes to inform all applicants, principals, and manufacturers that, in line with the World Health Organization Global Benchmarking Maturity Level 4 requirements, international good regulatory practices and MCAZ's Policy on transparency, accountability and communication, the Authority will begin publishing Zimbabwe Public Assessment Reports (ZimPARs) for registered and refused medicinal product applications (products refused for failure to meet regulatory timelines will be excluded).

These reports will be made publicly available on the MCAZ website (https://shorturl.at/Kj9vQ) and/or relevant regulatory platforms.

Implementation Details:

a. Implementation of the above is as per the Guideline on Drafting and Publishing Zimbabwe Public Assessment Reports (ZimPARs) (https://shorturl.at/JMXuD)
b. The ZimPARs shall contain non-confidential information as guided by Section 73 of the Medicines and Allied Substances Control Act [Chapter 15:03]. Any confidential and intellectual property will be redacted before publication of the report.
c. This procedure will impact applications registered or refused from **January 2025 onwards**.

Appended are ZimPAR templates for registered and refused applications in line with WHO recommendations.

To access the Evaluations and Registration (MA) Public Access Information Portal, please scan the QR code provided in this circular.

Yours faithfully,
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

……
R. T. Rukwata (Mr.)
DIRECTOR GENERAL
/mam

ZIMBABWE PUBLIC ASSESSMENT REPORT (ZIMPAR) FOR REGISTERED MEDICINES

(Generic name, strength, dosage form (Trade name))

Medicine Status:

Name of FPP Manufacturer:

TABLE OF CONTENTS

ZimPAR_Medicine name including dosage form and strength (Trade name)

1.0 Introduction

1. **Medicine Overview**: *Provide a brief description of the medicine, including its generic name, strength, dosage form, brand name, and therapeutic class. Mention the main active ingredient and specify whether it's a generic/biosimilar/innovator.*
2. **Mechanism of Action:**
3. **Date of registration:**
4. **Date of renewal/reregistration:**

1.1 Medicine Details

1.1.1 Registration Number:
1.1.2 Pharmacological Classification:
1.1.3 Category for Distribution:
1.1.4 Country of Origin:

1.2 Information for Users

1.2.1 Visual Description:
1.2.2 Primary Packing Material:
1.2.3 Secondary Packing Materials:
1.2.4 Pack size(s):
1.2.5 Shelf-life and Storage Condition:
1.2.6 Route of Administration:
1.2.7 Therapeutic Indications:

2.0 Scientific Discussion

2.1 Quality Aspects

2.1.1 Quality of Active Pharmaceutical Ingredient(s) (API):

2.1.1.1 **General Properties:** *Describe the chemical and physical properties of the API.*
2.1.1.2 **Manufacture:** *Compliance with GMP standards.*
2.1.1.3 **Stability and Container Closure System:** *Describe the stability studies conducted and the container closure system used.*

2.1.2 Quality of the Finished Pharmaceutical Product (FPP):

2.1.2.1 **Formulation:** *List the ingredients.*
2.1.2.2 **Manufacture:** *State the manufacturer, manufacturing site address and compliance with GMP standards.*
2.1.2.3 **Stability and Container Closure System:** *Describe the stability studies conducted and the container closure system used.*

ZimPAR_Medicine name including dosage form and strength (Trade name)

2.2 Non-Clinical Aspects *(For biosimilars and innovative medicines only)*

2.2.1 **Pharmacology:** *Summarize the pharmacological studies conducted, including primary and secondary pharmacodynamics.*

2.2.2 **Pharmacokinetics:** *Provide an overview of the pharmacokinetic studies, including absorption, distribution, metabolism, and excretion.*

2.2.3 **Toxicology:** *Summarize the toxicological studies, including single-dose toxicity, repeated-dose toxicity, genotoxicity, carcinogenicity, and reproductive toxicity.*

For generic applications the following text can be used if applicable. This medicine is a generic formulation of (…state the innovator medicine…). Reference is made to the preclinical data obtained with the innovator medicine. Based on this data no further non-clinical studies are required. ´

2.3 Clinical Aspects

2.3.1 **Clinical Pharmacology:** *(Non-proprietors and Innovators)*

2.3.2 **Pharmacokinetics:** *Summarize the clinical pharmacokinetic studies, including bioavailability, bioequivalence, and special population studies.*

2.3.3 **Pharmacodynamics:** *Provide an overview of the clinical pharmacodynamic studies.*

2.3.4 **Clinical Efficacy:** *(Innovative medicines)*

2.3.4.1 **Study Design**: *Describe the design of the clinical studies, including the study population, endpoints, and statistical methods.*

2.3.4.2 **Results:** *Summarize the results of the clinical studies, including efficacy outcomes and any subgroup analyses.*

2.3.4.3 **Discussion:** *Discuss the clinical relevance of the study results and any limitations.*

2.4 Clinical Safety

2.4.1 **Adverse Events:** *Summarize the safety data from clinical studies, including the incidence and severity of adverse events.*

2.4.2 **Special Populations:** *Discuss the safety profile in special populations, such as the elderly, children, and patients with renal or hepatic impairment.*

2.4.3 **Post-Marketing Experience:** *Provide any relevant post-marketing safety data.*

For generic applications with bioequivalence studies please focus on the following:

2.4.4 **Study Design:** *Describe the design of the clinical studies, including the number of participants, study duration, and endpoints.*

2.4.5 **Primary and Secondary Objectives:** *State the primary and secondary objectives of the studies*.

2.4.6 **Monitored Parameters:** *List the parameters monitored during the studies (e.g., Tmax, Cmax, AUC).*

ZimPAR_Medicine name including dosage form and strength (Trade name)

2.4.7 **Analytical Methods:** *Describe the analytical methods used to assess the study results.*

2.4.8 **Statistical Methods:** *Outline the statistical methods used to analyze the data.*

2.4.9 **Results:** *Summarize the key findings.*

3.0 Overall benefit/risk assessment and conclusion

3.1 Benefit-Risk Analysis: *Provide a detailed analysis of the benefits and risks associated with the medicine based on its quality and relevant comparison with a suitable reference/comparator.*

For non-proprietary medicines, you can use the following text as applicable:

Non-proprietary name of the medicine…. is a generic/biosimilar medicine that has met the acceptable minimum quality standards and is bioequivalent/similar to the reference medicine. Therefore, its benefits and risks are considered to be the same as those of reference medicine.

For proprietary medicines, you can use the following text as applicable:

Proprietary name of the medicine…. has met the acceptable minimum quality, non-clinical and clinical standards and is considered safe and efficacious. Therefore, its benefits outweigh risks.

The overall benefit/risk balance of…*state the proprietary name of the medicine* …is positive.

3.2 Conclusion: *State the final decision based on the assessment.*

The Registration Committee, based on a favourable benefit/risk balance decided to register …*state the generic name and trade name of the medicine*….

Document issuance date:

The revision date corresponds to that of the original Zimbabwe Public Assessment Report. This document reflects the data available at the time of product registration and will not be updated with new information related to the product's quality, efficacy, or safety. Please contact us at mcaz@mcaz.co.zw for feedback and inquiries regarding this ZimPAR.

Medicines Control Authority of Zimbabwe

EVRF 84

ZIMBABWE PUBLIC ASSESSMENT REPORT (ZIMPAR) FOR REFUSED PRODUCTS

(Generic name, strength, dosage form (Trade name))

Medicine Status:

Name of FPP Manufacturer:

TABLE OF CONTENTS

1.0 Introduction

1.1 Medicine Overview: Provide a brief description of the medicine, including its generic name, strength, dosage form and brand name. Mention the main active ingredient and specify whether it's a generic/biosimilar/innovator.

1.2 Date of receipt:

1.3 Date of refusal:

2.0 Overall benefit/risk assessment and conclusion

2.1 Benefit-Risk Analysis: Provide a detailed analysis of the benefits and risks associated with the medicine based on its quality and relevant comparison with a suitable reference/comparator.

For non-proprietary medicines, you can use the following text as applicable:

Non-proprietary name of the medicine…. is a generic/biosimilar medicine that has not met the acceptable minimum quality standards and is not bioequivalent/similar to the reference medicine. Therefore, its benefits and risks are not considered to be the same as those of reference medicine.

For proprietary medicines, you can use the following text as applicable:
Proprietary name of the medicine…. has not met the acceptable minimum quality, non-clinical and clinical standards.

The overall benefit/risk balance of…*state the non-proprietary/proprietary name of the medicine* …is negative.

2.2 Conclusion: *State the final decision made based on the assessment.*
The Registration Committee, based on an unfavourable benefit/risk balance refused…*state the generic and trade name of the medicine*…

Document issuance date:

The revision date corresponds to that of the original Zimbabwe Public Assessment Report. This document reflects the data available at the time of product registration and will not be updated with new information related to the product's quality, efficacy, or safety. Please contact us at mcaz@mcaz.co.zw for feedback and inquiries regarding this ZimPAR.