



EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Handling a Returned Registration /Approval Certificate of a Product			
SOP Number: EVR 21		Revision Number: 3	
		Document Level: 3	
Date Issued for training: 03/10/2024		Effective Date: 08/10/2024	
		Review Date: 10/2026	
Reviewed by:	P. ZVAREVASHE Name	[Signature] Signature	01/10/2024 Date
Approved by HoU/HOD:	Z. A. Makoni Name	[Signature] Signature	02/10/2024 Date
Authorised for use by: (Quality Manager)	A. Chikwanda Name	[Signature] Signature	08/10/2024 Date

1.0 PURPOSE

To enable a Regulatory Officer to successfully process a registration certificate (form M.C. 16) / approval certificate (form CM2) that has been returned due to errors and reissue a new certificate.

2.0 SCOPE

This procedure shall be performed by a Regulatory Officer when a registration certificate M.C.16 for a human allopathic medicine, or a veterinary medicine or approval certificate (form CM2) for a human complementary medicine has been returned due to errors and there is need to reissue a new registration/approval certificate.

3.0 FREQUENCY

Whenever a registration certificate, for a human allopathic medicine, or a veterinary medicine (form M.C.16) or an approval certificate (form CM2) for a human complementary medicine has been returned due to errors and there is need to issue a new registration/ approval certificate.

4.0 LOCATION

- 4.1 The Master Copy of this SOP is kept by the Quality Manager's office.
- 4.2 Controlled copies are kept by the Head of Evaluations & Registration Division and Evaluations & Registration Division staff.
- 4.3 Controlled copies issued to staff will be kept at points of use in the division

5.0 DEFINITIONS

- 5.1 **C-Book "EVRB02"**: The current Medicines Register in which all registered Human products and Veterinary products are recorded
- 5.2 **CM-Book "EVRB12"**: The current Medicines Register in which all registered Complementary medicine products are recorded
- 5.3 **Certificates EVRB 26**: A register of returned certificates for human allopathic medicines, human complementary medicines and veterinary medicines
- 5.4 **Application file**: A collection of documents which are submitted as an application for registration of a medicine
- 5.5 **Application Number**: An alpha-numeric number used as a reference code for a particular new (pending), application in the ZIMDIS programme, prior to registration. This number is used from the date of receipt of the application to the date of issue of a registration certificate
- 5.6 **Registration Number**: A numeric number used as a reference code for a particular registered product in the ZIMDIS programme
- 5.7 **Applicant**: The person by whom or on whose behalf, an application for registration is made
- 5.8 **Trade Name**: The proprietary name given to the product by the applicant
- 5.9 **Generic Name**: The WHO-recommended international non-proprietary name (rINN) for an active pharmaceutical ingredient that is generally accepted as the official name

6.0 RESPONSIBILITY

- 6.1 The Chief Regulatory Officer and/or Administrative Regulatory Officer or designate is responsible for allocating the returned certificate.
- 6.2 The Regulatory Officer is responsible for preparing and issuing the registration certificate (formM.C.16) or approval certificate (form CM2).
- 6.3 The Chief Regulatory Officer and/or Head- EVR or their designates verifies the correctness of the registration certificate (formM.C.16) or approval certificate (form CM2).
- 6.4 Director-General signs and endorses the registration certificate (formM.C.16) or approval certificate (form CM2) with an embossed seal
- 6.5 Quality Manager/Designate is responsible for monitoring compliance to the procedure, Quality Management System (QMS), International and other relevant standards,

7.0 PROCEDURE

- 7.1 After a returned registration certificate (formM.C.16) or approval certificate (form CM2) is received the Chief Regulatory Officer and/or Administrative Regulatory Officer or designate shall allocate the certificate to the Regulatory officer.
- 7.2 **Entering the product information of the product in the EVRB 26 "Register of returned Certificates"**:

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- 7.2.1 Enter the date the certificate was returned
- 7.2.2 Enter the file number of product on the returned certificate
- 7.2.3 Enter the reason for the return
- 7.2.4 Enter the initials of the officer the file has been allocated to
- 7.2.5 Record the investigation findings
- 7.2.6 Record the corrective action
- 7.2.7 Record the date the revised certificate is sent

7.3 **Completing the Registration Certificate Template, M.C.16 / Approval Certificate CM2**

- 7.3.1 Enter the file number allocated from file EVRB02 “C-Book” or EVRB12 “CM Book”.
- 7.3.2 Record the product’s approved generic name
- 7.3.3 Record the trade name.
- 7.3.4 Record the dosage form and colour as described on the application form (MC8 form or CM1 form).
- 7.3.5 Record the registration number as allocated in the C-Book, EVRB02 or CM Book, EVRB12
- 7.3.6 Record the shelf-life in months, packaging and the storage conditions (e.g.36 months below 30°C when packed in HDPE bottle)
- 7.3.7 Record the category for distribution, in full and abbreviation in parenthesis e.g. **Prescription Preparations (PP).**
- 7.3.8 Enter the name and physical address of the manufacturer(s) as stated on the MC8 form or CM1 form.
- 7.3.9 Enter the name and address of the principal as declared on MC8 form or CM1 form.
- 7.3.10 Enter the name of the applicant as declared on MC8 form or CM1 form
- 7.3.11 Enter the address where the certificate, M.C.16 would be kept, as declared on MC8 form or CM1 form.
- 7.3.12 Enter the date of registration/approval, on which an entry was made in file EVRB02 “C-Book” or the EVRB12 “CM-Book”.
- 7.3.13 Record whether the product would be **wholly manufactured in, or imported into, or partially manufactured in** Zimbabwe, check the MC8 form or CM1 form.
- 7.3.14 Record the conditions imposed by the Committee, for all products: **Subject to compliance with labelling**, for anti-TB drugs: **To be distributed in public health institutions only.**
- 7.3.15 Record the date of issue of certificate. This should be the date the revised certificate is sent to the Director-General for signing.
- 7.3.16 Compare the information on the certificate, with that in the ZIMDIS, the Evaluation report and documents that came with the certificate to be revised for correctness.
- 7.3.17 Send the certificate, checklist form for correctness of information on certificates “EVRF25”, and updated application form (MC8 form /CM1 form) to the Chief Regulatory Officer or Head-EVR or their designate for review

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- 7.3.18 Send the reviewed certificate, to the Director-General's Office for signing and seal of Zimbabwe.
- 7.3.19 Make a photocopy of the signed certificate, quote the alpha numeric application number at the top-right corner of the certificate and send it to the product file in the filing room.
- 7.3.20 Send the certificate to the applicant
- 7.3.21 The returned certificates shall be labelled "RETURNED" and filed in the respective product files.

8.0 APPENDICES/ ATTACHMENTS

- 8.1 Attachment I: Registration Certificate template (MC16)
- 8.2 Attachment II: Approval certificate template (CM2)

9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	Copy of registration certificate	Infinity
N/A	ZIMDIS database in computer	Infinity
EVRB12	Entry in CM-Book	Infinity
EVRB02	Entry in C-Book	Infinity
N/A	Cover letter for Registration /Approval Certificate	Infinity

10.0 REFERENCES

- 10.1 Statutory Instrument 150 of 1991
- 10.2 SOP MR 4.0 Writing Standard Operating Procedure
- 10.3 SOP MR 4.13 Control of Records
- 10.4 Statutory Instrument 97 of 2015

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for change
0	April 2018	Rolling review
1	April 2021	System Improvement
2	January 2022	System improvement

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Number: *(OFFICIAL USE)*

It is hereby certified that a medicine has been registered as follows:

1. Approved name of medicine: Click or tap here to enter text.
2. Trade mark of medicine: Click or tap here to enter text.
3. The form in which the medicine is presented and the colour thereof: Click or tap here to enter text.
4. Approved name of the active ingredient(s) and strength: Click or tap here to enter text.
5. Registration number of the medicine: *(OFFICIAL USE)*
6. Shelf life of medicines in months: *(OFFICIAL USE)*
7. Category for distribution of medicine: *(OFFICIAL USE)*
8. Name and address of manufacturer(s): Click or tap here to enter text.
9. Name and address of principal: Click or tap here to enter text.
10. Name and address of applicant Click or tap here to enter text.
11. Address at which certificate will be kept: Click or tap here to enter text.
12. Date of original registration: *(OFFICIAL USE)*
13. The medicine will be **IMPORTED INTO** Zimbabwe
14. Conditions of registration imposed by the Authority: *See annexure*
15. Date of issue of certificate: *(OFFICIAL USE)*

Issued at Harare this *(OFFICIAL USE)* day of *(OFFICIAL USE)*

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Director-General

ANNEXURE TO THE REGISTRATION CERTIFICATE FOR FILE NUMBER (OFFICIAL USE)

Date of expiry of registration: (OFFICIAL USE)

GENERAL CONDITIONS

1. Compliance with labelling requirements;
2. Subject to renewal of registration **every five (5) years** on condition of demonstration of quality, safety, and efficacy;
3. Mandatory reporting of individual case safety reports (ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects;
4. Applicant and/or manufacturer is required to have a functional pharmacovigilance system in place for their medical products;
5. Applicant and/or manufacturer is required to designate a responsible qualified person for pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the applicant;
6. Periodic safety update reports (PSURs) and periodic benefit risk evaluation reports (PBERs) are generated for innovator products and biological products. For generic products, these should be generated if there are safety concerns*;
7. Compliance with any request by the Medicines Control Authority of Zimbabwe to conduct post-authorisation safety and efficacy studies whenever the need may arise.

NB: Please note that the conditions stated above, in this annexure are also part of the legal provisions for existence of a national vigilance systems based on requirements for section 33, section 33(2) (iii), 33(3) and 29 (1)(b) of the Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03], MCAZ National Pharmacovigilance handbook 2016 Edition, MCAZ circular 1/2000 dated 21st March 2000, MCAZ Pharmacovigilance Guideline for Pharmaceutical Industry MCAZ/PVCT/GL-02 dated 3rd March 2021, Guideline for Pharmacovigilance of COVID-19 Vaccines MCAZ/PVCT/GL-03, dated 11 June 2021, and Zimbabwe National Adverse Events Following Immunization (AEFIs) Guideline 2017.

PRODUCT-SPECIFIC CONDITIONS FOR REGISTRATION

API manufacturer(s): Click or tap here to enter text.

Approved batch size(s): Click or tap here to enter text.

Written commitment(s) by the FPP manufacturer: Click or tap here to enter text.

* Risk management plan, pharmacovigilance plan in line with International Conference of Harmonization (ICH E2E), periodic safety update reports (PSURs) and periodic benefit risk evaluation report (PBER) is a format of safety report described by the ICH-E2C (R2) guideline which is used as a basis for the EU periodic safety update report (PSUR). The report is produced by the manufacturer and/or applicant at defined time points after a chemical entity innovator medicine including vaccine has been registered in Zimbabwe in line with other regulatory international requirements. The motive of the report is to provide comprehensive and up-to-date information about the safety of a medicine. The report needs to summarize any new evidence on safety, efficacy and effectiveness that might affect the balance of risks and benefits. It provides details about the risks to Regulatory authorities and identifies where risk management initiatives may be required.

**ANNEXURE TO THE REGISTRATION CERTIFICATE FOR FILE NUMBER
(OFFICIAL USE)**

Approved product label(s):

Number: **CM0*****

It is hereby notified that a Complementary Medicine has been approved as follows:

1. Approved name of Complementary Medicine:
2. Trade name of Complementary Medicine:
3. The form in which the Complementary Medicine is presented and the colour thereof:
4. Active ingredient(s) and strength:
5. Approval number of Complementary Medicine: **202x/CM0*****
6. Shelf Life of Complementary Medicine in months:
7. Category for distribution of Complementary Medicine:
8. Name and address of manufacturer(s):
9. Name and address of principal:
10. Name and address of applicant:
11. Address at which certificate will be kept
12. Date of Original Approval:
13. The complementary medicine will be:
14. Conditions of Approval imposed by Authority: *see annexure.*
15. Date of issue of certificate:
16. Issued at Harare this xx day of

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Director – General

ANNEXURE TO THE APPROVAL CERTIFICATE FOR FILE NUMBER:

Date of expiry of registration:

GENERAL CONDITIONS

1. Compliance with labelling requirements;
2. Subject to renewal of registration **every five (5) years** on condition of demonstration of quality, safety, and efficacy;
3. Mandatory reporting of individual case safety reports (ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects;
4. Applicant and/or manufacturer is required to have a functional pharmacovigilance system in place for their medical products;
5. Applicant and/or manufacturer is required to designate a responsible qualified person for pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the applicant;
6. Periodic safety update reports (PSURs) and periodic benefit risk evaluation reports (PBERs) are generated for innovator products and biological products. For generic products, these should be generated if there are safety concerns¹;
7. Compliance with any request by the Medicines Control Authority of Zimbabwe to conduct post-authorisation safety and efficacy studies whenever the need may arise.

NB: Please note that the conditions stated above, in this annexure are also part of the legal provisions for existence of a national vigilance systems based on requirements for section 33, section 33(2) (iii), 33(3) and 29 (1)(b) of the Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03], MCAZ National Pharmacovigilance handbook 2016 Edition, MCAZ circular 1/2000 dated 21st March 2000, MCAZ Pharmacovigilance Guideline for Pharmaceutical Industry MCAZ/PVCT/GL-02 dated 3rd March 2021, Guideline for Pharmacovigilance of COVID-19 Vaccines MCAZ/PVCT/GL-03, dated 11 June 2021, and Zimbabwe National Adverse Events Following Immunization (AEFIs) Guideline 2017.

¹ Risk management plan, pharmacovigilance plan in line with International Conference of Harmonization (ICH E2E), periodic safety update reports (PSURs) and periodic benefit risk evaluation report (PBER) is a format of safety report described by the ICH-E2C (R2) guideline which is used as a basis for the EU periodic safety update report (PSUR). The report is produced by the manufacturer and/or applicant at defined time points after a chemical entity innovator medicine including vaccine has been registered in Zimbabwe in line with other regulatory international requirements. The motive of the report is to provide comprehensive and up-to-date information about the safety of a medicine. The report needs to summarize any new evidence on safety, efficacy and effectiveness that might affect the balance of risks and benefits. It provides details about the risks to Regulatory authorities and identifies where risk management initiatives may be required.

ANNEXURE TO THE APPROVAL CERTIFICATE FOR FILE NUMBER:

Approved product label(s):
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