



Medicines Control Authority of Zimbabwe

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Medicines Control Authority
of Zimbabwe

EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Issuing of a WHO – Type Certificate of Pharmaceutical Product			
SOP Number: EVR 20		Revision Number: 3	
		Document Level: 3	
Date Issued for training: 06/06/2025		Effective Date: 06/06/2025	
		Review Date: 06/2027	
Reviewed by:	RUTENDO T KADZUNGE Name	<i>Rutendo</i> Signature	05/06/2025 Date
Approved by HoU/HoD:	G. MATIMBA Name	<i>G. Matimba</i> Signature	05/06/2025 Date
Authorised for use by: (Quality Manager)	A. CHIKWARA Name	<i>A. Chikwara</i> Signature	06/06/2025 Date

1.0 PURPOSE

To establish a procedure for issuing of a WHO –type Certificate of Pharmaceutical Product for registered human or veterinary medicines.

2.0 SCOPE

Applies when issuing a Certificate of Pharmaceutical Product for a registered Human Medicine or Veterinary Medicine in the WHO-recommended format for the purpose of establishing the status of the product in Zimbabwe, the exporting country. It is issued for a single product, per importing country, because manufacturing arrangements and approved information for different pharmaceutical forms and strengths can vary.

3.0 FREQUENCY

Whenever an applicant submits an application for a WHO-type Certificate of Pharmaceutical Product, EVRF40 for a registered human or veterinary medicine for purposes of registration and marketing of the product outside of Zimbabwe.

4.0 LOCATION

- 4.1 The master copy of this procedure is kept in the Quality Office.
- 4.2 A controlled copy is kept in the Evaluations & Registration Division file.

TITLE: Standard Operating Procedure for Issuing of a WHO – Type Certificate of Pharmaceutical Product

SOP Number: EVR 20

Revision Number: 3

Page 2 of 4

5.0 DEFINITIONS

- 5.1 **MC8 Form:** An application form for registration of medicines.
- 5.2 **File 18a “EVRB05”:** The current register used as a reference number generator for a particular product to be exported and marketed outside Zimbabwe.
- 5.3 **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
- 5.4 **Fee schedule:** An official MCAZ document showing all the fees for various services offered to the public by the Authority. The document is either the gazette schedule or a circular based on the gazetted schedule, which is signed by the Director General.
- 5.5 **File Number:** A numeric number used as a reference code for a particular registered product in the ZIMDIS programme.
- 5.6 **Applicant:** The person by whom or on whose behalf, an application for registration is made.
- 5.7 **Trade Name:** The proprietary name given to the product by a the applicant.
- 5.8 **Generic Name:** The WHO-recommended international non-proprietary name (rINN) for an active pharmaceutical ingredient that is generally accepted as the official name
- 5.9 **Date of registration:** Date of original registration as captured in the Registration Certificate
- 5.10 **ZIMDIS:** Zimbabwe Drug Information System. An electronic database for applications for registration.

6. RESPONSIBILITY

- 6.1 The Regulatory Officer is responsible for preparing and issuing the Certificate of Pharmaceutical Product
- 6.2 The Chief Regulatory Officer and/or Head- EVR or their designates verifies the correctness of the Certificate of Pharmaceutical Product
- 6.3 The Finance Officer is responsible for issuing a receipt as proof of payment for the Certificate of Pharmaceutical Product
- 6.3 The Director-General (or designate) signs and endorses the certificate with an embossed seal
- 6.4 The Quality Manager/Designate shall be responsible for monitoring compliance of this procedure to Quality Management Standards (QMS), International and other relevant standards.

Reviewed by: <i>R. Radzunge</i>	Approved by HoU/HoD: <i>AM</i>	Authorised for use by QM:- <i>[Signature]</i>
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TITLE: Standard Operating Procedure for Issuing of a WHO -Type Certificate of Pharmaceutical Product

SOP Number: EVR 20

Revision Number: 3

Page 3 of 4

7.0 PROCEDURE

7.1 Preparations for Issue of a WHO -Type Certificate of Pharmaceutical Product

- 7.1.1 Upon receipt of the application with the attached proof of payment for a Certificate of Pharmaceutical Product, EVRF40 (Attachment 1), verify the fees paid plus Value Added Tax as gazetted in the MCAZ fee schedule. The fees paid should reflect one certificate per product per importing country.
- 7.1.2 When verified, notify the Finance Unit through email to issue a receipt for the Certificate of Pharmaceutical Product/s. If more money is required, communicate this to the applicant.
- 7.1.3 Upon receiving a copy of the receipt from the Finance Unit, retrieve module 1 of the product application file with the registration certificate and the MC8 Form using the file number.
- 7.1.4 Fill in the reference book, File 18a to get the reference number for the particular product to be exported and marketed outside Zimbabwe
- 7.1.5 Fill in the WHO -Type Certificate of Pharmaceutical Product template, EVRF 40 using information from the registration certificate.

7.2 Entering the product information of the product in the EVRB05 "File 18a" (new certificate only)

- 7.2.1 Enter the date of issue of the WHO -type Certificate of Pharmaceutical Product.
- 7.2.2 Enter a reference number, i.e., next number in sequence.
- 7.2.3 Record the name of the applicant, trade name of the product, if applicable and the name of the requesting/importing country.
- 7.2.4 Record the file number of the product.

7.3 Completing the WHO -Type Certificate of Pharmaceutical Product Template

- 7.3.1 Enter the reference number allocated from file EVRB05 "File 18a" which has 3 parts separated by slashes (xx/18A/yyyy), where "XX" is the reference number (as stated in 7.2.2 above) and "YYYY" is the year of issue of the Certificate of Pharmaceutical Product.
- 7.3.2 Complete the relevant sections of the Certificate of Pharmaceutical Product template, EVRF40.
- 7.3.3 Send the Certificate of Pharmaceutical Product, the MC8 form and the registration certificate to the designated reviewer.
- 7.3.4 Send the reviewed certificate to the Director – General's office for signing and stamp.
- 7.3.5 Make a photocopy of the signed certificate, quote the file number and send it to the product file in the filing room.
- 7.3.6 Send the certificate to the applicant

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TITLE: Standard Operating Procedure for Issuing of a WHO – Type Certificate of Pharmaceutical Product

SOP Number: EVR 20

Revision Number: 3

Page 4 of 4

8.0 APPENDICES/ATTACHMENTS

- 8.1 Attachment 1: WHO -Type Certificate of Pharmaceutical Product template (EVRF 40)

9.0 RECORDS

Document Number	Title of Record	Retention Period
EVRF 40	WHO – type Certificate of Pharmaceutical Product Template	Infinity
N/A	Copy of letter of certification	Infinity
EVRB05	Entry in File 18a	Infinity

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
 10.2 SOP MR 4.13 Control of Records
 10.3 MCAZ Gazetted Fee Schedule

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	April 2018	Rolling review
01	April 2021	Response to WHO GBT IDP
02	May 2023	Rolling review

Reviewed by: <i>R. Radezunge</i>	Approved by HoU/HoD: <i>dmab</i>	Authorised for use by QM: <i>ADL</i>
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