



Medicines Control Authority of Zimbabwe



EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Issuing a Registration Certificate of a Medicinal Product (Human Allopathic Medicines)			
SOP Number: EVR 03		Revision Number: 8 Document Level: 3	
Date issued for training: 19/08/2025		Effective Date: 11/09/2025	
		Review Date: 09/2027	
Reviewed by:	P. ZVAREVASHE Name	 Signature	09/09/2025 Date
Approved by HoU/HoD:	P. L. C. MATIRI Name	 Signature	11/09/2025 Date
Authorised for use by: (Quality Manager)	A. CHIKWORE Name	 Signature	11/09/2025 Date

1.0 PURPOSE

To enable a Regulatory Officer to successfully issue a registration certificate of a human allopathic medicinal product

2.0 SCOPE

- 2.1 This procedure shall be performed by a Regulatory Officer when preparing a marketing authorisation certificate for a human allopathic medicine after approval of registration or approval of a renewal or reinstatement of such a product by the Registration Committee.
- 2.2 To note this procedure shall be performed concurrently with the following procedures: **EVR25 (Procedure for publishing SmPC)** and **EVR31 (Procedure for drafting a Zimbabwe Public Assessment Report)**.

3.0 FREQUENCY

Whenever a new application for marketing authorisation, a renewal or the reinstatement of a cancelled product has been approved by the Registration Committee.

4.0 LOCATION

- 4.1 The Master Copy of this SOP is kept by the Quality 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.

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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 **A-Book "EVRB01":** A register, EVRB01 of all new applications for registration of human products which have been submitted to the MCAZ
- 5.3 **Re-instatements Book:** A register, EVRB30 for all new applications, responses, and additional information for re-instatements for human allopathic medicines
- 5.4 **Application file:** A collection of documents 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. 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 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 **MC8:** Application form for registration of a medicine (human allopathic and veterinary medicines)
- 5.10 **MC16:** registration certificate for human allopathic and veterinary medicines.
- 5.11 **SmPC:** Summary of Product Characteristics
- 5.12 **ZimPAR:** Zimbabwe Public Assessment Report

6.0 RESPONSIBILITY

- 6.1 The Regulatory Officer or their designate is responsible for preparing and issuing the marketing authorisation certificate, SmPC and ZimPAR
- 6.2 The Chief Regulatory Officer and/or Head- EVR or their designates verify the correctness of the marketing authorisation certificate, SmPC and ZimPAR
- 6.3 Director-General signs and endorses the certificate with an embossed seal.
- 6.4 The Head of Division has the overall responsibility of ensuring that this procedure is always adhered to.
- 6.5 The Quality Manager/Designate shall be responsible for monitoring compliance to the procedure, Quality Management System, relevant national and international standards.

Reviewed by: <i>M. Mavurira</i>	Approved by HoU/HoD: <i>H. M. M. M.</i>	Authorised by QM: <i>---</i>
Date: <i>09/09/2025</i>	Date: <i>14/09/2025</i>	Date: <i>11/09/2025</i>

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7.0 PROCEDURE

7.1 Preparations for Issue of a Registration certificate

- 7.1.1 Retrieve the product application file and cross-check whether all previous issues raised with respect to document review, laboratory analysis, GMP inspection have been resolved.
- 7.1.2 Check whether the Registration Committee has approved marketing authorisation of the product (refer to the minutes of the Registration Committee meeting).
- 7.1.3 Cross-check the recorded conditions for registration, amendment or reinstatement of the product recorded in the minutes.
- 7.1.4 Verify whether the applicant has accepted, in writing, the proposed conditions of marketing authorisation.
- 7.1.5 If the applicant objects to the proposed registration conditions table the applicant's appeals in the next meeting of the respective committee.
- 7.1.6 If the applicant has accepted the conditions, fill in the registration certificate template (MC16) using information from the most recent MC8 form in the product file and the conditions of registration recorded in the minutes and accepted by the applicant.
- 7.1.7 Notify the regulatory officers responsible for ZimPARs through email to initiate the drafting of these respective documents as per procedures **EVR31 (Procedure for drafting a Zimbabwe Public Assessment Report)**.

7.2 Entering the product information of the product in the EVRB02 "C-Book" for human allopathic medicines and Veterinary medicines (new certificate only)

- 7.2.1 Enter a file number, i.e., next number in sequence.
- 7.2.2 Record the product's application number.
- 7.2.3 Record the product's approved name.
- 7.2.4 Record the product's trade name, if applicable.
- 7.2.5 Record the dosage form of the product (e.g., tablet, capsule, solution etc.).
- 7.2.6 Record the name of the applicant.
- 7.2.7 Enter the registration number which has 3 parts separated by slashes (2014/12.8/4901), where the first part is the year of registration, the second part is the numerical pharmacological class, and the last part is the file number (as stated in 7.2.1 above).
- 7.2.8 Enter the category for distribution as recorded in the Committee meeting minutes and verify with Section 39 of **SI 150 of 1991 Sixth Schedule 'Categories for The Distribution of Medicines'**.
- 7.2.9 Enter the shelf life approved by the Registration Committee, in months. Double check whether this is the same as recorded in the evaluation report and accepted by the applicant.
- 7.2.10 Enter the date of issue of the registration certificate.

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7.2.11 Notify the regulatory officers responsible for the ZimPARs to take note of the allocated file number for each approved product application. This number will be included in the respective SmPC and ZimPAR. (Refer to procedures **EVR25** and **EVR31**.)

7.3 Entering the product information of the product in the EVRB30 “Re-instatements Book” reinstatements of human allopathic medicines.

7.3.1 Enter the product information at the back of file EVRB30 “Re-instatements Book” reinstatements of human allopathic medicines (Follow steps 7.2.2 to 7.2.11 above).

7.4 Completing the Registration Certificate Template (MC16)

7.4.1 Enter the file number allocated from file EVRB02 “C-Book”

7.4.2 Record the product’s approved generic name.

7.4.3 Record the trade name.

7.4.4 Record the dosage form and colour as described on the MC8 form

7.4.5 Record the approved name of the active ingredient(s) and strength.

7.4.6 Record the registration number as allocated in the C-Book.

7.4.7 Record the shelf-life in months, packaging, and the storage conditions (e.g., 36 months below 30°C when packed in HDPE bottle).

7.4.8 Record the category for distribution, in full and abbreviation in parenthesis e.g., **Prescription Preparations (P.P.)**.

7.4.9 Enter the name and physical address of the manufacturer(s) as stated on the MC8 form.

7.4.10 Enter the name and address of the principal as declared on MC8 form.

7.4.11 Enter the name of the applicant as declared on MC8 form.

7.4.12 Enter the address where the certificate would be kept, as declared on MC8 form.

7.4.13 Enter the date of registration, date on which an entry was made in file EVRB02 “C-Book”.

7.4.14 Record whether the product would be **wholly manufactured in**, or **imported into**, or **partially manufactured**, or **imported into and partially manufactured** in Zimbabwe, check the MC8 form.

7.4.15 Record the conditions imposed by the Authority, for all products: **See annexure NB: the annexure details the following**

i. General Conditions (herewith underlisted)

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.

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Date: 09/09/2025	Date: 09/09/2025	Date: 11/09/2025

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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 person for Pharmacovigilance (QPPV) to oversee 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 Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise.

ii. Product Specific conditions (herewith underlisted)

1. API Manufacturer(s)
2. Approved batch size(s)
3. Written commitment(s) by the FPP manufacturer
4. Approved label

- 7.4.16 Record the conditions imposed by the Authority, for anti-TB drugs: **To be distributed in public health institutions.**
- 7.4.17 Record the date of issue of certificate. This should be the same as the date of entry in C-Book for new products.
- 7.4.18 Record the date of issue of the certificate (date of signing) which is the same as date as in 7.4.17.
- 7.4.19 Compare the information on the certificate with that in the ZIMDIS and Evaluation report for correctness.
- 7.4.20 Send the certificate, checklist form for correctness of information on certificates "EVRF25", and updated MC8 form to the second reviewer Senior Regulatory Officer, Chief Regulatory Officer or Head-EVR or their designate for the initial review.
- 7.4.21 Send the certificate, checklist form for correctness of information on certificates "EVRF25", and updated MC8 form to the Chief Regulatory Officer or Head-EVR or their designate for the final review.
- 7.4.22 Send the reviewed certificate to the Director-General's office for signing and seal. **(Ensure to attach/ send via email the finalised SmPC and ZimPAR for the product application when sending the certificate to the Director-General)**
- 7.4.23 Make a photocopy of the signed certificate, quote the alpha-numeric application number at the top-right corner of the registration certificate, and send it to the product file in the filing room. Upload the scanned copy on SharePoint. **(Ensure to upload and share for publishing the SmPC and ZimPAR as per procedures EVR25 and EVR31).**
- 7.4.24 Send the certificate and cover letter for registration to the applicant as per procedure **EVR16 (Procedure for correspondence with applicants).**

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7.5 Preparations for Issue of a registration certificate for renewals/reinstatements

- 7.5.1 Retrieve the product renewal application file and cross-check whether all previous issues raised with respect to document review, laboratory analysis, GMP inspection have been resolved.
- 7.5.2 Check whether the Registration Committee has approved the proposed renewal of the product (refer to the minutes of the Registration Committee meeting).
- 7.5.3 Cross-check the recorded conditions for registration, renewal or reinstatement of the product recorded in the minutes.
- 7.5.4 Verify that all approved variations have been included in the renewal application. Unapproved variations will not be incorporated and approved in the renewal application.
- 7.5.5 Verify whether the applicant has included a revised (if applicable), signed, and dated MC8 form, incorporating the approved variations, if any were submitted for that application. If the MC8 form was not revised due to variations, ensure that the details at registration of the product application are still the same as submitted in the submitted MC8 form.
- 7.5.6 If the applicant has not provided a revised MC8 form, communicate with the applicant via email. The Chief regulatory Officer should be copied in all emails sent to clients as per **SOP EVR16 (Procedure for correspondence with applicants)**.
- 7.5.7 If the applicant has provided a revised (if applicable) MC8 form, fill-in the registration certificate template, MC16 using information from the most recent MC8 application form in the product file and the conditions of marketing authorisation recorded in the minutes and accepted by the applicant.
- 7.5.8 Complete the registration certificate template, MC16 and where applicable, incorporate any necessary changes.
- 7.5.9 Record the date of issue of the certificate (date of signing).
- 7.5.10 Compare the information on the certificate with that in ZIMDIS and Evaluation report for correctness. Ensure that the renewal period aligns with regulatory requirements.
- 7.5.11 Follow steps **7.4.20** to **7.4.24**
- 7.5.12 Ensure that the product database is updated with the new expiry date.
- 7.5.13 Send an email notification for the availability of the new and revised certificate to the applicant. When sending the certificate to the applicant the regulatory officer shall advise the applicant to return the previous certificate before the authority can provide them with the new certificate.
- 7.5.14 The regulatory officer shall take the revised marketing authorisation certificate and cover letter to main gate reception, upon being given the old certificate the regulatory officer shall enter in the EVR main gate client correspondence book details of the revised certificate to be collected.

Reviewed by: <i>M. Muneer</i>	Approved by HoU/HoD: <i>M. Muneer</i>	Authorised by OM: <i>M. Muneer</i>
Date: 09/09/2025	Date: 09/09/2025	Date: 11/09/2025

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8.0 APPENDICES/ ATTACHMENTS

8.1 Appendix I: Completed MC16 template

8.2 Attachment I: Checklist form for correctness of information on certificates EVRF25

9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	Copy of registration certificate	Infinity
N/A	ZIMDIS database in computer	Infinity
EVRB01	Entry in A Book	Infinity
EVRB02	Entry in C-Book	Infinity
EVRB12	Entry in CMA-Book	Infinity
EVRB16	Entry in H Book	Infinity
N/A	Cover letter for Registration Certificate	Infinity
EVRB30	Entry in Re-instatements book	Infinity
EVRF25	Checklist form for correctness of information on certificates	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

10.5 Medicines and Allied Substances Control Act (MASCA) chapter 15:03

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	April 2010	System improvement
1	April 2012	System improvement
2	October 2014	System Improvement

Reviewed by: <i>Pharevashe</i>	Approved by HoU/HoD: <i>11/10/2025</i>	Authorised by QM: <i>11/10/2025</i>
Date: <i>09/09/2025</i>	Date: <i>09/09/2025</i>	Date: <i>11/10/2025</i>

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3	April 2018	Inclusion of standard operating procedures for issuing registration certificate for re-in statements and variations for registration of Human Allopathic Medicines, Human Complementary Medicines, and Veterinary medicines System improvement
4	October 2019	Rolling review
5	January 2022	System improvement: further clarification of medicines registration conditions requirements, in line with MASCA chapter 15:03 including additional compliance with critical international good regulatory best practices to ensure that effective, quality, and safe medicines are available to the public
6	November 2022	The additional step of final review by the Chief Regulatory Officer or Head-EVR or their designee is to ensure that all information is accurate and compliant with regulatory standards before sending to the Director-General for signature and seal.
7	March 2025	Continuous improvement Separating the processes of issuing registration and approval certificates for human allopathic, veterinary and complementary medicines. Aligning the issuance of the registration certificate with the processing of an SmPC and a ZimPAR..

Reviewed by: <i>M. Mavera</i>	Approved by HoU/HoD: <i>[Signature]</i>	Authorised by QM: <i>[Signature]</i>
Date: 09/09/2025	Date: 09/09/2025	Date: 11/09/2025

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Appendix I: Completed MC16 template

Medicines Control Authority of Zimbabwe
Medicines and Allied Substances Control Act
(Chapter 15:03)
REGISTRATION CERTIFICATE
CONFIDENTIAL

Number: 6259

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

1. Approved name of medicine: CLOTRIMAZOLE
2. Trade mark of medicine: CP-CLOTRIMAZOLE VAGINAL TABLETS
3. The form in which the medicine is presented and the colour thereof: WHITE TO OFF-WHITE COLOURED, OVAL-SHAPED TABLETS TAPERED AT ONE END AND FLAT ON THE OTHER END
4. Approved name of the active ingredient(s) and strength: CLOTRIMAZOLE 100MG
5. Registration number of the medicine: 2022/14,176259
6. Shelf life of medicine in months: 36 MONTHS WHEN STORED BELOW 30 °C IN ALUPE BLISTER, PROTECT FROM LIGHT AND MOISTURE. PACK SIZE: 1 x 6 TABLETS WITH 1 APPLICATOR
7. Category for distribution of medicine: PHARMACIST INITIATED MEDICINES (P.I.M.)
8. Name and address of manufacturer: INTERMED, NO.4, G.K. INDUSTRIAL ESTATE, ARCOT ROAD, PORUR, CHENNAI-600116, INDIA
9. Name and address of principal: COSPHARM INVESTMENTS PTY LTD, ERF 492 DANTE STREET, PROSPERITA, WINDHOEK, NAMIBIA
10. Name and address of applicant: COSPHARM INVESTMENTS PTY LTD, ERF 492 DANTE STREET, PROSPERITA, WINDHOEK, NAMIBIA
11. Address at which certificate will be kept: COSPHARM INVESTMENTS PTY LTD, ERF 492 DANTE STREET, PROSPERITA, WINDHOEK, NAMIBIA
12. Date of original registration: 17TH MARCH 2022
13. The medicine will be IMPORTED INTO Zimbabwe
14. Conditions of registration imposed by the Authority: See annexure
15. Date of issue of certificate: 17TH MARCH 2022

Issued at Harare this 17TH day of MARCH 2022

.....
Director-General

CERTIFICATE
REGISTRATION

This certificate must be returned to the Authority if cancelled, withdrawn or if the registration of the medicine is withdrawn or when requested to do so by the Director-General. Return to the Authority if cancelled.

Reviewed by: <i>M. Mavurashu</i>	Approved by HoU/HoD: <i>J. M. M. M.</i>	Authorised by QM: <i>M. M. M. M.</i>
Date: 09/09/2025	Date: 09/09/2025	Date: 11/09/2025

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The template for the registration certificate is based on Form MC 16 in Section 2 of the Medicines and Allied Substances Control (General) Regulations

ANNEXES TO THE REGISTRATION CERTIFICATE FOR FILE NUMBER 6171

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 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 Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise.

PRODUCT SPECIFIC CONDITIONS

API manufacturer(s): Amoli Organics Private Limited, No. 322/4, 40 Shed Area,
G.I.D.C., Vapi – 396 195, State - Gujarat, India.

Approved batch size(s): 75 000 pessaries

Written commitment(s) by the FPP manufacturer:

Primary stability study commitment

The Applicant provided a commitment (dated 8 January 2018) to continue long-term testing of Clotrimazole 100mg pessaries for a period of time sufficient to cover the whole provisional shelf-life and to report any out-of-specification results or significant changes immediately to MCAZ for the batches A2001, A2002 and A2003, packed in Al-PE blister packs.

Commitment stability studies

Since stability data on three production scale batches was not provided with the application, the Applicant provided a commitment (dated 15 June 2018) to put three production scale batches of batch size 75,000 pessaries of Clotrimazole 100mg pessaries on long-term stability testing. Any out-of-specification results or significant changes during the study will immediately be reported to MCAZ. The approved stability protocol will be used for commitment batches.

Reviewed by: <i>Pharmaceutical</i>	Approved by HoU/HoD: <i>Dr. M. M. M.</i>	Authorised by OM: <i>---</i>
Date: <i>09/09/2025</i>	Date: <i>09/09/2025</i>	Date: <i>11/09/2025</i>

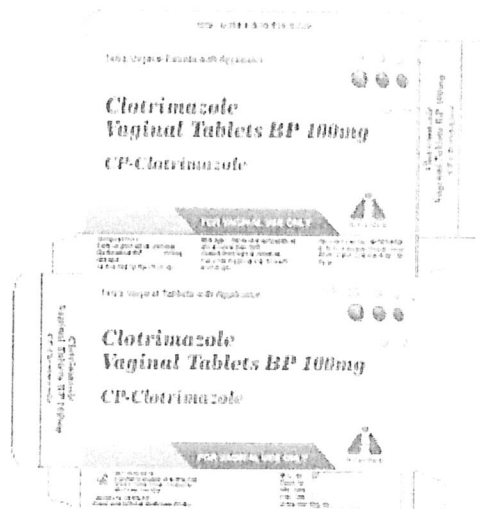
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Approved label:



NB: Please note that the MCAZ registration conditions stated above 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 (PBRER) 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.

Reviewed by: <i>M. Maverahe</i>	Approved by HoU/HoD: <i>pp. Amak</i>	Authorised by QM: <i>[Signature]</i>
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