

CONTROLLED COPY**00 000001**Medicines Control Authority
of Zimbabwe**Medicines Control Authority of Zimbabwe****EVALUATIONS AND REGISTRATION DIVISION**

TITLE: Standard Operating Procedure for Preparation of Information for Issuing of a Gazette Notice			
SOP Number: EVR 10		Revision Number: 4 Document Level: 3	
Date Issued for training: 16/06/2025		Effective Date: 16/06/2025	
Page 1 of 4		Review Date: 06/2027	
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1.0 PURPOSE

To outline procedures that will enable a Regulatory Officer to successfully prepare information on human allopathic, human complementary and veterinary medicinal products i.e. approved, refused and cancelled medicines for gazetting.

2.0 SCOPE

This procedure shall be performed by a Regulatory Officer annually during the month of January of each year by compiling information from the ZIMDIS for all approved, refused and cancelled human allopathic, human complementary and veterinary medicines. The procedure does not apply to pending and withdrawn human allopathic, human complementary and veterinary medicines.

3.0 FREQUENCY

The procedure shall be performed once a year.

4.0 LOCATION

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

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5.0 DEFINITIONS

- 5.1 **EVR:** Evaluations and Registration Division
- 5.2 **ZIMDIS:** Zimbabwe Drug Information System (electronic data base)
- 5.3 **HoD:** Head of Division
- 5.4 **C-Book:** Register of approved human and veterinary medicines
- 5.5 **D-Book:** Register for refused human and veterinary medicines
- 5.6 **CMA- Book:** Register for approved human complementary medicines

6.0 RESPONSIBILITY

- 6.1 It is the responsibility of the Regulatory Officer in charge of ZIMDIS maintenance and Head of Division to ensure that information for gazette notices for approved, refused and cancelled human allopathic, human complementary and veterinary medicines is disseminated to the Legal Unit for gazetting.
- 6.2 The Quality Manager/Designate shall be responsible for monitoring compliance of this procedure to Quality Management Standards (QMS), International and other relevant standards.

7.0 PROCEDURE

- 7.1 Procedure for preparation of information for issuing of gazette notice (s) is outlined below as follows:
 - 7.1.1 Retrieve individual reports from the ZIMDIS for products approved, refused and cancelled in the previous year from January to December. The individual reports on products should be retrieved under the following gazette notice titles:
 - 7.1.1.1 Approved human allopathic medicines
 - 7.1.1.2 Approved human complementary medicines
 - 7.1.1.3 Approved veterinary medicines
 - 7.1.1.4 Refused human allopathic medicines
 - 7.1.1.5 Refused veterinary medicines
 - 7.1.1.6 Refused human complementary medicines
 - 7.1.1.7 Cancelled human allopathic medicines
 - 7.1.1.8 Cancelled human complementary medicines
 - 7.1.1.9 Cancelled veterinary medicines
- 7.2 Ensure that information on each report is correct and free from typographical errors.
- 7.3 Verify that the information on each product was entered correctly by checking the information in C-book and CMA-book against the information from the ZIMDIS reports for human and veterinary approved products.

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- 7.4 Verify that the information on each product was entered correctly by checking the information in D-book against the information from the ZIMDIS reports for human and veterinary refused products.
- 7.5 Verify that the information on each product was entered correctly by checking the information in Registration, Complementary and Veterinary Committee minutes. against the information from the ZIMDIS reports for human allopathic, human complementary and veterinary approved product.
- 7.6 Write a memo which should be signed by the HoD-EVR to the Legal Unit, addressed to the Legal manager expressing the Division's intention to publish gazette notices.
- 7.7 The Memo should be sent to the Legal Unit accompanied by the reports from ZIMDIS on approved, refused and cancelled medicines.
- 7.8 The Legal unit will reply, providing gazette notice numbers to the relevant report intended to be gazetted (see 7.1).
- 7.9 Allocate gazette notice numbers to each category of medicines in line with 7.1 in the ZIMDIS.
- 7.10 Print the relevant reports bearing the gazette notice numbers and send the final gazette notices to Legal Unit for publishing.
- 7.11 Keep copies of all approved, refused and cancelled gazette notice final documents in EVR file for Gazette Notices, EV 43.

N.B. Before publishing the cancelled and refused products gazette notices, a period of 30 days for appeals should be observed to enable applicants to appeal if they wish to do so. This is in line with Part VII section 62 of Medicines and Allied Substances Control Act [Chapter 15:03].

8.0 APPENDICES/ ATTACHMENTS

N/A



9.0 RECORDS

Document Number	Title of Record	Retention Period
EV 43	Copy of Gazette Notices	Infinity

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records

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11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	October 2014	System Improvement
1	April 2018	Rolling review
2	April 2021	Rolling review
3	May 2023	Rolling review



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