Medicines Control Authority of Zimbabwe

EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Screening New Applications			
SOP Number: EVR09	**Revision Number**: 4 **Document Level**: 03		Page **1** of **4**
Date Issued for training: 08/04/21	**Effective Date**: 10/06/2021		**Review Date**: 06/2023.
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1.0 PURPOSE

To establish a procedure for conducting the screening of new applications for registration.

2.0 SCOPE

Applies to the procedure of screening new applications for completeness.

3.0 FREQUENCY

The procedure is applied to each new application for registration before evaluation as determined by EVR Guidance document on screening, EVG03.

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 **A Book:** A register of all new applications for registration of human allopathic products which have been submitted to the MCAZ.
5.2 **H Book:** A register of all new applications for registration of veterinary product which have been submitted to the MCAZ.

5.3 **CM book:** A register of all new applications for registration of human complementary products which have been submitted to the MCAZ.

6.0 RESPONSIBILITY

6.1 It is the responsibility of the Regulatory Officer/Screening Officer to ensure that all applications are screened before they proceed to evaluation.

6.2 The Head of the Division is accountable for the implementation of this procedure.

7.0 PROCEDURE

7.1 Using the A-Book (EVRB01), H Book (EVRB16) or CM book (EVRB10) extract new application for registration that is yet to be screened.

7.2 In the appropriate book, under the "motivation" column, enter the phrase "Screened"

7.3 Fill in the product information into the appropriate screening checklist template, using the application form for the product located in Volume 1 of the product dossier. Also, enter the appropriate GMP status of the product manufacturer.

7.4 Go through the entire screening form and product dossier, entering into the screening form whether the required information has been submitted or not.

7.5 Upon completing the form, send the report to a second reviewer for second review

7.6 The second reviewer shall make comments and an overall recommendation based on the decision tree appended as Appendix 1 of this Standard Operating Procedure. The following are possible recommendations:

- 7.6.1 If there are 3 or more critical deficiencies, then the recommendation should be "intend to refuse to register"
- 7.6.2 If there are 2 or fewer deficiencies, then the recommendation should be "proceed to evaluate"
- 7.6.3 If any one of the noted deficiencies is clinical data for human allopathic medicines, then the recommendation should be "intend to refuse to register"

7.7 The second reviewer returns the reviewed report to the screener to make the necessary changes

7.8 The screener enters the outcome of the screening in the appropriate book under motivation as either "passed" or "failed"

7.9 When an application has failed screening, the report is tabled in the following Registration Committee meeting, with the recommendation of "intend to refuse to register".

7.10 Should the Committee uphold the recommendation a letter of intent to refuse to register together should then be sent to the applicant.

7.11 The screening report and letter should be uploaded onto SharePoint.

8.0 APPENDICES/ATTACHMENTS

8.1 Appendix I: Decision tree table

9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	Screening report	Infinity
N/A	Letter of intent to refuse to register	Infinity
EVRB01	A-Book	Infinity
EVRB16	H Book	Infinity
EVRB10	CM book	Infinity

10.0 REFERENCES

10.1 EVG03: Guidance document on screening
10.2 SOP MR 4.0 Writing Standard Operating Procedure
10.3 SOP MR 4.13 Control of Records

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	April 2010	Rolling review
1	January 2012	System Improvement
2	October 2014	System Improvement
3	April 2018	Rolling review and System Improvement

APPENDIX I: Decision Tree: Recommendations for Screened New Applications