



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
Reviewed by:	L.T MAKHURANE Name	[Signature] Signature	08/04/2021 Date
Approved by HoU/HoD:	G. R. MATIMBA Name	[Signature] Signature	08/04/2021 Date
Authorised for use by: (Quality Manager)	A. CHIKWANE Name	[Signature] Signature	10/06/2021 Date

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.

TITLE: Standard Operating Procedure for Screening New Applications		
SOP Number: EVR 09	Revision Number: 4	Page 2 of 5

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

Reviewed by: L. T. Makhurane <i>LM</i>	Approved by HoU/HoD: G. R. Matimba <i>GRM</i>	Authorised for use by QM: :
Date: 08/04/2021	Date: 09/04/2021	Date: 10/06/2021

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

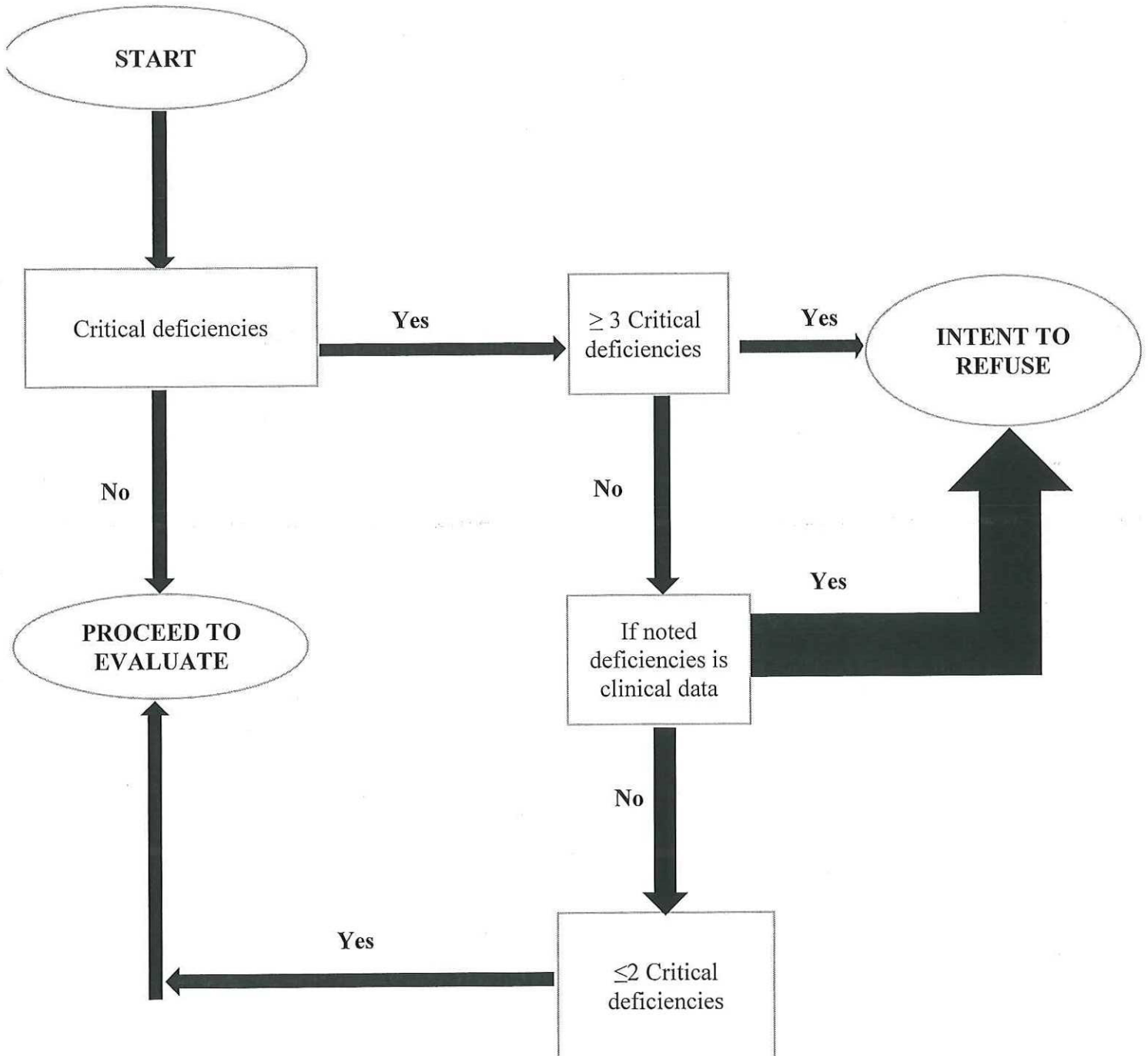
- 10.1 EVG03: Guidance document on screening
- 10.2 SOP MR 4.0 Writing Standard Operating Procedure
- 10.3 SOP MR 4.13 Control of Records

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

Reviewed by: L. T. Makhurane <i>LM</i>	Approved by HoU/HoD: G. R. Matimba <i>GM</i>	Authorised for use by QM: : <i>[Signature]</i>
Date: 08/04/2021	Date: 09/04/2021	Date: 10/06/2021

APPENDIX I: Decision Tree: Recommendations for Screened New Applications



Reviewed by: L. T. Makhurane <i>lache</i>	Approved by HoU/HoD: G. R. Matimba <i>gmat</i>	Authorised for use by QM: : <i>[Signature]</i>
Date: 08/04/2021	Date: 09/04/2021	Date: <i>10/06/2021</i>

TITLE: Standard Operating Procedure for Screening New Applications

SOP Number: EVR 09

Revision Number: 4

Page 5 of 5

Reviewed by:

L. T. Makhurane



Date: 08/04/2021

Approved by HoU/HoD:

G. R. Matimba

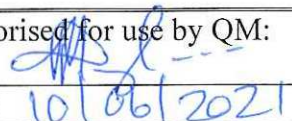


Date: 09/04/2021

Authorised for use by QM:

:

Date:



10/06/2021