



Medicines Control Authority of Zimbabwe

EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Evaluation of Application for Emergency Use Authorisation of medical products			
SOP Number: EVR 15		Revision Number: 2	
		Document Level: 3	
Date Issued for training: 26/07/2024		Effective Date: 26/07/2024	
Review Date: 07/2026			
Reviewed by:	Nenyasha Masangudza Name	 Signature	25/07/24 Date
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Authorised for use by: (Quality Manager)	Alphosene Chikowore Name	 Signature	26/07/2024 Date

1.0 PURPOSE

To define the way in which evaluators will perform evaluation of the different types of applications for Emergency Use Authorisation (EUA) of medical products.

2.0 SCOPE

The SOP is applicable to new applications, variations, responses and additional information for EUA applications.

3.0 FREQUENCY

Whenever information related to an application for EUA is being evaluated for completeness and acceptability.

4.0 LOCATION

- 4.1 The Master Copy of this SOP is kept in the Quality Office.
- 4.2 Controlled Copies shall be kept by the Head of Evaluations & Registration Division and Evaluations and Registration Division staff.
- 4.3 Controlled copies issued to staff shall be kept at points of use in the division.

5.0 DEFINITIONS

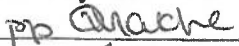
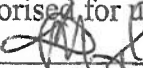
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6.0 RESPONSIBILITY

- 6.1 It is the responsibility of the Regulatory Officer to ensure that evaluation of applications for registration follow this procedure.
- 6.2 Head of Evaluations and Registration Division shall be responsible for ensuring that the procedure is adhered to all the times.
- 6.3 The Quality Manager/Designate is responsible for monitoring compliance to this procedure, the Quality Management System (QMS), international and other relevant standards.

7.0 PROCEDURE

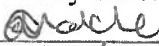
- 7.1 The Head EVR or a Senior Regulatory Officer shall determine if an application is eligible for the Emergence Use Authorisation (EUA) process. In order to qualify for assessment under this procedure, the following criteria must be met:
 - 7.1.1 The disease for which the product is intended is serious or immediately life threatening, has the potential of causing an outbreak, epidemic or pandemic and it is reasonable to consider the product for an EUL assessment, e.g., there are no licensed products for the indication or for a critical subpopulation (e.g., children);
 - 7.1.2 Existing products have not been successful in eradicating the disease or preventing outbreaks (in the case of vaccines and medicines);
 - 7.1.3 The product is manufactured in compliance with current Good Manufacturing Practices (GMP) in the case of medicines and vaccines;
 - 7.1.4 The applicant undertakes to complete the development of the product and apply for marketing authorisation once the product is licensed. For that purpose, the remaining clinical trials and other testing needed to complete the development of the product must already be underway at the time of the application for an EUL.
 - 7.1.5 There may be a consideration of reviewing a candidate product for EUL that does not meet all of the requirements. In such situations, the application letter and documentation provided to MCAZ should justify the application of the product although it does not meet all eligibility requirements
- 7.2 A meeting with all Senior Regulatory Officers (and any other Regulatory Officers as assigned) from all technical divisions shall be done within two (2) days of receipt of

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- application, to discuss the application, agree on timeline and agree on sections to be assessed.
- 7.3 Officers shall be assigned in teams to review different sections of the dossier e.g. for allopathic medicine: quality; phase I and phase II safety; phase III safety and phase III efficacy teams.
- 7.4 The application shall be evaluated by completing the appropriate form (EVRF63). During this process, the information submitted shall be evaluated against requirements of the MCAZ Guidelines for Emergency Use Authorisation of Medical Products and any other relevant current guidelines. During the process, observations, comments and conclusions will be written in red and queries in red highlighted in yellow.
- 7.5 Upon completion of the evaluation, the officers mentioned in 7.2 above shall share their reports to others and shall convene again at an agreed time to discuss their observations, comments and conclusions. A benefit-risk assessment shall be conducted in the meeting and the overall recommendation for the product shall be agreed on.
- 7.6 After the meeting in 7.5 above, a consolidated report will be compiled and shall include all the reports from the teams mentioned in 7.3 and the benefit-risk assessment and overall recommendation.
- 7.7 If further information is required, a letter shall be written to the applicant requesting for more information or clarifications. The letter will be signed by the Head-EVR or by the DG.
- 7.8 If adequate information was received, the report shall be tabled at a Special Registration Committee meeting if possible.
- 7.9 When a Special Registration Committee meeting is not held (due to timeline constraints or any other reason as directed by the Head-EVR or Director-General), the Director-General shall take the recommendations from the assessors and use his discretion to make a decision. The evaluation report and the letters to the applicant shall be tabled at the next Registration Committee meeting for the Committee's ratification.
- 7.10 A letter communicating the Authority's decision will be sent to the applicant. If an EUA letter is issued, it shall be signed by the Director-General.
- 7.11 When the applicant submits a response to queries raised, steps from 7.3 to 7.8 shall be followed.
- 7.12 When an application for a variation is submitted by an applicant for a product which was issued an Authorisation for Emergency Use, procedures from step 7.2 shall be followed.
- 7.13 When an application is received where the product is registered by a Stringent Regulatory Authority (SRA) or is WHO pre-qualified, and the assessment report is available, procedure from step 7.6 shall be followed.

8.0 APPENDICES/ ATTACHMENTS

- 8.1 Attachment I: Evaluation report form for Emergency Use Authorisation, EVRF 63

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9.0 RECORDS

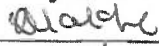
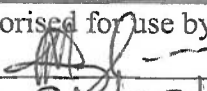
Document Number	Title of Record	Retention Period
N/A	Product File	Infinity
N/A	Letter of queries	Infinity
N/A	Authorization letter for Emergence Authorization Use	Infinity
N/A	Rejection letter for Emergence Authorization Use	Infinity

10.0 REFERENCES

- 10.1 MCAZ Guideline for Emergency Use Authorisation of Medical Products
- 10.2 Guidance on Submission of Covid-19 Vaccine Applications for Emergency Use Authorisation and Registration
- 10.3 SOP MR 4.0 Writing Standard Operating Procedure
- 10.4 SOP MR 4.13 Control of Records
- 10.5 WHO Emergency Use Listing Procedure Guideline

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	July 2021	Response to WHO GBT IDP
1	January 2022	Rolling review

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