



Medicines Control Authority of Zimbabwe

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Medicines Control Authority
of Zimbabwe

EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Issuing a Letter of No Objection, Searching and Retrieving of documents and Post-Dossier Submission Meeting requests for Scientific Advice			
SOP Number: EVR 34		Revision Number: 0	
		Document Level: 3	
Date issued for training: 7/09/25		Effective Date: 25/09/2025	
		Review Date: 09/202	
Written by:	N. Shamugan Name	 Signature	17/09/2025 Date
Approved by HoU/HoD:	Z. A. MAKOPU Name	pp. Olachi Signature	17/09/2025 Date
Authorised for use by: (Quality Manager)	A. CHIKWORE Name	pp. Mungu Signature	25/09/2025 Date

1.0 PURPOSE

To enable a Regulatory Officer to successfully issue a letter of no objection, search and retrieve requested documents and arrange a post-dossier submission meeting for scientific advice.

2.0 SCOPE

This procedure applies to the processing and issuance of letters of no objection, the searching and retrieval of documents previously submitted in application dossiers, and the arrangement of post-dossier submission meetings for scientific advice within the Evaluations and Registration Division. It covers all steps from receipt of a formal request with proof of payment to the final dispatch of the requested service or confirmation of the meeting.

3.0 FREQUENCY

This procedure shall be followed whenever an applicant submits a formal request for any of the following non-statutory services: Issuance of a letter of no objection, searching and retrieval of documents previously submitted in an application dossier and arrangement of a post-dossier submission meeting for scientific advice.

4.0 LOCATION

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- 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 shall be kept at points of use in the division.

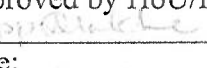
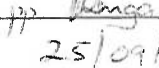
5.0 DEFINITIONS

- 5.1 **Applicant:** The person by whom or on whose behalf an application for registration is made.
- 5.2 **Letter of No Objection (LNO):** An official communication issued by the Authority indicating that it has no objection to a specific request or activity by an applicant.
- 5.3 **Post-dossier Submission Scientific Meeting:** A formal meeting requested by an applicant after submission of a dossier to discuss scientific or technical matters related to the application.
- 5.4 **Non-statutory Services:** Services provided by the Authority that are not mandated by law but are offered upon request, such as letters of no objection, document retrieval, and scientific meetings.

6.0 RESPONSIBILITY

- 6.1 The Regulatory Officer is responsible for preparing and issuing a letter of no objection.
- 6.2 The filing clerk is responsible for searching and retrieving requested information.
- 6.3 The Unit secretary is responsible for scheduling and confirming post-dossier submission scientific meetings.
- 6.4 The Finance Officer is responsible for issuing a receipt as proof of payment for the non-statutory services.
- 6.5 The Chief Regulatory Officer or designate shall review and sign letters of no objection and allocate officers for post-dossier submission scientific meetings.
- 6.6 The Head of Division has the overall responsibility of ensuring that this procedure is always adhered to.
- 6.7 The Quality Manager/Designate shall be responsible for monitoring compliance with the procedure, Quality Management System, and relevant national and international standards.

7.0 PROCEDURE

Written by: 	Approved by HoU/HoD: 	Authorised by QM: 
Date: 17/09/2025	Date: 17/09/2025	Date: 25/09/2025

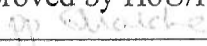
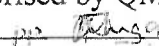
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7.1 Preparations for Issue of a Letter of No Objection

- 7.1.1 Upon receipt of the formal request for a letter of no objection with the attached proof of payment, the regulatory officer shall verify the fees. The fees paid should reflect per letter.
- 7.1.2 When verified, the regulatory officer shall notify the Finance Unit through email to issue a receipt for the search and retrieval. If more money is required, communicate this to the applicant.
- 7.1.3 Upon receiving a copy of the receipt from the Finance Unit, the Regulatory Officer shall draft the letter of no objection, log it in File 18, and send it to the CRO or designate for review within 48 hours of receipt of the request for the letter.
- 7.1.4 The CRO or designate shall review the letter and send it back to the Regulatory Officer, who incorporates the reviewer's corrections, if any, within 24 hours.
- 7.1.5 The regulatory officer shall send the letter to the CRO or designate for signing, who shall send it back to the Regulatory Officer for dispatch.
- 7.1.6 The Regulatory Officer shall make 3 copies of the letter and a scanned copy. The scanned copy is uploaded to SharePoint. One copy is sent for filing, another is sent to File 18, and the final copy is sent to the running file. The original copy is dispatched to the gate for collection, and an email with the scanned copy is sent to the Applicant.

7.2 Preparations for Searching and Retrieval of Documents

- 7.2.1 Upon receipt of the formal search and retrieval request for a document previously submitted in their application dossier with the attached proof of payment, the Regulatory Officer shall verify the fees. The fees paid should reflect per service.
- 7.2.2 When verified, the Regulatory Officer shall notify the Finance Unit through email to issue a receipt for the search and retrieval. If more money is required, communicate this to the applicant.
- 7.2.3 Upon receiving a copy of the receipt from the Finance Unit, the Regulatory Officer shall send an email to the filing clerk for the retrieval of the document from the filing room. The email shall include the Application number/ File number and the name of the document to be retrieved.

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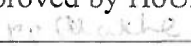
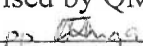
7.2.4 The filing clerk shall search and retrieve the document, scan and make a copy of the requested document(s). The scanned copy shall be sent to the Applicant via email, and the copy is dispatched to the gate for collection within three (3) days of receipt of the search and retrieval request.

7.3 Preparations for arranging a post-dossier submission meeting for scientific advice.

- 7.3.1 Upon receipt of the formal meeting request with the attached proof of payment, the Regulatory Officer shall verify the fees. The fees paid should reflect per service. The Regulatory Officer shall also verify if the meeting request is for a post-dossier submission scientific meeting.
- 7.3.2 When all the above have been verified, the Regulatory Officer shall notify the Finance Unit through email to issue a receipt for the post-dossier submission scientific meeting. If more money is required, communicate this to the applicant.
- 7.3.3 Upon receiving a copy of the receipt from the Finance Unit, the Regulatory Officer shall send an email to the Unit secretary for processing. The email shall include the name of the applicant, proposed dates of the meeting, and the meeting request form should be attached.
- 7.3.4 The Unit Secretary shall liaise with the CRO/ Designate to allocate officers for the meeting within 48 hours of receipt of the meeting request.
- 7.3.5 The Unit secretary shall contact the applicant, confirming the date and time of the meeting within three (3) days of receipt of the request. The scientific meeting shall be held within 7 days of receipt of the meeting request.

8.0 APPENDICES/ ATTACHMENTS

N/A

Written by: 	Approved by HoU/HoD: 	Authorised by QM: 
Date: 12/09/2025	Date: 17/09/2025	Date: 25/09/2025

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9.0 RECORDS

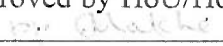
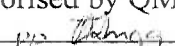
Document Number	Title of Record	Retention Period
N/A	Product file	Infinity
File 18	Correspondence book	Infinity

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records
- 10.3 Statutory Instrument 97 of 2015
- 10.4 Medicines and Allied Substances Control Act (MASCA) chapter 15:03

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
N/A	N/A	N/A

Written by: 	Approved by HoU/HoD: 	Authorised by QM: 
Date: 12/09/2025	Date: 12/09/2025	Date: 25/09/2025