



Medicines Control Authority of Zimbabwe

## EVALUATIONS AND REGISTRATION DIVISION

|                                                                     |                        |                          |                      |
|---------------------------------------------------------------------|------------------------|--------------------------|----------------------|
| TITLE: Standard Operating Procedure for Correspondence with Clients |                        |                          |                      |
| SOP Number: EVR 16                                                  |                        | Revision Number: 3       | Page 1 of 4          |
|                                                                     |                        | Document Level: 3        |                      |
| Date Issued for training: 29/07/25                                  |                        | Effective Date: 06/08/25 | Review Date: 08/2027 |
| Reviewed by:                                                        | <i>Nyasha Tanyanwa</i> | <i>QC</i>                | <i>28/07/25</i>      |
|                                                                     | Name                   | Signature                | Date                 |
| Approved by<br>HoU/HoD:                                             | <i>Zwainai Makoni</i>  | <i>[Signature]</i>       | <i>28/07/25</i>      |
|                                                                     | Name                   | Signature                | Date                 |
| Authorised for use by:<br>(Quality Manager)                         | <i>[Signature]</i>     | <i>[Signature]</i>       | <i>06/08/2025</i>    |
|                                                                     | Name                   | Signature                | Date                 |

**1.0 PURPOSE**

To establish a procedure for regulatory officers to effectively communicate with MCAZ clients seeking services from the Evaluations and Registration Division.

**2.0 SCOPE**

This procedure applies to the Evaluations and Registration Division personnel whenever there is need to communicate with the client.

**3.0 FREQUENCY**

The procedure should be followed whenever a client is communicated with.

**4.0 LOCATION**

- 4.1 The Master Copy of this SOP is kept by the Quality Manager.
- 4.2 A controlled copy is kept by the Head of Division
- 4.3 Controlled copies are issued to staff at points of use in the Division.
- 4.4 Approved copies are uploaded onto SharePoint.

**5.0 DEFINITIONS**

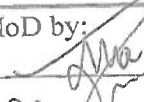
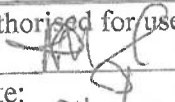
N/A

**6.0 RESPONSIBILITY**

- 6.1 It is the responsibility of the Regulatory Officer to draft correspondence to applicants following the appropriate timelines and procedures.
- 6.2 It is the responsibility of the Senior Regulatory Officers to review letters to be sent to clients before they are scanned and sent for signing.
- 6.3 It is the responsibility of the Chief Regulatory Officer (or designate) to sign all letters.
- 6.4 The Head of Division has the overall responsibility of ensuring that this SOP is adhered to at all times.
- 6.5 Quality Manager/Designate is responsible for monitoring compliance to the procedure, Quality Management System (QMS), International and other relevant standards.

**7.0 PROCEDURE****7.1 LETTER CORRESPONDENCE**

- 7.1.1 The Regulatory Officer shall process all work given according to the detailed procedure in the relevant SOP within the specified timelines
- 7.1.2 The Regulatory Officer shall check in the database of responsible contact person on SharePoint, in ZIMDIS and/or the product application cover letter to confirm the responsible contact person for the particular product application and include in the address.
- 7.1.3 The Regulatory Officer shall use the appropriate division template to draft the letter to be sent to the applicant.
- 7.1.4 When drafting a refuse to register letter, the regulatory officer shall notify the regulatory officer responsible for ZimPARs to start drafting the ZimPAR according to EVR 31 Standard Operating Procedure for the preparation of Public Assessment Reports for Human allopathic medicines following registration or refusal by the Registration Committee (Procedure 7.2 to 7.5)
- 7.1.5 The Regulatory Officer shall send the letter to the Senior Regulatory Officer for review.
- 7.1.6 After incorporating the reviewer's corrections, the Regulatory Officer shall send the letter to the Chief Regulatory Officer or the Director-General for signing depending on the decision to be communicated in the letter.  
For a refused product(s), the reviewed ZimPAR(s) for the refused product(s) along with a refusal letter should be sent to the Director-General for signing.

|                                                                                                  |                                                                                                           |                                                                                                                 |
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| Reviewed by:  | Approved HoU/HoD by:  | Authorised for use by QM:  |
| Date: 28/7/25                                                                                    | Date: 28/07/2025                                                                                          | Date: 06/08/2025                                                                                                |

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- 7.1.7 On receiving the signed document, the Regulatory Officer shall make three copies of the letters, one for the Running File (R/F), one for the Product File and another one for File 18 (Human Allopathic medicines correspondence)/ File 18c (Complementary Medicines Correspondence)/ File 12 (Veterinary Medicines Correspondence). Send the copies for filing. The Regulatory Officer shall also scan the signed document and upload on SharePoint for the Product File. For the ZimPAR of the refused product(s), the Regulatory Officer shall notify the regulatory officer responsible for ZimPARS. The regulatory officer responsible for ZimPARS shall follow steps 7.9 and 7.11 of EVRF 31 Standard Operating Procedure for the preparation of Public Assessment Reports for Human allopathic medicines following registration or refusal by the Registration Committee.
- 7.1.8 The Regulatory Officer shall take the physical letter to the reception and enter the details of the letter into the logbook at the reception, which will be signed by the applicants as proof of collection of the letter.
- 7.1.9 Where the Regulation Officer has the details of the customer's electronic mail, the Regulatory Officer shall send an email to the responsible contact person, informing them that the product-related correspondence is ready for collection at reception. A scanned, signed copy of the document must be attached. The client should be asked to confirm receipt, and the Chief Regulatory Officer must be copied on the email.
- 7.1.10 The Regulatory Officer shall print the electronic mail trail and file in the respective file.

## 7.2 E-MAIL CORRESPONDENCE

- 7.2.1 On receiving an e-mail from a client, an acknowledgement of receipt should be sent immediately. Where a response cannot be provided immediately, an acknowledgement of receipt of the e-mail should be sent within 3 working days. Emails that cannot be responded to immediately should be marked as unread and flagged to be read later. A statement informing the applicant when they should expect a response from the officer should accompany acknowledgement of receipt. The response should then be given by the promised date.
- 7.2.2 The Chief Regulatory Officer should be copied in all emails sent to clients.
- 7.2.3 In the event that an officer is out of office for whatever reason and cannot access their e-mails, automatic "out of office" notification should be activated in the regulatory officer's Microsoft Outlook email account. The "out of office" notifications should state the period the officer is

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| Date: 28/9/25          | Date: 28/07/2025               | Date: 06/08/2025                    |

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unavailable on email and direct the client to another officer who can assist them. Prior notice should be given to the officer whose details will be stated as an alternative contact in the "out of office" notification.

## 8.0 APPENDICES/ ATTACHMENTS

N/A

## 9.0 RECORDS

| Document Number | Title of Record      | Retention Period |
|-----------------|----------------------|------------------|
| N/A             | Product File         | Infinity         |
| File 18         | Correspondences 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 EVR Communication Matrix

## 11.0 HISTORY

| DOCUMENT HISTORY |                |                                                                                                                                                                                                          |
|------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Revision Number  | Date Approved  | Reason for change                                                                                                                                                                                        |
| 0                | March 2017     | System Improvement                                                                                                                                                                                       |
| 1                | September 2019 | System Improvement                                                                                                                                                                                       |
| 2                | November 2022  | System improvement by incorporating procedure that allows the sending of correspondence via email.<br><br>System Improvement by incorporating drafting and publishing of the ZimPAR for refused products |

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|---------------------------------|-----------------------------------------|----------------------------------------------|
| Reviewed by: <i>[Signature]</i> | Approved HoU/HoD by: <i>[Signature]</i> | Authorised for use by QM: <i>[Signature]</i> |
| Date: 28/07/25                  | Date: 28/07/2025                        | Date: 06/08/2025                             |