MCAZ Medicines Control Authority of Zimbabwe

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

TITLE: Standard Operating Procedure for Communication with Internal and External Customers			
SOP Number: PV 38	**Revision Number**: 1 **Document Level**: 3		Page **1** of **15**
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Reviewed by:	R. P. Chaitezvi Name	Signature	12/4/23 Date
Approved by HoU/HoD:	P. P. Nyambayo Name	pp Signature	13/4/2023 Date
Authorised for use by: (Quality Manager)	A. Chikewore Name	Signature	25/4/2023 Date

1.0 PURPOSE

To establish a procedure for regulatory officers to effectively communicate with MCAZ internal and external customers.

2.0 SCOPE

This procedure applies to the Pharmacovigilance and Clinical Trials division personnel where there is a need for internal or external communication.

3.0 FREQUENCY

As and when it is necessary for purposes of internal or external communication.

4.0 LOCATION

4.1 The Master Copy of this SOP will be kept in the Quality Office.

4.2 A controlled copy will be kept in a designated place in the Pharmacovigilance and Clinical Trials Division.

5.0 DEFINITIONS

5.1 **Memo:** a signed message or other information in writing sent by one person or department to another in the same business organization.

5.2 **Letter:** a written, typed or printed communication addressed to an individual or organization usually sent in an envelope by post or messenger

5.3 **Correspondence**: any written or digital form of communication exchanged by two or more parties

5.4 **Email:** messages distributed by electronic means from one computer user to one or more recipients via a network. It is a means or system for transmitting messages electronically which is ideal for generating a written record of communication.

5.5 **Adverse event following immunization (AEFI):** Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding symptom or disease.

5.6 **Adverse Drug Reaction (ADR):** A response to a medicine which is noxious and unintended, which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function

5.7 **ERICE Declaration:** The declaration on communication Drug Safety Information drawn up at the International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily, 24-27 September 1997

5.8 **Output:** Physical and digital documents and files originating from the division, including but not limited to official signed letters, guidelines, handbooks, product certificates, and training certificates.

6.0 RESPONSIBILITY

6.1 It is the responsibility of the Regulatory Officer to draft correspondence following the applicable timelines and procedures.

6.2 It is the responsibility of the Senior Regulatory Officers to review correspondence prior to dispatch.

6.3 The Head of Division has the overall responsibility of ensuring that this SOP is adhered to at all times.

6.4 Quality Manager/Designate - responsible for monitoring compliance to the procedure, Quality Management System (QMS), International and other relevant standards.

7.0 PROCEDURE

A Communicating with External Customers

7.1 Communication with external customers should be done in accordance with the communication matrix (Attachment 1) and in compliance with the requirements and guidelines set forth in Zimbabwe National Pharmacovigilance Policy Handbook, the Medicines and Allied substance Control Act (MASCA) and Regulations, Guidelines for Good Clinical Trial Practice in Zimbabwe, Guidelines for Clinical Trial Application and Authorization in Zimbabwe, Pharmacovigilance Guideline for Pharmaceutical Industry, Guidelines, AEFI Surveillance Guidelines , Guidelines for Conducting Good Clinical Practice (GCP) Inspections in Zimbabwe, Pharmacy Guidelines for Investigational Medical Products and the Authority's strategic plan.

7.2 All correspondence shall be treated as **confidential and proprietary to MCAZ** and handled in compliance with Section 73 of MASCA.

7.3 Communicating with Pharmacovigilance Provincial and District Sites

7.3.1 Correspondence directed to provincial and district pharmacovigilance centers should be addressed to the coordinator or focal person for the site.

7.3.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.3.2.1 Recipient's address- The healthcare facility's name and postal address should be included and where the letter is directed to a particular individual, their title should be stated. Any other relevant personnel should also be copied

7.3.2.2 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers

7.3.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.3.2.4 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.3.3 Conduct a spelling and grammar check and send the letter for review

7.3.4 Make corrections or changes as required and dispatch the letter. For letters requiring the Director General's signature, send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate

7.3.5 After dispatching the hard copy of the signed letter, send a notification email to the PV center focal person.

7.3.6 For feedback letters for ICSRs submitted via the E-PV system, a scanned copy of the signed letter shall also be uploaded and sent via the E-PV platform

7.4 Communicating With Public Hospitals, Private Hospitals and Clinics

7.4.1 All correspondence directed to healthcare centers must be reviewed and approved by the Head of Division (HOD) or a Senior Regulatory Officer (SRO) prior to dispatch

7.4.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.4.2.1 Recipient's address- The healthcare facility's name and postal address should be included and where the letter is directed to a particular individual, their title should be stated. Any other relevant personnel should also be copied

7.4.2.2 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers

7.4.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.4.2.4 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.4.2.5 Recipient's address- The healthcare facility's name and postal address should be included and where the letter is directed to a particular individual, their title should be stated. Any other relevant personnel should also be copied

7.4.2.6 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers

7.4.2.7 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.4.2.8 Attachments /enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.4.3 Conduct a spelling and grammar check and send the letter for review

7.4.4 Make corrections or changes as required and dispatch the letter. For letters requiring the Director General's signature, send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate

7.5 Communicating With Manufacturers, Applicants, Principals and Marketing Authorisation Holders

7.5.1 Communication with manufactures, applicants, principals and marketing authorization holders may be done using official signed letters, email, gazette notices and through the telephone in accordance with the communication matrix (QF62). All correspondence directed to manufacturers, applicants, principals and marketing authorization holders must be reviewed and approved by the HOD or a Senior Regulatory Officer prior to dispatch

7.5.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.5.2.1 Recipient's address- The organization's name and postal address should be included and where the letter is directed to a particular individual, their title should be stated e.g. The Quality Assurance Manager, The Regulatory Affairs Manager. Any other relevant personnel should also be copied. For letters to be dispatched outside Zimbabwe, names of countries should be capitalized and in bold. For letters to be dispatched within Zimbabwe, names of cities should be capitalized and in bold.

7.5.2.2 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers e.g. file numbers, variation references or application references.

7.5.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.5.2.4 Time limits: Response deadlines should be included in the last line of the letter

7.5.2.5 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.5.3 Conduct a spelling and grammar check and send the letter for review

7.5.4 Make corrections or changes as required and dispatch the letter. For letters requiring the Director General's signature, send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate

7.5.5 After dispatching the hard copy of the signed letter, send a notification email to the manufacturer or marketing authorization holder and/or the local representative.

7.6 Communicating With Public Health Programmes and Governmental Agencies

7.6.1 All correspondence directed to public health programme representatives or to health ministry representatives and officials must be, approved and signed by the Director General, the HOD or a Senior Regulatory Officer

7.6.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.6.2.1 Recipient's address- The organization/unit/programme name and postal address should be included and where the letter is directed to a particular individual, their title should be stated. Any other relevant personnel should also be copied

7.6.2.2 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers

7.6.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.6.2.4 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.6.3 Conduct a spelling and grammar check and send the letter for review

7.6.4 Make corrections or changes as required and dispatch the letter. For letters requiring the Director General's signature, send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate to the Director General's office.

7.6.6 Letters should be hand delivered or submitted by post through the Administration Unit

7.7 Communicating With Regional and International Agencies, Non-Governmental Organizations and Professional Associations

7.7.1 All correspondence directed to regional and international agencies e.g. WHO, UMC must be, approved and signed by the Director General, the HOD or a Senior Regulatory Officer

7.7.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.7.2.1 Recipient's address- The organization' name and postal address should be included and where the letter is directed to a particular individual/representative, their title should be stated. Any other relevant personnel/organization should also be copied

7.7.2.2 Heading: In bold text, the heading can include a brief description of the nature of the correspondence and reference numbers

7.7.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.7.2.4 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.7.3 Conduct a spelling and grammar check and send the letter for review to a Senior Regulatory officer

7.7.4 Make corrections or changes as required and send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate to the HOD or Director General for signing

7.7.5 Letters should be hand delivered or submitted by post through the Administration Unit

7.8 Communication in Emergency Situations

7.8.1 In emergency situations disrupting workplace operations, stakeholders should be made aware of alternative platforms and communication tools to submit their documentation and queries as exemplified by Circular 9-2020 through the Public Relations division. Email addresses and phone numbers for submission of queries should be explicitly stated.

7.8.2 Information on the alternative submission platforms provided by the Public Relations unit should be circulated widely using the in-house PVCT Stakeholders communication list

7.9 Safety Alerts/Notifications and Risk Communication

7.9.1 Identify any safety issues that may require communication. The following safety issues may be considered as a guide:

7.9.1.1 Suspension, withdrawal or revocation of a marketing authorization for safety reasons,

7.9.1.2 New safety information such as new contraindications, warnings or undesirable effects

7.9.1.3 Product defects that may lead to safety concerns and recalls

7.9.1.4 Restrictions of indication or reductions of dose

7.9.1.5 Emerging safety concerns that may give rise to media/public interest

7.9.1.6 Adverse event clusters

7.9.2 Medicine safety information should be ethically and effectively communicated in terms of both content and method. In accordance with the requirements of the ERICE Declaration, facts, hypotheses and conclusions should be distinguished, uncertainty acknowledged, and information provided in ways that meet both general and individual needs. Medicines information directed to the public in whatever form should be balanced with respect to risks and benefits.

7.9.3 The safety issue/concern should be considered at the Pharmacovigilance and Clinical Trials Committee Meeting. The Committee will decide on whether secretariat should facilitate the communication and which

communication tools should be used e.g. Circular notice, Bulletin article, alerts/notices on the website or official social media handles. Where the Committee decides that the applicant, marketing authorization holder or other stakeholder should issue facilitate the communication, the concerned party should be notified in writing

7.9.4 Prepare the first draft for internal review and circulate to relevant regulatory officers for review. Implement the comments as appropriate and send the updated draft to the Head of Division for review.

7.9.5 Make any amendments as appropriate and send the draft communication, evaluation report, PVCT Meeting Minute extract and a memo to the Director General for authorization. Where website updates are required, the Request for Website Update Form (ICTF 03) should be completed, appended with required signatures and sent together with the draft.

7.9.6 The safety communication/alert should be finalized and circulated to the appropriate stakeholders as per the in-house PVCT Stakeholders communication list.

7.9.7 For urgent safety issues that need to be communicated before the next Committee meeting, an evaluation report, draft correspondence and memo, signed by the Head of Division, shall be sent to the Director General for consideration. Should the Director General approve the request, the safety communication/alert will be finalized and disseminated as appropriate and the Committee will be notified at the next meeting.

7.9.8 Periodic safety communication should also be provided as follows:

7.9.8.1 Information of Individual Case Safety Reports received annually, including reports from the Targeted Spontaneous Reporting Program for ARVs, anti-TBs and other Essential Medicines, Adverse Events Following Immunization, Serious Adverse Event from authorized clinical trials, Serious Adverse Event reports from Pharmaceutical Industry and Electronic Adverse Drug Reaction Reports, to be included in the MCAZ Annual Report

7.9.8.2 AEFI summary reports to Provincial EPI manager as and when necessary

7.9.8.3 ADR and AEFI summary reports to Provincial Medical Directors, Provincial Nursing Officers and Provincial pharmacists

7.9.8.4 ADR and AEFI reports to provincial and regional Pharmacovigilance sites

7.9.8.5 ICSR summary reports, confirmed signals and package insert update summaries in the Medicines Information Bulletin

7.9.8.6 Vaccine safety information on the MCAZ Website, including factsheets from the Vaccine Safety Net. This information should be revised at least biannually

7.9.9 Safety communication to the public via the Authority's official social media platforms, through newspaper articles, radio channels, television and press releases should be referred to the Public Relations team.

7.10 Letters Communicating PVCT Committee Decisions

7.10.1 Confirmation of the local representative responsible for the particular product application or the Principal Investigator name shall be done in the local representative's database or the K book as appropriate.

7.10.2 The appropriate reference book and division template shall be used to generate a draft letter to be sent to the client.

7.10.3 A draft letter shall be sent to the Senior Regulatory officer/ Head of Division for review. Alternatively, letters may be sent to the focal person for the referenced matter for review, e.g. focal person for promotional material, safety reviews etc. as appropriate if the SRO has approved this arrangement. For letters to be signed by the Director-General, a hard copy draft will be sent to the Director-General's office following the Head of Division's review.

7.10.4 After incorporating the reviewer's comments and/or corrections, the letter shall be printed using the appropriate letterhead and signed or sent to the Head of Division or Director-General for signing.

7.10.5 At least five copies of the signed letter shall be made, and one copy placed in each of the product/clinical trial file, respective MCAZ file 18b/5/26/44 as appropriate, running file, division correspondence file and the Regulatory Officer's daily/monthly work file. An exception would be feedback letters for AEFIs and ADRs for which only four copies shall be made.

7.10.6 The original signed letter shall be taken to the gate reception and the details entered into the division logbook at the gate reception, which will be signed by the recipients as proof of collection of the letter. Letters requiring hand delivery or the use of postal services such as DHL/Fedex shall be sent to the Administration Office for dispatch.

7.10.7 An email shall be sent to the client or local representative notifying them that a letter is available for collection from the reception.

7.11 Email Correspondence

7.11.1 The PVCT Administrative Regulatory Officer shall maintain an Excel tracking system to ensure that all email enquiries from external customers are processed and feedback written to the customer within 5 working days.

7.11.2 On receiving an email from a client, an acknowledgement of receipt shall be sent promptly by at least one regulatory officer on the recipient list. Where a response cannot be provided immediately, the necessary queries

and investigations shall be conducted and an appropriate response availed within five working days. Alternatively, an email indicating when the client can expect to receive a response can be sent.

7.11.3 The Senior Regulatory officer and/or Focal person in relation to the query, as well as the PVCT Administrative Regulatory Officer shall be copied in all emails sent to clients.

7.11.4 Regulatory officers shall ensure that "out of office" notifications are activated in their respective Microsoft Outlook email accounts when they are not available for extended periods of time. If an officer is not available or away on business / vacation leave, they should request an alternative officer to respond and address any queries related to their work within 5 working days

7.11.5 The Division shall maintain a list of focal persons as well as Regulatory Officers responsible for all division activities.

7.12 Telephone Communications

7.12.1 When answering telephone calls, the Regulatory Officer shall ensure that they state the division/unit and their name.

7.12.2 The Regulatory Officer shall take note of the query and the client's details. The Regulatory Officer shall ensure that they understand the client's requirements by paraphrasing their request and confirming with them.

7.12.3 The query shall be addressed where possible. Alternatively, the call can be referred to the focal person or Senior Regulatory Officers as appropriate. In such instances, the Regulatory Officer shall communicate to the client that the call is being transferred and also highlight the nature of the query to the officer to whom the call is being transferred.

7.12.4 When taking messages for other staff members, the Regulatory officer shall ensure that they capture the caller's name, phone number and brief details about the enquiry.

7.12.5 Queries from media houses or other organizations requiring the Authority's official position should be referred to the Public Relations division.

7.13 Communication with Clinical Research Organisations, Principal Investigators and Other Clinical Trial Research Team Members

7.13.1 Communication with Principal Investigators, Co-investigators, Study Coordinators, Pharmacists of Record and Study Pharmacists for clinical trials may be done using official signed letters, email and through the telephone in accordance with the communication matrix (QF 62) All correspondence directed to clinical trial research team members must be

reviewed and approved by the HOD or a Senior Regulatory Officer prior to dispatch

7.13.2 Prepare a draft letter in a factual, concise and legally acceptable way taking into consideration the following:

7.13.2.1 Recipient's address- The organization's name and postal address should be included and all correspondence, with the exception of Section 75 letters, should be directed to the Principal Investigator, with any other relevant personnel copied.

7.13.2.2 Heading: In bold text, the heading should include the scientific title of the clinical trial and the current approved protocol version

7.13.2.3 Previous correspondence or other relevant documents: If the letter is in response to a previous letter or some other document, refer to that letter/document by its date and/or reference number, title and version number in the first line of the letter.

7.13.2.4 Time limits: Response deadlines should be included in the last line of the letter

7.13.2.5 Attachments/enclosures: Any documents to be sent with the letter should be described in the text of the letter

7.13.3 Conduct a spelling and grammar check and send the letter for review. Make corrections or changes as required and dispatch the letter. For letters requiring the Director General's signature, send a draft of the letter and supporting documents (e.g. a memo, evaluation report and/or minute extracts) as appropriate to the Director General's office.

7.13.4 The original signed letter shall be taken to the gate reception and the details entered into the division logbook at the gate reception, which will be signed by the recipients as proof of collection of the letter.

7.13.5 An email shall be sent to the PI or Study Coordinator notifying them that a letter is available for collection from the reception.

7.14 Communicating Via the E-PV System

7.14.1 The following information may be communicated via the E-PV system using scanned copies of official MCAZ signed letters:

7.14.1.1 Requests for additional information

7.14.1.2 PVCT Committee Causality Assessment decisions and feedback letters

7.14.2 .Prepare a draft letter in a factual, concise and legally acceptable way

7.14.3 Conduct a spelling and grammar check and send the letter for review to the Senior Regulatory Officer for review

7.14.4 Finalize the letter and upload and send a scanned copy of the signed letter to through the E-PV platform. The original signed letter can be sent via post or taken to the gate reception as appropriate and the details entered

into the division logbook at the gate reception, which will be signed by the recipients as proof of collection of the letter.

7.15 Communicating Via the E-CTR System

7.15.1 The following information may be communicated via the E-PV system using scanned copies of official MCAZ signed letters:

- 7.15.1.1 Requests for additional information and query letters
- 7.15.1.2 PVCT Committee decisions and feedback letters
- 7.15.1.3 Approval letters for protocol amendments, Section 75 applications
- 7.15.1.4 Correspondence regarding GCP inspections
- 7.15.1.5 Clinical trial approval letters

7.15.2 Prepare a draft letter in a factual, concise and legally acceptable way

7.15.3 Conduct a spelling and grammar check and send the letter for review to the Senior Regulatory Officer and/or Head of Division for review. All clinical trial authorization or disapproval letters shall be signed by the Director General as per the Standard Operating Procedure for the Process of Authorization and Disapproval of a Clinical Trial Application of a medicine in Human Participants (PV05).

7.15.4 Finalize the letter and upload and send a scanned copy of the signed letter to through the E-PV platform. The original signed letter can be sent via post or taken to the gate reception as appropriate and the details entered into the division logbook at the gate reception, which will be signed by the recipients as proof of collection of the letter.

B Internal Communication

7.16 Memos

7.16.1 Interdivisional requests and notifications shall be communicated via memos in accordance with the communication matrix (QF 62). The responsible Regulatory Officer or Focal Person will draft a memo for the purposes of communicating interdivisional notifications and requests in the format shown in Appendix I.

7.16.2 The draft memo will be sent to a Senior Regulatory Officer for review. If a Senior Regulatory officer prepares a memo, it may be reviewed by a different Senior Regulatory officer or the Head of Division.

7.16.3 The responsible officer will make the necessary corrections and facilitate signing either by the responsible officer/ Head of Division as appropriate.

7.16.4 The hard copy of the memo will be placed in the out tray for dispatch and an electronic PDF version will be sent via email. A copy of the memo shall be placed in the division File FVP 225 –Internal Memos.

7.17 Receipt of External Documents from Stakeholders

7.17.1 The HOD receives all hard copy and electronic documents and assigns each document to the relevant officer by writing the initials of the officer on the document.

7.17.2 In the absence of the HOD, the SROs will do so on behalf of the HOD

7.17.3 The Administrative Regulatory Officer records the title of the document and all other relevant information as per the columns in the Staff work book record (FVP O 13)

7.17.4 All incoming documents should be given a traceable reference number as per the relevant receipting book and file.

C Control of Non-conforming Outputs

7.18 Rectifying/Rescinding Outputs with Errors

7.18.1 On receiving a notification of any official outputs with errors e.g. correspondence with grammatical errors, product cancellation mistakes, mistakes on product certificates and training certificates or errors in protocol versions, the responsible Regulatory Officer shall make sufficient arrangements to obtain the original copy of the correspondence or output from the client

7.18.2 The Regulatory Officer shall make the appropriate corrections, retaining the original MCAZ output and shall send the defective output and the corrected output to a Senior Regulatory Officer for review.

7.18.3 Once the Senior Regulatory Officer has reviewed the output and granted approval for its dispatch, the Regulatory officer shall follow the usual dispatch process. For Letters, the MCAZ Reference shall be maintained

7.18.4 The Regulatory Officer shall keep the original defective copy of the output and a photocopy of the corrected output in the appropriate file e.g. Clinical Trial File or Product File where applicable. The original copy with errors shall be clearly marked as, "Non-conforming output" and the revised corrected copy shall be marked as "Conforming output"

7.18.5 For outputs that have been uploaded to the website e.g. circulars, guidelines etc., the Regulatory officer shall ensure the non-conforming version is taken down from the website and the corrected copy uploaded. The original filed hard copy with errors shall be clearly marked as, "Non-conforming Output" and the revised corrected copy shall be marked as "Conforming Output"

7.18.6 Details of the non-conforming output should be recorded in FVP 277 – Register for non-conforming Outputs

8.0 APPENDICES/ATTACHMENTS

8.1 Attachment I: Division Communication Matrix (QF62)
8.2 Attachment II: Request for Website Update Form (ICTF 03)
8.3 Appendix I: Memorandum template

9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	"K" Book: Clinical trials	5 years
N/A	"L" Book : Clinical trial amendments	5 years
N/A	AEFI Book: AEFIs	5 years
N/A	TSR Record book: TSR of Anti TBs, ARVs and Essential Medicines in the	5 years
N/A	Samples Register: Samples	5 years
N/A	ADR/SAE book: Pharmaceutical Industry	5 years
N/A	Monthly Schedule Time Log Book	5 years
FVP 13	Staff work book record	5 years
FVP 277	Register for non-conforming Outputs	5 years

10.0 REFERENCES

10.1 SOP MR 4.0: Standard Operating Procedure for Writing Standard Operating Procedure
10.2 SOP PV05: Standard Operating Procedure for the Process of Authorization and Disapproval of a Clinical Trial Application of a medicine in Human Participants
10.3 MCAZ Circular 9 of 2020

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	November 2020	Rolling Review

Reviewed by:	Approved by HoU/HoD	Authorised for use by QM:
Date:	Date: 13/4/2023	Date: 25/4/2023

APPENDIX I: MEMORANDUM TEMPLATE

MCAZ Medicines Control Authority of Zimbabwe

MEMORANDUM

TO : Name - Designation
FROM : Name - Designation
CC : Name - Designation
DATE : Day Month Year
SUBJECT :

Regards

Name (Title)

Reviewed by:	Approved by HoU/HoD	Authorised for use by QM:
Date: 12/4/2023	Date: pp HoD 13/4/2023	Date: 20/4/2023

PHARMACOVIGILANC AND CLINICAL TRIALS DIVISION (PVCT)

COMMUNICATION MATRIX

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
MCAZ Divisions and Units	Interdivisional notifications, Interdivisional requests	As and when necessary	Notice Board Memo Email Telephone	Whenever there is: Requests intended for a particular division or unit Notifications intended for a particular division of unit	The Regulatory Officer The Senior Regulatory Officer The Head of Division
Director General	Applicable notifications Applicable requests	As and when necessary	Memo Email Telephone In-person Letter	As and when necessary	The Regulatory Officer The Senior Regulatory Officer The Head of Division

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
The Head of Division	Applicable notifications	As and when necessary	Memo Email Telephone In-person Letter	As and when necessary	The Regulatory Officer The Senior Regulatory Officer
Applicants for registered medicines	Acknowledgement of receipt of applications	Upon receipt of an application for a variation to a registered medicine	Official MCAZ Letter	As and when an application is received	The Regulatory Officer
	Committee decisions for submitted applications	After an application has been tabled at the relevant Committee Meeting, and a decision has been made by the Committee	Official MCAZ Letter	After every Committee meeting	The Regulatory Officer The Head of Division The Director Genereal
	Status updates for submitted applications	Whenever a request for status update is received	Official MCAZ Letter Email Telephone	As and when necessary	The Regulatory Officer
	Request for payment /Proof of payment for submitted applications	Whenever an application requiring payment is received without any proof of payment	Official MCAZ Letter Email Telephone	As and when necessary	The Regulatory Officer
	Relevant notifications on	As and when necessary	Official MCAZ Letter Email	As and when necessary	The Regulatory Officer

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
	change of guidelines, acts or regulations affecting registered medicines		Circular Website		The Head of Division The Director General
	Retention fees statements	At the beginning of every year, before the 31st of January	Official MCAZ Letter	Annually	The Regulatory Officer The Head of Division The Director General
	Retention fees reminders	At the beginning of every year, before the 31st of January	Official MCAZ Letter	Annually	The Regulatory Officer The Head of Division The Director General
	Retention fees intent to cancel	August	Official MCAZ Letter	Annually	The Director General
	Cancellation notifications	August	Official MCAZ Letter Government Gazette	Annually	The Director General

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
	Cancellation and withdrawal of registered medicines	As and when necessary	Official MCAZ Letter Government Gazette	As and when an application is received	The Director General
Principal Investigators Co-investigators Study Coordinators	Acknowledgement of receipt of applications to conduct clinical trials	Upon receipt of an application to conduct a clinical trial in Zimbabwe	Official MCAZ Letter	As and when an application is received	The Regulatory Officer
	GCP Inspections, correspondence. Reports and notifications	As and when necessary	Official MCAZ Letter Telephone In person (Physical visits)	As and when necessary	The Regulatory Officer The Head of Division
	Committee decisions for submitted applications	After the application has been tabled at the relevant Committee Meeting, and a decision has been made by the Committee	Official MCAZ Letter	After every Committee Meeting	The Regulatory Officer The Head of Division The Director General
	Status updates for submitted applications	Whenever a request for status updates is received	Official MCAZ Letter Email Telephone	As and when necessary	The Regulatory Officer
	Request for payment/ Proof of	Whenever an application requiring payment is	Official MCAZ Letter Email	As and when necessary	The Regulatory Officer

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
	payment for submitted applications	received without any proof of payment	Telephone		
The Secretary for Health and Child Care	All communication concerning the MoHCC, its provinces, districts, departments or units	As and when necessary	Official MCAZ Letter	As and when necessary	The Director-General
Ministry of Health and Child Care departments and units, staff	All communication concerning the MoHCC, its provinces, districts, departments or units	As and when necessary	Official MCAZ Letter Email Telephone In person (physical visits)	As and when necessary	The Director General The Regulatory Officer The Head of Division
Healthcare Professionals	Medicines Safety Issues	As and when necessary	Official MCAZ Letter Email Telephone In-person (Physical visits) Circular Website	As and when necessary	The Director General The Regulatory Officer The Head of Division
Members of the general public	Medicines safety enquiries or notifications	As and when necessary	Official MCAZ Letter Circular Email	As and when necessary	The Director General

INTERESTED PARTY	WHAT TO COMMUNICATE	WHEN TO COMMUNICATE	HOW TO COMMUNICATE	HOW OFTEN	WHO COMMUNICATES
	Clinical trial enquiries and notifications		Telephone In person (Physical visits) Circular Website		The Regulatory Officer The Head of Division

Approved by HoU/HoD: L. CHIRINDA 29/4/2021

Name Signature Date