MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)

Guidelines for the Notification of a Medicinal Product Problem/Defect and Recall Procedure

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A. INTRODUCTION AND DEFINITIONS

Introduction

When medicines, vaccines or medical device products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information must be reported to the Medicines Control Authority of Zimbabwe (MCAZ).

The Medicines Control Authority of Zimbabwe Medicines Products Recall Guidelines are intended to ensure that in the event of a necessary recall, the recall operations are effectively and efficiently carried out by the manufacturer, importer, distributor or certificate holder of pharmaceutical product (hereafter known as the applicant) in order to safeguard public health.

The role of the MCAZ in a recall is to protect public and animal health by ensuring that accessible medicines including vaccines, allied substances and medical devices are safe, effective and of good quality through enforcement of adherence to standards by manufacturers, distributors, pharmacies, hospitals and clinics. The MCAZ also asses the nature of product defect and the adequacy of the recall of the product and to monitor the progress and effectiveness of the recall. The MCAZ may alert the public of the product problem and instruct the applicant to recall and dispose of the product according to the nature of the product defect and/or recall. Each applicant, manufacture or wholesaler is supposed to advise MCAZ of the names, after hours and telephone numbers of two persons who have authority and qualifications to discuss, and if necessary implement a recall.

Definitions

Applicant

Means the person or entity by, or on whose behalf, an application for registration is made, in terms of the Medicines and Allied Substances Control Act (MASCA) Chapter 15:03 Section 2.

Medicine

Medicine means any substance, or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in:

a. the diagnosis, treatment, mitigation, alleviation or prevention of disease or its symptoms; or
b. the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or its symptoms; or
c. altering, modifying, correcting or restoring any organic function in human beings or in animals.

Please note that vaccines and biologicals are included under the MASCA Chapter 15:03 definition of a medicine.

Product Defect

A medicine, vaccine or medical device product that is not of the correct quality, safety or efficacy as defined by its Marketing Authorisation which may pose risk to the users.

Recall

A process for withdrawing or removing a medicine, vaccine and/or medical device product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/ or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, wholesale dealer applicant or the MCAZ.

For more information on Counterfeit products please refer to the Zimbabwe National Pharmacovigilance Policy and Guidelines Handbook section on Substandard/Spurious/Falsely Labelled/Falsified/ Counterfeit Medical Products (SSFFCs).

Withdrawal or Cancellation of Registration and/or Withdrawal of a listed product-The total removal of a medicinal product from the market that could be due to an irreversible quality, safety or efficacy concern due to published research findings or non-compliance to current GMP. The withdrawal or cancellation maybe voluntarily initiated by the applicant or manufacturer or by the MCAZ.

B. STAGES OF RECALL PROCEDURE

The procedure is divided into six stages, which are set out below, with a reference to the Section in which detailed information is given,

Recall Stages		See Section
1.	**Notification to the MCAZ**	**1**
	Receipt of Medicinal Product Problem Report Information on problem of medicine, vaccine and/or medical device products, see also Medicine, Vaccine or Medical Device Problem Report Form PVF 46 under Appendix I.	**1**
2.	**Initiation of a Recall**	**2**
	Information Required for Assessment of Recall Information on product, problem and distribution is required, see also- Recall Notification Form PVF47 under Appendix I.	
3.	**Assessment of Recall** The classification, level and strategy of recall are determined depending on the potential hazard of the defective product and the extent of product distribution.	**3**
4.	**Recall** Letters and press release (if required) are dispatched to relevant firms for notifying on the recall. See Recall Reply Form PVF48 under Appendix II.	**4**
5.	**Progress of Recall and Report** Progress reports and final report are submitted to the MCAZ. See Final Report Form PVF49 under Appendix III.	**5**
6.	**Evaluation of the Recall** The effectiveness of the recall is monitored by the MCAZ.	**6**
7.	**Reinstatement of Supply**	

1. NOTIFICATION OF A MEDICINAL PRODUCT PROBLEM AND /OR DEFECT

Recall might be initiated as a result of reports or complaints on quality, safety or efficacy on a medicine, vaccine or medical device product referred to the applicant from a variety of sources. The reports or complaints may be referred by manufacturers, wholesalers, retailers, hospital pharmacies, research institutes, medical practitioners, dentists, patients and/or the public. Recall might also be initiated as a result of analysis and testing of samples of medicinal products by the manufacturers and MCAZ for batch samples that do not meet specifications such as assay, impurities etc. Recall of medicine and/or vaccine/medical device products manufactured outside Zimbabwe might be initiated by the local or external health authorities, or from information received directly from such authorities including National Regulatory Agencies. (NRAs).

Certain information is essential to permit the assessment of the validity of the report of quality defects, safety or efficacy problem with medicines and/or vaccine/medical device products, the potential danger to public or consumers and the action appropriate to the situation. A Medicine, Vaccine or Medical Device Product Problem Report Form PVF46 under Appendix 1 is used to report medicines and/or vaccine/medical device problems to the MCAZ.

Serious problems which may lead to recall of Class I or Class II (refer to recall classification under Section 3) must be reported to the MCAZ within 24 hours after receipt of the complaint or report of the investigation. The Medicine, Vaccine or Medical Device Product Problem Report Form PFV46 (Appendix 1) together with opinions on toxicological or therapeutic hazards and the action proposed by the NRAs (if any) should be submitted to the MCAZ. For less serious problems which would result in a Class III recall, the Medicine, Vaccine or Medical Device Product Problem Report Form should be sent to the MCAZ no later than 72 hours after receipt of complaint or report of a problem.
It should be noted that the applicant has to send the Medicine, Vaccine or Medical Device Product Problem Report Form PFV46 (Appendix 1) to the MCAZ prior to their decision to recall the product.

In case of a potential significant health hazard to patients during weekends or public holidays the applicant may within 24 hours initiate action which could include precautionary measures to block or quarantine stock prior to the initiation of the recall.

When the need for recall has been established, additional information is required so that an appropriate recall strategy may be devised. A summary of the information required is provided under Section 2.

2. INITIATION OF RECALL/ INFORMATION REQUIRED FOR ASSESSMENT OF RECALL

When the MCAZ and/or applicant and manufacturer decides to initiate a recall on a medicine and/or vaccine/medical device, it is required to notify the recall situations with the Recall Notification Form (PVF47) under Appendix I including information outlined below to the MCAZ immediately after the decision to make a recall is made. The MCAZ will also inform other key stakeholders of the intent to recall the product such as the Directorate Pharmacy Services - MoHCC.

The information required may include:

1) Details of the Problem

- name, telephone and e-mail address of the person reporting the problem;
- date of report;
- physical location of the problem;
- nature of the problem;
- number of similar report received;
- results of tests and other investigations on suspected product or other product samples.

2) Details of the Product

- name of the product and description including active ingredients, dosage form, strength, registration number, pack size or type; batch number(s) and expiry date;
- manufacturer/ distributors contact telephone and email address;
- date manufactured, date released or imported to Zimbabwe
- quantity of the batch, date and amount manufactured, released or imported to Zimbabwe;
- local distribution list;
- distribution list of product exported outside Zimbabwe; -
- whether the product is meant to be sterile.

3) Health hazard evaluation and proposed action

- type of hazard, and evaluation of health hazard to user;
- action proposed by the applicant or manufacturer;
- proposed recall classification and level; and
- availability of alternative product.

3. ASSESSMENT OF RECALL

3.1 Recall Strategy

Each recall is a unique exercise. There are a number of factors common to all recalls that need to be considered in tailoring an appropriate recall strategy. These include the nature of the deficiency in the product, the incidence of complaints, public safety, distribution networks, recovery procedures, resources for corrective action and availability of alternative products.

In determining the recall strategy, the applicant should consider the factors which may affect the duration of the recall action and should inform the MCAZ. The recall should be completed by the date as directed by the MCAZ.

When the required information (Section 2) is available, the appropriate strategy should be proposed by the applicant and/or manufacturer to MCAZ. The proposed recall strategy should be agreed by the MCAZ before implementation and the agreement should be reached in 24hrs of submission of notification form. The actual implementation of the recall includes use of the basic steps which are summarized in Section B and these will be common to all strategies.

In the recall strategy, the applicant should mention the following:

a) Indicate the proposed level in the distribution chain to which the recall is extending (see level of recall below), if the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;

b) In case of *consumer level* recall, additional information should be mentioned-

- Indicate the location of recall distribution channels for consumers;
- Indicate the proposed refund mechanism at the recall distribution channels, the conditions of refund (applicable to opened products, expired products or parallel-imported products) and methods of refund (by means of money, credit notes or product replacement etc.);

c) Indicate the method of notification;

d) Indicate how the message of recall will be delivered to customers e.g. press release or recall letters etc;

e) If the applicant and/or manufacturer has a website, it should consider posting the recall notification on it as an additional method of recall notification;

f) Report on what have the customers been instructed to do with the recalled product;

- It is necessary for recalling firms to know the name and title of the recall contact person for each of its consignees. Addressing a recall letter to a recall contact person will expedite the recall process and reduce the potential for the recall letter to get misdirected;

g) If product is to be returned, explain the mechanics of the process;

h) Explain if the recall will create a market shortage that will impact on the consumer; -

i) Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to the external or local manufacturer; and

j) Inform MCAZ before product destruction, the proposed method of destruction would be reviewed and MCAZ may choose to witness the destruction. A product Certificate of destruction after destruction of the product should be submitted to the MCAZ.

3.2 Classification of Recalls

Recalls are classified according to the following system:

3.2.1 Class I recall

Occur when products are potentially life-threatening or could cause a serious risk to health.

Examples of Class I Defects

- Wrong Product (label and contents are different products)
- Correct product but wrong strength, with serous medical consequences
- Microbial contamination of sterile injection or ophthalmic product
- Chemical contamination with serious medical consequences
- Mix up of some products with more than one container involved
- Wrong active ingredient in a multi-component product with serious medical consequences
- Lack of effectiveness for a life threating condition.

3.2.2 Class II recall

Occur when product defects could cause illness or mistreatment, but are not Class I.

Examples of Class II Defects

- Mislabeling e.g. wrong or missing text or figures
- Missing or incorrect information- leaflets or inserts
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- Chemical/ physical contamination (significant impurities, cross contamination, particulates)
- Mix up of products in containers
- Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
- Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products)
- Lack of efficacy/effectiveness for medical condition that is not life threatening.

3.2.3 Class III recall

Occur when product defects may not pose a significant hazard to health ie low risk to health but recall may be initiated for other reasons, due to quality, safety or efficacy concerns.

Examples of Class III Defects

- Faulty packaging e.g. wrong or missing batch number or expiry date

- Faulty closure
- Contamination- microbial spoilage, dirt or detritus, particulate matter

Class I or Class II recalls are considered to be urgent safety-related recalls. They must be reported to the MCAZ for further evaluation and investigation. Class III recalls are considered to be minimum risk to public health but should however still be reported to the MCAZ.

Note: Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. The classification is determined by the MCAZ. Expert advice might be sought where the nature of the hazard or its significant is not clear. Decision made by other stringent regulatory authorities internationally will also be considered.

The Guidelines do not apply to the recall of a medicine, vaccine or medical device related to regulatory issues such as cancellation of registration due to non-payment of retention fees, approved change of applicant, manufacturer, labeling, package insert or other registered particulars. Regulatory issues in which there is lack of compliance to cGMP may lead to a recall and/or a cancellation of registration.

3.3 Levels of recall

As with classification, the level (or depth) of a recall is to be assigned in agreement with the MCAZ. In determining the recall level, the principal factors to be considered are the significance of the hazard (if any), the channels by which the medicine, vaccine or medical device pharmaceutical products have been distributed, and the level to which distribution has taken place. Again, expert opinion may be necessary to determine the significance of the hazard or risk.

There are three levels of recall: wholesale, retail and consumer.

3.3.1 Wholesale level

Includes all parties involved in wholesale distribution and may include wholesalers and retail pharmacies.

3.3.2 Retail level

Includes:

- All public and private hospital pharmacies;
- Retail pharmacies;
- Clinical investigators and the institutions in which clinical investigations are performed;
- Medical, dental and other health care practitioners;
- Nursing homes and other related institutions;
- Other retail outlets e.g. medicine shops, supermarkets and health food stores;

- **NB:** In the case where consumers that are known to be in possession of the affected products, a plan should be put in place where specific telephone calls are made to these consumers or recall letters sent to arrange for return of the recalled product.

3.3.3 Consumer level

Includes patients and other consumers.

4. COMMUNICATION TO PUBLIC

4.1 Recall letters

In case of a recall, the applicant and manufacturer may prepare letters with a factual statement of the reasons for the recall of the product, together with specific details that will allow the product to be easily identified. The recall communication shall not contain any material that can be viewed as promotional in nature. The letter may be sent by mail, facsimile or e-mail to the clients. The recall letter needs prior approval by the MCAZ unless the matter is urgent and there is immediate hazard or risk to the patients. The letter may also be referred to as alert notice or dear doctor letter. The MCAZ may also write a circular on the recall in addition to the letter from the applicant, and manufacture.

The recall letter should use company letterhead; include date and name and title of signatory. The text of recall letter may include:

a. **Description of the medicinal product:** name of the product; Zimbabwe registration number; name of manufacturer, pack size; dosage form; batch number(s) and expiry date;
b. **Hazard and risk associated with the product:** The reason for the recall should be concisely explained. It should be made clear that further distribution or use of the product should cease immediately.
c. **Instruction for recall of the product:** The method of return, disposal or correction and refund mechanism of the product. Proof of delivery of communication by the healthcare professional e.g., read receipt of an e-mail or list of addresses for recall letters that are posted is acceptable. Each posted recall letter could contain a "Return to Sender" address and the recall agency will be able to evaluate which Healthcare professional have not received the letters. The applicant/or manufacturer should clearly identify a hotline number for enquiry.

For retail level recall, the applicant should have confirmation for returning all the stock on hand from the consignees using the Recall Reply Form PVF Form 48 under Appendix II. As the Distributor has batch traceability records it is acceptable that the Distributor send out the Recall Reply Form PVF Form 48 to their customers and follow-up with non-responders.

Responsibilities in the case of a recall must be defined in the Quality Assurance Agreement between applicant and their chosen distributor.

If safety to the public is involved and distribution is limited, the applicant may contact the clients of the information listed above by telephone and followed by a recall letter. The letter should be retained for a period of not less than 3 months to ensure that product still in transit or on its way to retail or hospital is adequately managed and quarantined.

4.2 Press Release approved by MCAZ

Rapid alert to public is usually reserved for hazards classified as Class I, and where appropriate Class II, or situation where other means for controlling the hazard appear inadequate. Rapid alert to public may be issued through appropriate channels which may include press release approved by the MCAZ. **Please note that all press release statements associated with a product Defect and Recall must be approved by MCAZ prior to publication or release in the press to avoid unnecessary panic to the public and consumers or miscommunications.**

Information that should be included in the media statements is:

1. Clear outline of the problem
2. Clear product information identifying the product use
3. Possible effects (without creating fear to the consumer)
4. What should the consumer do
5. Company information and contact details of responsible person(s)

5. RESPONSIBILITIES OF APPLICANT, PRINCIPALS AND MANUFACTURERS

The applicant and manufacturer has responsibilities in relation to recall of medicines, vaccines and/or medical devices products in three general areas:

a. in maintaining records and establishing procedures which will assist in facilitating recall should such action become necessary; and
b. in taking the prime responsibility for implementing recall in the situation where it is necessary.

c. In further investigating the case of the product defect and recall and providing the corrective and prevention actions.

5.1 Records

The applicant, distributors and manufacturer should maintain records for all the medicines manufactured or distributed by them in accordance with the following:

For manufacturers

- A system should be in operation whereby the complete and up-to-date histories of all batches of products from the starting materials to the finished products are progressively recorded;
- The system should allow the determination of utilization and disposal of all starting materials and bulk products.

For distributors

- Records of all sales or distribution (including professional samples and export to other countries) of medicines, vaccines and/or medical devices should be retained or kept readily accessible to permit a complete and rapid recall of any lot or batch of a pharmaceutical product.

The complete records pertaining to manufacturing and distribution should be retained for two years after the date of transaction or one year after the expiry date of the batch whichever longer.

Besides, the applicant and manufacturer should retain records of problem reports received about each product. Problem reports should be evaluated by competent personnel and appropriate action taken. The evaluation of each report and the action taken should be shown in the records.

All the above records should be readily available and easy to follow so as to expedite a recall whenever necessary. A copy of manufacturing/ import and distribution records should be sent to the MCAZ when a recall is implemented.

NB. In some cases due to the parallel importation of medicines into Zimbabwe, the importer and/or distributor will be responsible to liase with the external applicant and manufacturer to comply with MCAZ medicine recall and defect guidelines and decisions.

5.2 Recall Procedure

As mentioned in Section B, applicant should prepare procedures for recall action which are consistent with the Guidelines and which are applicable to their own operations. All senior personnel should be familiar with their responsibilities in connection with the procedure and of the records system for pharmaceutical products.

5.3 Problem Reporting

Where evaluation of a problem report concerning a medicine indicates that recall may be necessary, the report must be conveyed with the least possible delay to the MCAZ, including medicines that have been exported-only and not supplied in Zimbabwe. Any batch of a formulated product that has been distributed, or any batch of a starting material that is found not to comply with the approved product specifications or a relevant standard of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PICS), must also be reported if it has been used in a distributed product.

5.4 Recall

Applicant has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages (Section B). **However, no recall, regardless of class of recall, should be undertaken without consultation with the MCAZ.**

A responsible personnel for recall should be appointed to coordinate the recall and his/her name and contact phone number should be notified to the MCAZ. In addition, this personnel has to report the progress of recall regularly to the MCAZ.

For Class I recall, applicant and manufacturer should notify its clients within 24 hours upon the decision of recall and quarantine undistributed stock immediately. The company personnel may be utilized to immediately disseminate information on the recall. This includes telephone advice to quarantine stock pending recall or possible recall followed by recall letters if necessary. A Recall Reply Form PVF 48 (Appendix II) should be sent to all consignees to confirm quantity of stock on hand and have all of them returned. The reply form PVF 48 should be kept for inspection by the MCAZ. All Class I recalls should be completed within a time as found suitable for the case agreed by the MCAZ.

For consumer level recall, the applicant and manufacture should set up sufficient recall distribution channels for collection of recalled products. Information of location of the recall distribution channels their operating hours and duration, conditions of refund as well as method of refund should be noticed to consumers by effective means.

Applicant and manufactures representatives may be utilized to recover stock which is the subject of recall, providing the provisions are observed in relation to unauthorized possession of certain stock, e.g. narcotics

Applicant may also be required to notify external recipients of recall actions that affect them.

5.5 Refund Mechanism

Applicant, manufacture and distributor should set up a refund mechanism for the recalled products and is responsible for the refund.

5.6 Post-recall

After the timeframe directed by the MCAZ to complete the recall, or at other agreed times, the applicant is to provide the MCAZ with an interim report during the recall process for the monitoring of progress within 7 calendar days after initiation of the recall. The interim report should contain the following information:

- the number of organizations or persons to whom the defective product has been supplied;
- the date and means of notifying them of the recall;
- the number of responses received from them;
- the names of the non-responders;
- the quantity of stock returned;
- the quantity of stock that has been off shelves pending return to applicant;
- the estimated time frame for the completion of the recall.

A final report (refer Final Report Form PVF 49 under Appendix III) containing the following information should be submitted to MCAZ within 14 calendar days after commencing of the recall:

- the circumstances leading to the recall;
- the consequent action taken by the applicant or manufacturer;
- the extent of distribution of the relevant batches in Zimbabwe and external; -
- the result of the recall
    - the quantity of stock returned, corrected, outstanding;
    - the quantity of stock used by the consignees and;
    - the quantity of stock not located;
    - date of recall completion;
- confirmation (using Recall Reply Form PVF48 under Appendix II) where practicable, the retailers have returned all the recalled products to the applicant or manufacture and the customers have received the recall letter;
- the method of destruction or disposal of the recalled products; and

The applicant or manufacture should report to MCAZ with relevant explanation and obtain its approval if the final report cannot be submitted within 14 calendar days after commencing of the recall. After completion of the recall, a report on investigation results on the problem and the action proposed to be implemented in future to prevent a recurrence of the problem should be submitted to MCAZ in a timely manner, not more than 30 calendar days after the recall.

NB. These reports establish the effectiveness of the recall and unless satisfactory reports are received, further recall action may have to be considered.

6. EVALUATION OF THE RECALL

The evaluation consists of a check on the effectiveness of the recall and an investigation of the reason for the recall as well as the remedial action taken to prevent a recurrence of the problem.

6.1 Check on the Effectiveness of Recall Action

It is the applicant and manufacturer responsibility to assure that the recall is effective.

The MCAZ examines the recall reports and the signed Recall Reply Form PVF 49 submitted by the applicant and assesses the effectiveness of the recall action. Recall records may be inspected and in some case the MCAZ may contact a percentage of customers in the distribution list as a means of assuring that the applicant is carrying out its recall responsibilities. If MCAZ finds the recall to be ineffective, the applicant and/or manufacture will be asked to take appropriate steps, including re-issuing recall letters.

6.2 Investigation of the Reasons for Recall and Initiation of Remedial Action

On completion of a recall, the applicant and manufacture are requested to provide a report of the investigation on the problem and details of the remedial action proposed to prevent a recurrence of the problem which gave rise to the recall (Section 5). Where the nature of the problem and appropriate remedial action are not apparent, investigation and in some cases current Good Manufacturing Practice (cGMP) audits may be necessary, including a product-based cGMP inspection conducted by MCAZ inspectors.

Where a recall is initiated following a report submitted by a party from external regulatory authorities, the report is to be provided with an outline of the results of investigation and a summary of the recall.

7. REINSTATEMENT OF SUPPLY

The quality of the products shall conform to specific requirements including finished product specifications before resuming the supply to public. **The applicant and manufacture must seek approval from the MCAZ for reinstatement of the medicine and/or vaccine/medical device previously "totally recalled".**

7.1 Implementation of Remedial Action

The applicant shall identify the root cause of the problem and implement the corrective action accordingly. Furthermore, preventive action shall be imposed to prevent recurrence of the problem in the future. In some cases adequate time is required for research and product development to reformulate or change the packaging or to exclude and/or reduce impurities and degradation products etc.

7.2 Submission of Analytical Report

After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the applicant shall submit analytical report(s) of the new batch tested by external accredited laboratory to the MCAZ as a proof of product quality if applicable. If the independent laboratory does not have the capacity in terms of equipment to analyze the product e.g. analysis of vaccines or large molecular weight medicines. The manufacture can perform the analysis and submit the results to the MCAZ for verification. If MCAZ is concerned with the quality of the manufacture, GMP inspection of the site could be conducted.

The submitted report(s) will be evaluated by the MCAZ. After evaluation, the MCAZ would inform the applicant whether the submitted reports are satisfactory.

7.3 Verification of corrective action

When the MCAZ is satisfied by the submitted reports, samples of the first batch of the product (being manufactured by the local manufacturer / being imported) will be collected for examination by the MCAZ before the product can be distributed. After the MCAZ has approved the distribution of the product, samples from the next consecutive two batches should be submitted for analysis as part of the verification process if applicable. The cost for analysis will be borne by the applicant and/or manufacturer. Where necessary a third party independent analysis maybe required in exceptional cases at the cost of the manufacturer or applicant after approval by the MCAZ.

Note:

- **Appendix 1- Medicine, Vaccine or Medical Device Product problem defect form (PVF 46)** should be used to report problem of Medicine, Vaccine or Medical Device products on quality, safety or efficacy, which are thought to have arisen during manufacture, storage, or handling. Problems of this nature are usually found in a single batch of a product and may require laboratory analysis investigation by the MCAZ.

- **Appendix 1 Part 2-Recall notification form (PVF47)** should be filled when decision of a recall is established.

- When the reported problem may lead to Class I or II recall, it should be reported to the MCAZ ***within 48 hours*** by written letter or email of this scanned form (Appendix 1) Medicine, Vaccine or Medical Device Product Problem Defect form PVF46.

- If Class I or II recall is required, PVF46 and PVF47 forms should be reported to the MCAZ immediately by email or signed letter.

- The applicant shall NOT wait to submit this information until ALL applicable information in PVF47 is prepared and assembled prior to notification to the MCAZ.

- For problem or defect that may lead to Class III recall, Medicine, Vaccine or Medical Device Product Problem Defect form PVF46 should be returned by email and signed letter to MCAZ ***not later than 72 hours***. When Class III recall is required, the scanned forms PVF46 and PVF47 forms under appendix 1 should be submitted by email and signed letter.

- **Appendix II Recall Reply Form PVF48**

- **Appendix III Final Report Form PVF 49**

- **Appendix IV** Report on medicinal (Pharmaceutical) Product defect or problem for completion by all other parties (healthcare professionals and the public) except the manufacturer.

Please submit all completed forms and signed letters and emails to the Director-General, Medicines Control Authority of Zimbabwe (MCAZ), 106 Baines Avenue, Harare, Telephone: 708255/792165; Cell 0772145191-3 Email: mcaz@mcaz.co.zw, Website: www.mcaz.co.zw

APPENDIX I

Medicines Control Authority of Zimbabwe

PVF 46

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

MEDICINE, VACCINE OR MEDICAL DEVICE PRODUCT PROBLEM/DEFECT FORM

To be completed by Manufactures and/or Applicants

Reporting Applicant (reporting the problem of medicine to MCAZ)	
Name of contact	Position/ Occupation
Organization	
Address	
E-mail address	
Tel (office) (mobile)	Fax
Product problem occurred in Zimbabwe? If not, location of problem:	
Nature of the problem	
Date of receiving complaint	
Source of Complaint ☐ Patient ☐ Customer ☐ Retailer ☐ Self-inspection ☐ Other: _____	
Number of similar reports received	
Description of the problem (use separate sheet if space is inadequate)	
Samples submitted for analysis to MCAZ at manufacturer's cost if required and method of analysis ……. …….....	
Results of tests/ investigation on suspect or other samples	

Has manufacturer/ distributor been contacted? □ No □ Yes (please write down their names)
Other relevant information (attach photos, package insert and press release of external national regulatory agencies of the product if any)

DETAILS OF THE PRODUCT		
Name of the product (as in product registration certificate)		Zimbabwe Registration Number
Active Ingredients & Strength		
Indications		
Dosage form		Pack size
Batch number		Expiry date
Distribution of products □ Public Hospitals □ Private hospitals □ Pharmacies □ Medicine stores □ Public Clinics □ Private doctors □ Others (specify)		
Manufacturer		
Name		
Address		
Tel	Fax	Manufacture date
Quantity of the batch manufactured		Date and quantity released
Quantity on hold		Quantity distributed: local external
Importer		
Name		
Address		
Tel	Fax	Import date
Quantity of the batch imported		Date and quantity released
Quantity on hold		Quantity distributed: local re-exported
Local Distributors (please attach distribution list)		
No. of local distributors		
Name		
Address		
Contact Person		Tel (office & mobile)
Quantity on hold		Quantity distributed: local re-exported
Exporter		
Has the product been exported outside Zimbabwe? □ Yes □ No If yes, specify the exported countries.		

Name of Reporter: Post:

Contact no. (mobile): _____ _____

Date: _____ _____

Signature of Reporter: _____

PVF 47

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

RECALL NOTIFICATION FORM

RISK ASSESSMENT			
Type of hazard and risk ☐ Safety ☐ Quality ☐ Labeling ☐ Compliance Issue ☐ Other (specify)			
Evaluation of Health Hazard to users (e.g. effects on users, possibility of occurrence) (attached expert advice if any)			
Proposed recall classification ☐ Class I		☐ Class II	☐ Class III
PROPOSED ACTION (WITH AGREEMENT OF MCAZ)			
Recall start date		Proposed recall end date	
Telephone/Mobile for enquiry			
Telephone/Mobile operating hours:	Mon- Fri	Sat	
Responsible personnel of recall		Tel (office & mobile)	
Proposed recall level	☐ Wholesale	☐ Retail	☐ Consumer
Location of distribution channels *(For Consumer level recall only)*			
Operating hours and duration of the distribution channels *(For Consumer level recall only)*			
Means of Refund at the distribution channels ☐ Money ☐ Credit Note ☐ Replacement ☐ Other			
Conditions of Refund at the distribution channels			

Proposed recall strategy (use separate sheet if space is inadequate)

Name of Reporter: _____ Post:
Contact no. _____ (mobile): _____ Date:

_____ _____

Signature of Reporter:
Submit signed form to
Medicines Control Authority of Zimbabwe (MCAZ),
106 Baines Avenue

Telephone: 708255/792165; Cell 0772145191-3 Email: mcaz@mcaz.co.zw

APPENDIX II

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

PVF 48

FINAL REPORT FORM

Recall Reply Form

To	:	
Attention	:	
Email	:	
Number		
Postal Address	:	
Subject	:	
From	:	
Contact person	:	
Telephone Number	:	

We do/ do not * have stock which is subject to this recall.

We have reported and returned all the stock on hand to <Applicant Name>

(please delete as appropriate)*

Stock received:

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Unused stock subject to recall (currently in quarantine):

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Any other relevant details:

_____

_____

I declare that the information provided by me in this reply form is complete and true to the best of my knowledge.

Signature: _____ Date: _____

APPENDIX III

Medicines Control Authority of Zimbabwe

PVF 49

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

FINAL REPORT FORM

Note: Use separate form for each medicinal product reported.

This report should be returned by original and scanned form by email to the MCAZ within 14 days after commencing recall.

Details of the recalled products	
Name of the product	Zimbabwe Registration number
Active ingredients & strength	
Dosage form	Pack size
Batch number	Expiry date
Reasons for recall	
Extent of Distribution	
Imported/ manufactured quantity	
Quantity exported	Countries of Export
Quantity distributed in Zimbabwe	No. of Consignee
Action taken by the Applicant	
Result of Recall	
Quantity of stock returned	Quantity of stock outstanding
Quantity of stock used or sold by the consignees	
Quantity of stock not located	
No. of Recall Reply Form received from consignees on all stock returned/ reported	
Disposal Plan	
Method of Disposal □ Destroy □ Return to external manufacturer □ Others, please specify:	
Details of the disposal method	

Applicant Name : _____

Name of Recall personnel : _____ Signature : _____

Date : _____

Submit signed form to:

The Director-General
Medicines Control Authority of Zimbabwe
106 Baines Avenue
P O Box 10559
Harare

APPENDIX IV

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

PVF 05

REPORT ON MEDICINAL (PHARMACEUTICAL) PRODUCT DEFECT OR PROBLEM

To be completed by Pharmacists, Pharmacy Technicians, Medical Practitioners, Nurses, Veterinary Surgeons and other Distributors of Medicines.

<table>
<tr><td colspan="4">1. Product Name (Brand and Generic)</td></tr>
<tr><td colspan="2">2. Description of the Device</td><td>3. Intended Use</td><td>4. Size/Type of Container</td><td>5. Registration No.</td></tr>
<tr><td colspan="2">6. Batch Number</td><td colspan="3">7. Expiry Date</td></tr>
<tr><td colspan="5">8. Name and Address of Manufacturer</td></tr>
<tr><td colspan="5">9. Name and Title of Reporter</td></tr>
<tr><td colspan="5">10. Your Practice Location and Address of Hospital, Clinic, Retail Surgery etc.</td></tr>
<tr><td colspan="3">11. Phone Number</td><td colspan="2">12. Date Problem Occurred or Observed</td></tr>
<tr><td colspan="5">13. If requested will the actual product involved be available for examination by MCAZ.
YES **NO**</td></tr>
<tr><td colspan="3">14. Signature of Reporter</td><td colspan="2">15. Date</td></tr>
<tr><td colspan="5">16. Defects/Problem Noted or Suspected (see a-j below)</td></tr>
</table>

NATURE OF DEFECT OR PROBLEM

a) Presence of foreign material
b) Unusual odour
c) Colour changes
d) Fungal growth
e) Suspected contamination
f) Parenteral solution - leaks, particulate matter, discoloration etc.
g) Wrong label, wrong packaging, wrong strength
h) Lack of therapeutic response
i) Leakages
J) Other (specify)

Return To: The Director-General
Medicines Control Authority of Zimbabwe
106 Baines Avenue
P O Box 10559
Harare
Fax: (04) 736980 Tel: 708255/792165/ 2901327-31
E-mail: mcaz@mcaz.co.zw

for Office Use Only

Report Number:
Date Received:

REFERENCES

Guidance for Industry: Product Recalls, Including Removals and Corrections
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

Medicines and allied substances control regulations
http://www.mcaz.co.zw/medicines and allied substances control regulations si 150 of 1991.pdf

Pharmaceutical Products Recall Guidelines, 2014, Traders Licensing and Compliance Division of Drug Office Department of health Hong Kong SAR, China
https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Pharmaceutical_Products Recall Guidelines.pdf

Republic of Kenya, Pharmacy and Poisons Board, Guidelines for product recall and product withdrawals, 2nd Edition, June 2006,
http://pharmacyboardkenya.org/downloads/guidelines for product recall.pdf