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Medicines Control Authority
of Zimbabwe



Medicines Control Authority of Zimbabwe

LICENSING AND ENFORCEMENT DIVISION

TITLE: Standard Operating Procedure for Receiving and Processing Suspected Defective, Substandard and Falsified (SF) Medical Products, and Recalls			
SOP Number: LE 67		Revision Number: 5	
		Document Level: 3	
Date Issued for training: 09/10/2025		Effective Date: 21/10/2025	
		Review Date: 10/10/2025	
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	Name	Signature	Date

1.0 PURPOSE

To establish a procedure for receiving and processing suspected Defective, Substandard and Falsified (SF) Medical Products, Recalls, and WHO International Alerts.

2.0 SCOPE

- 2.1 This procedure applies to all pharmaceutical product defect/substandard or falsified medicines reports which arise from external customers or from the ongoing pre-distribution or post-market surveillance sampling program conducted by MCAZ. This applies for all product quality, safety or efficacy problems received at MCAZ for all medicinal products for human and veterinary use. The SOP also applies to handling voluntary recalls initiated by manufacturers.
- 2.2 This procedure applies when there is GMP non-compliance leading to product quality, safety or efficacy problems or when risk signals are detected from Adverse drug reaction (ADRs) or Adverse events following immunization monitoring (AEFIs).
- 2.3 This procedure also applies when WHO International Alerts on Substandard and Falsified (SF) medical products are received by the National SF focal points in the Licensing and Enforcement Division.
- 2.4 This procedure also applies when sharing relevant alerts on Substandard and Falsified Medical Products reported in Zimbabwe with WHO and other relevant global organizations like ZAZIBONA and relevant African harmonization collaborations.

3.0 FREQUENCY

Each time Suspected Defective, Substandard and Falsified (SF) Medical Products are noted and or when there is need for recalls.

4.0 LOCATION

- 4.1 The master copy is kept in the Quality Manager's office.
- 4.2 Controlled copies are kept by the Head of Division.
- 4.3 Controlled copies issued to staff will be kept at points of use in the Division.
- 4.4 Scanned Copy shall be stored on Share-Point

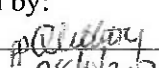
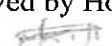
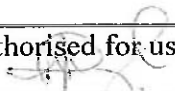
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5.0 DEFINITIONS

- 5.1 **Product defect:** in this context can be a Defective, Substandard and Falsified Medical Product.
- 5.2 **Substandard medical products** also referred to as "out of specification," are authorized medical products that fail to meet either their quality standards or specifications, or both.
- 5.3 **Falsified medical products** are products that deliberately or fraudulently misrepresent their identity, composition or source.
- 5.4 **Defect classification:** recalls are classified with regard to the relative health hazard associated with the use of or exposure to the recalled product. There are three possible classifications:
 - 5.4.1 **Class I:** Defects are potentially life threatening.
 - 5.4.2 **Class II:** Defects could cause illnesses or mistreatment, but are not Class I.
 - 5.4.3 **Class III:** Defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.
- 5.5 **Depth of recall:** level within the distribution channel from which a product is recalled, i.e. wholesale, retail, user/consumer.
- 5.6 **Batch Recall:** the action of withdrawing a batch from the distribution chain and users. A batch recall may be partial, in that the batch is only withdrawn from selected distributors or users.
- 5.7 **CRO:** Chief Regulatory Officer or their designate
- 5.8 **HLED:** Head, Licensing and Enforcement Division or their designate
- 5.9 **PMS:** Post Marketing Surveillance
- 5.10 **Client:** Importer / Manufacturer / Health Institution / Individual

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6.0 RESPONSIBILITY

- 6.1 It is the responsibility of every regulatory officer to follow this procedure when handling medicine products defect reports.
- 6.2 It is the responsibility of the CRO Enforcement to ensure that this procedure is adhered to at all times.
- 6.3 National SF Focal Points shall be responsible for receiving and disseminating WHO alerts to the relevant organizations.
- 6.4 National SF Focal Points shall be responsible for notifying WHO on reports incidences received within the country.
- 6.5 Quality Office to verify that the Licensing and Enforcement department officers adhere to this procedure and issues are adequately resolved.

7.0 PROCEDURE

- 7.1 On receiving a product defect report in the Division, the CRO or designate shall make an entry into the Product Defects Record Book (LED 057). The defect report shall be assigned a number sequentially. The product defect may be received through the form (Medicine, Vaccine or Medical Device Product Problem/Defect Form (LEF 63)) for manufacturers and the form (Report on Medicinal (Pharmaceutical) Product Defect of Problem (LEF 80)) for health professionals or submitted through any other relevant means of communication to encourage reporting.
- 7.2 The CRO shall assign a Regulatory Officer (RO) to process the defect within 24hrs of receiving the defect report in the division.
- 7.3 In the relevant situation, the RO shall draft a letter informing the client(s) to quarantine all the medicines from the suspected defective batch and to await further instructions from the Authority. The client(s) to be communicated to shall be agreed upon between the CRO and the RO. In cases where the product is registered and distributed by many wholesalers, there is need to ensure that all distributors are contacted through Recall Reply (Form LEF 61).
- 7.4 The letter shall be reviewed and signed by the HLED, then the RO shall send the letter to the client. The client must be advised to respond within 5 days to acknowledge receipt of the letter detailing the following:
 - 7.4.1 The quantity of medicines from the suspected defective batch that was distributed to the market.
 - 7.4.2 The quantity of the medicines from the suspected defective batch that is in stock.
 - 7.4.3 Any other batches which might potentially be defective.
 - 7.4.4 Where the medicines were distributed to (in the case of a distributor / manufacturer).
 - 7.4.5 Importation documents and/or invoices from the supplier.
- 7.5 Whilst waiting for the response from the client, the RO shall also visit at least three (3) pharmacies or hospitals to check if the same defective batch problem is being experienced in different institutions. The RO shall make a formal report back to the CRO.

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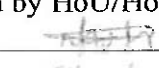
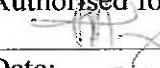
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- 7.6 After receiving a response from the client, the CRO shall convene a meeting (composed of the RO handling the matter, CRO, one SRO and two regulatory officers) to review the defect report, the response. The RO shall initiate a risk and impact assessment of the defect using the Product Defects Risk Assessment form (LEF 86) within 24hrs of receipt of the response considering but not limited to the following:
- 7.6.1 The type of the product
 - 7.6.2 The nature of the defect
 - 7.6.3 The extent of the defect
 - 7.6.4 The spread of the defect
 - 7.6.5 The clinical risk
 - 7.6.6 The report back as indicated in 7.5.
- 7.7 The risk assessment team shall consist of the RO handling the matter, CRO, one SRO and two regulatory officers.
- 7.8 After having considered all the available information, the risk assessment meeting shall make an informed recommendation on the appropriate action. The recommended actions may be one or more of those listed but not limited to those listed as follows:
- 7.8.1 Recall of the batches
 - 7.8.2 Quarantine of remaining stock at manufacturer / wholesaler / retailer before disposal.
 - 7.8.3 Follow-up GMP inspection.
 - 7.8.4 Further investigation and enforcement action.
 - 7.8.5 Distribution of information to all concerned health professionals.
 - 7.8.6 Testing of other batches / related products by the laboratory.
 - 7.8.7 Communication to regional or international partners.
 - 7.8.8 Public communication.
 - 7.8.9 Filing without follow-up (no further action)
- 7.9 For voluntary recalls that are initiated by manufacturers or wholesalers, the reporter shall be required to complete the form Recall Notification form (LEF62) available on MCAZ website. The received Recall Notification shall be handled as prescribed in this same procedure from item 7.6 – 7.8, with consideration of the submitted information and further clarification from the reporter where applicable.
- 7.10 After a decision has been made, the CRO shall assign a RO to draft a letter informing the client of the detailed course of action to be taken. This should be done within 24hrs of receipt of the initial response from the client.
- 7.10.1 In the situation where the risk assessment result considers the risk to patient health to be very low / negligible, the defect report can be filed (without follow up actions) with a recommendation to monitor for similar reports and the defect report is closed by the CRO. The RO shall review the risk / impact assessment and the draft letter for review by CRO within 48hrs of receipt.
- 7.11 Where the decision is an instruction to the client to institute a recall, the client should be informed to consider the timelines and instructions in the MCAZ Recall Guideline. The recall letter should first be reviewed by the HLED before being sent to the DG for signing. The risk assessment, defect report form and any other documentation supporting the decision should be attached to the draft letter.

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- 7.11.1 Decisions involving recalls, public communication, communication to international partners, and distribution of information to all concerned health professionals should be reviewed by the HLED first before they are sent to the DG for signing.
- 7.12 Where the decision is not a recall, the draft letters shall be reviewed and signed by the HLED.
- 7.13 During the recall the RO shall follow up on the client to ensure they submit all the reports as is instructed in the MCAZ Recall Guideline. The initial report shall be noted and filed in the file for defects and recalls.
- 7.14 When the client has completed the recall as per the Authority's instructions, they should submit a final recall report and a failure investigation report to the Authority.
- 7.15 The CRO shall assign an RO to do the first review of the final recall report and failure investigation report. The first review shall be done and sent to the CRO within 72hrs of being assigned the report. The CRO shall assign an SRO / themselves to do the second review of the final recall report. The second review shall be done within 48hrs of receipt of the assignment. The evaluations and reviews should be to assess among other things, the following.
- 7.15.1 The investigations carried out,
- 7.15.2 The findings of the investigations,
- 7.15.3 The recall success rate,
- 7.15.4 History of the incident.
- 7.15.5 Any other reports which may be related.
- 7.15.6 The distribution pattern of the batch (e.g. restricted to known hospitals, widespread through wholesalers, parallel distribution).
- 7.15.7 Volume of product in the market (e.g. total volume of product distributed with expiry dates, countries involved (for locally manufactured products) and the consumption rate of the product.
- 7.15.8 Authentication and/or distinguishing features that may be made known to the public.
- 7.15.9 Probability that other batches are affected in the same way, and their distribution.
- 7.15.10 Any remaining stock with the distributor.
- 7.15.11 Effectiveness of the recall (if a voluntary recall has been planned or carried out).
- 7.15.12 Details of the investigation(s) carried into the cause of the defect by the wholesaler / manufacturer.
- 7.15.13 Corrective/preventative/follow-up action taken/proposed by the wholesaler / manufacturer.
- 7.15.14 Overall conclusions.
- 7.16 For registered products the reports and evaluation report will then be tabled in the next relevant Committee meeting.
- 7.17 After the meetings, the course of action will be as recommended by the Committees.
- 7.17.1 For locally manufactured products, the defect reports and any other reports are tabled before the Licensing and Advertising Committee.

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- 7.17.2 For products manufactured outside of Zimbabwe, the defect reports and any other reports are tabled before the Evaluations and Registrations Committee
- 7.17.3 Staff should make recommendations for the disposal of all the affected products in quarantine to ensure they do not find their way back to the market and follow through any necessary destruction procedures. Evidence of such disposal should form part of the close out of the matter.
- 7.18 Inspectors shall be available to witness and verify, to the extent possible, the quarantine of suspected and SF medical products by inspecting, quantifying and securing the medicines at the concerned site. The same shall apply for disposal process where inspectors will need to first verify the recalled quantities of the products and all the quarantined products before disposal.
- 7.19 National Focal points:
- Handling of incidents of substandard and falsified medical products**
- 7.19.1 Shall conduct a search of the WHO database at soon as an incident of SF medical products has been detected and notified to him or her.
- 7.19.2 Upon completion of the investigation on the suspected SF product, the focal points shall inform the Head of Division and the Director General of the findings. The Director General shall consider conducting a national alert or notice to be made and or a Recall as stated in section 7.8 of the product from the market.
- 7.19.3 The national focal point shall subsequently report to the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
- 7.19.4 The regulatory officer shall record the details of the incident in file LED 057 .NOTE: A team of relevant regulatory specialists shall be set up which constitutes relevant external stakeholders/experts to discuss and make decisions on these alerts. The team shall focus on protection of public health, mitigating the risk posed by the substandard or falsified products and investigating the origin.
- * Records of all meetings and all decisions that are made shall be kept.
- 7.20 National Focal Points:
- Receiving and disseminating WHO alerts to the relevant organizations.**
- 7.20.1 Upon receiving the WHO International Alerts on Substandard and Falsified Medical Products in circulation globally, the focal person shall review the Alert and send an email to the following organizations:
- Public Hospitals Association of Zimbabwe
 - Retail Association of Zimbabwe
 - Development Partners
 - Ministry of Health and Child Care
 - Pharmaceutical Society of Zimbabwe (PSZ)
 - All technical Divisions
 - The PR Office for the website update

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7.20.2 The focal person shall also be responsible for sharing relevant alerts on Substandard and Falsified Medical Products reported in Zimbabwe with WHO and other relevant global organizations like ZAZIBONA and relevant African harmonization collaborations.

7.21 Methodologies for Detecting and Preventing Substandard and Falsified Medicines and Medical Devices

7.21.1 The RO shall ensure that the following methodologies are utilized in order to enhance detection and prevention of occurrence of SF medicines and medical devices on the Zimbabwean market (in accordance to Guidelines for the Notification of Medicinal Product Problem or Defect and Recall procedure in Zimbabwe)

- i. Maintaining a public database of authorized products, Marketing Authorization holders and authorized pharmaceutical manufacturers
- ii. Adhering to the Code of conduct/ethics for regulators
- iii. Adhering to the procedure for consignment verification at ports of Entry
- iv. Capacity building of stakeholders e.g Port Authorities, Clearing agents, Police force working at ports of entry
- v. Use of Authentication and detection technologies
- vi. Risk-based post-marketing surveillance

7.21.2 If the product is suspectedly falsified, the RO shall initiate a risk assessment to determine the severity of the product problem.

7.21.3 The RO shall conduct an investigation in conjunction with the Zimbabwe Republic Police, Criminal Investigation Department Drugs and Narcotics, within 24 hours for critical products and 48 hours for non-critical products.

7.21.4 The RO shall ensure that all the batches of the falsified medical product or medical devices, depending on the quantities shall either be confiscated and quarantined at MCAZ or quarantined at site whilst investigations are pending finalization.

7.21.5 Once investigations are done the products shall be disposed of at a designated destruction site and a certificate of destruction shall be issued.

8.0 APPENDICES/ATTACHMENTS

- 8.1 Attachment I: Medicine, Vaccine or Medical Device Product Problem/Defect Report (Form LEF 63)
- 8.2 Attachment II: Recall Notification (Form LEF 62)
- 8.3 Attachment III: Recall Reply (Form LEF 61)
- 8.4 Attachment IV: Final Report (Form LEF 60)
- 8.5 Attachment V: Medicinal Product Problem Report (Form LEF 80)
- 8.6 Attachment VI: Product Defects Risk Assessment (Form LEF 86)

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9.0 RECORDS

Document Number	Title of Record	Retention Period
LED 125	Defective Medicines Reports and Recalls File	5 years
LED 057	Product Defects/Recall Record Book	5 years

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records
- 10.3 Medicines and Allied Substances Control Act, [Chapter 15:03]
- 10.4 Medicines and Allied Substances Control (General) Regulations, Statutory Instrument 150 of 1991.
- 10.5 <https://www.who.int/medicines/publications/drugalerts/en/>
- 10.6 Guideline for Licensing and Enforcement Division, Code of Conduct for Inspectors
- 10.7 Guideline on Post Marketing Surveillance
- 10.8 Guidelines for the Notification of Medicinal Product Problem or Defect and Recall procedure in Zimbabwe

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	February 2018	Continuous improvement
1	November 2020	Continuous improvement
2	February 2022	Continuous improvement
3	September 2022	System improvement.
4	April 2023	System improvement

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