MEDICINES CONTROL AGENCY

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GUIDELINE FOR RECALL OF MEDICINES AND RELATED PRODUCTS

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TABLE OF CONTENTS

1. INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of medicines and related products in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

1.1.2. The Medicines and Related Products Regulations, 2019 ("Regulations") details the legal requirements.

1.2 BACKGROUND

1.2.1. When medicines or related products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy or lack of performance, they may be subjected to a recall.

1.2.2. Most recalls are initiated by marketing authorisation holders (MAHs), manufacturers/importers or distributors (suppliers) on a voluntary basis, or by medicines regulatory authorities.

1.2.3. The role of the MCA in a recall is to assess the adequacy of the decision on the recall of the product and to monitor the progress and effectiveness of the recall.

1.2.4. The MCA expects the MAH, manufacturer/importer or distributor to take full responsibility for recalls of medicines or related products, including follow-up checks to ensure that the recalls are successful and that corrective actions are taken.

1.2.5. If the recalling performance is deemed inadequate the MCA will take appropriate actions to remove the product from sale or use.

1.2.6. The MCA can also initiate the recall of medicines or related products in addition to 1.2.1 when registration thereof has been cancelled or when medicines or related products are sold illegally in The Gambia.

1.2.7. The MCA may instruct the MAH, manufacturer/importer or distributor to recall and dispose of the product according to the circumstances.

1.2.8. The MCA may alert the public of the product problem.

1.3 INTERPRETATION AND ABBREVIATIONS

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm**

1.4 PURPOSE AND SCOPE

1.4.1. The guideline is intended to ensure that in the event of a necessary recall, the recall operations are carried out appropriately by the MAH, manufacturer/importer or distributor in order to safeguard public health.

1.4.2. The guideline applies to medicines and related products as defined in the Act and the Regulations.

2. NOTIFICATION / INITIATION OF A RECALL

2.1. The recall can be initiated as a result of reports or complaints on quality, safety or efficacy of a medicine or related product by the MAH, manufacturer/importer and distributor or referred to them from various sources such as manufacturers, wholesalers, retailers and hospital pharmacies, research institutes, medical practitioners, dentists, patients, MCA, foreign regulatory authorities and World Health Organization (WHO).

2.2. A report may relate to an adverse drug reaction of a particular batch(es), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, substandard or falsified product including adulterated medicines, or faulty related products such as medical devices or non-performance of a medical device, etc.

2.3. A recall might also be initiated nationally as a result of analysis and testing of samples of medicines or related products by the manufacturer or MCA. Recall of medicines or related products manufactured outside of The Gambia might be initiated by the MCA or foreign regulatory authorities, or from information received directly from such authorities.

2.4. It is imperative that before or upon initiating a recall, the applicant immediately (within 24 hours) on becoming aware of a problem, notifies the MCA of the potential recall in writing by email (info@mca.gm) or deliver by hand. Therefore it is advisable that no recall, regardless of the level, should be undertaken without consultation with the MCA and without agreement on the recall strategy.

2.5. However, in case of a potential significant health hazard to patients, the MAH, manufacturer/importer or distributor may disseminate information on the recall immediately. This includes precautionary measures to quarantine stock whilst in contact with MCA for appropriate action.

2.6. The MAH, manufacturer/importer or distributor shall not wait to notify the MCA until ALL applicable information is prepared and assembled. This immediate notification is necessary to allow the MCA to review and comment on the written notification and to offer guidance and assistance in the recall process.

3. INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL

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

3.2. The MAH, manufacturer/importer or distributor should gather all relevant information on the recall, which includes the product, its distribution channels, and action proposed.

3.3. 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 in Section 3.8.

3.4. The MAH, manufacturer/importer or distributor should make available to the MCA all the relevant information regarding the recall on the **Recall Information Form** (MCA-F-303/01), available on the MCA website www.mca.gm. The information required may be included in the form but not only limited to it.

3.5. In determining the recall strategy, the MAH, manufacturer/importer or distributor should consider the factors which may affect the duration of the recall action and should inform the MCA.

3.6. When the required information is available, the appropriate strategy should be proposed to the MCA. The proposed recall strategy should be agreed by the MCA before implementation (see Section 2.4). The actual implementation of the recall includes use of the basic steps which are summarised in Appendix 1 and these will be common to all strategies.

3.7. The recall should be completed by the date as agreed with the MCA.

3.8. In the recall strategy, the MAH, manufacturer/importer or distributor should mention the following:

- Indicate the proposed level in the distribution chain to which the recall is extending (see type of recall below), if the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;
- In case of *consumer level* recall, additional information should be mentioned:
  - Indicate the location of recall spots for consumers (preferably not less than 7 recall spots covering the seven health regions), their operation time and duration as appropriate;
  - Indicate the hotlines number(s) for enquiry and the corresponding operating hours;
- Indicate the method of recall notification (e.g. mail, phone, facsimile, email);
- Indicate how the message of recall will be delivered to customers e.g. press release or recall letters, etc;
- If the MAH, manufacturer/importer or distributor has a website, it should be considered posting the recall notification on it as an additional method of recall notification;
- Report on what have the customers been instructed to do with the recalled product;
- If products are to be returned, explain the mechanism of the process;
- Explain if the recall will create a market shortage that will impact on the consumer;
- Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to manufacturer;
- Inform MCA before product destruction, the proposed method of destruction would be reviewed and MCA to witness the destruction

exercise. For details on destruction refer to the MCA guideline for Safe Disposal of Medicines and Related Products.

4. CLASSIFICATION AND TYPES (LEVELS) OF RECALLS

Classes

4.1. Recalls are classified into both the **class** according to the level of health hazard involved (risk to the patient) and **type** which denotes the depth or extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc.

4.2. Class I or Class II recalls are considered to be urgent safety-related recalls and must be reported to the MCA immediately for further evaluation and investigation.

4.3. Class III recalls are considered to be non-safety-related recalls.

4.4. Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. Expert advice might be sought where the nature of the hazard or its significance is not clear.

4.5. Decisions on the Class and Type (Level) of a recall to be initiated are a matter of the MCA in consultation with the MAH, manufacturer/importer or distributor and shall be based on the evidence and/or expert opinion of the MCA.

Classification	Description	Examples
Class I (Safety related)	Product defects are dangerous/ potentially life-threatening that predictably or probably could result in serious health risk/adverse reactions or even death and could cause permanent debilitating health issues.	• Wrong Product (label and contents are different products) • Correct product but wrong strength, with serious medical consequences • Microbial contamination of sterile injection or ophthalmic product • Chemical contamination with serious medical consequences • Mix up of some products ("rogues") with more than one container involved • Wrong active ingredient in a multi-component product with serious medical consequences
Class II (Safety related)	Product defects could cause illness, temporary or medically reversible adverse health problem or mistreatment and the recovery of the patient is likely	• Mislabelling 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 ("rogues") • 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)

Class III (Non-Safety related)	Product defects may not pose a significant hazard to health, but is defective and is unlikely to cause any adverse health reaction; withdrawal may be initiated for other reasons, or which do not comply with the regulatory requirements in terms of printed packaging material, product specification, labelling, etc.	• Faulty packaging e.g. wrong or missing batch number or expiry date • Faulty closure • Contamination- microbial spoilage, dirt or detritus, particulate matter

Types (Level)

4.6. In determining the recall type (level or depth), the principal factors to be considered are the significance of the hazard (if any), the channels by which the medicines or related products have been distributed, and the level to which distribution has taken place.

4.7. There are three types of recalls, A, B and C.

Type A

4.8. A type A recall is designed to reach all suppliers of medicines or related products (all distribution points) i.e. hospitals, health centres, clinics (public as well as private), wholesalers, central medical store, regional medical stores, retailers and individual customers or patients through press release (radio, television, print media).
Action: Recall letter to all distribution points plus press release.

Type B

4.9. A type B recall is designed to reach hospitals, health centres, clinics (public as well as private), wholesalers, central medical store (CMS), regional medical stores (RMS), and retailers.
Action: Recall letter to all distribution points.

Type C

4.10. A type C recall is designed to reach wholesale level, CMS, RMS, hospitals and clinics which can be reached by means of a representative calling on.
Action: Recall letters to representatives at distribution points where the medicines or related product have been distributed.

5. RECALL LETTERS AND PRESS RELEASE

Letters

5.1. Recall letters should include factual statements of the reasons for the recall of the product, together with special details that will allow the product to be easily identified.

5.2. The text of the recall letter is to be sent to the MCA for approval before being despatched.

5.3. The approved recall letter may be sent within 24 hours of receiving approval and a signed copy of the approved recall letter is to be sent to the MCA.

5.4. If safety to the public is involved and distribution is limited, the MAH, manufacturer/importer or distributor may contact the clients of the information listed below by telephone and followed by a recall letter.

5.5. Recall communication from the MAH, manufacturer/importer or distributor to the distribution chain should be written in accordance with the following:

- Should be on the company's letterhead and signed by the Responsible Pharmacist or authorised person.
- The subject of the letter should indicate that it is an **"Urgent Medicine Recall" or "Urgent Related Product Recall".**
- The heading should also indicate the classification and type of the recall.
- Name of the product and manufacturer and where applicable the dosage form, strength, registration number, pack size, batch number(s), expiry date and any other relevant information necessary to allow absolute identification.
- Nature of the defect (brief and to the point).
- Urgency of the action.
- Reason for the recall.
- Indication of a health risk (this should also state exactly what the product may do if taken, i.e. adverse reactions). It should be made clear that further distribution or use of the product should cease immediately.
- Provide specific information on what should be done in respect of the recalled medicine or related product and method of recovery or product correction, which will be used.
- Contact telephone number and facsimile return numbers or email addresses.
- There should be a request for a written response to confirm receipt and understanding of the action to be taken.
- Where necessary a follow-up communication shall be sent to those who failed to respond to the initial recall communication.
- Where recalled stock has been distributed to a limited number of facilities and the recall letter is not to be sent to all facilities, the letter should include the following:

  "*If any of the recalled stock could have been transferred from your facility to another, please let that facility know or alternatively inform us so that we can make contact with the facility supplied from your facility*".

Press Release

5.6. 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.

5.7. In the case of a recall where a press release is indicated, jointly the MAH, manufacturer/importer or distributor and the MCA make the text of the press release.

5.8. The press release should contain sufficient and relevant details to uniquely define the product, together with a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the consumer/client.

5.9. The media release will be issued by the MAH, manufacturer/importer or distributor and an access telephone number of the MAH, manufacturer/importer or distributor should be given for further information.

5.10. In the event that the MAH, manufacturer/importer or distributor refuses to do a press release the MCA will do the release.

5.11. The choice of the media should be done in consultation with the MCA and consideration should be given to the need to inform the public in the major local languages.

5.12. The MCA will publish the recall details in the form of a notice on the MCA website.

6. RESPONSIBILITIES OF MAH, MANUFACTURER/IMPORTER OR DISTRIBUTOR

6.1. MAH, manufacturer/importer or distributor are responsible to maintain records and establish procedures which will facilitate a recall and taking the prime responsibility for implementing a recall where it is necessary including the costs.

6.2. The complete records pertaining to distribution should be retained for one year after the expiry date of each batch (see MCA *Guideline for Storage and Distribution of Medicines and Related Products*).

6.3. The MAH, manufacturer/importer or distributor as well as the MCA 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.

6.4. Recalled medicines should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

6.5. The particular storage conditions applicable to medicines which are subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question (see MCA *Guideline for Storage and Distribution of Medicines and Related Products*)

7. POST RECALL PROCEDURES

7.1. Within two weeks of the recall having been instituted the MCA shall be furnished by the MAH, manufacturer/importer or distributor with a final report on the effectiveness of the recall on the **Recall Report Form** (MCA-F-303/02), available from the MCA website www.mca.gm.

7.2. The report should include but not limited to the following:

- Details on the investigation into the cause of the defect.
- The corrective actions proposed/implemented and the dates of implementation to prevent a recurrence of the problem.
- The extent of distribution of the relevant batch in The Gambia as well as outside.
- The success of the recall i.e. quantity of stock returned, corrected, outstanding, etc.
- Confirmation, where applicable, (e.g. wholesalers, health facilities, retailers customers, other international regulatory authorities) that the recall letter was received.
- The method of disposal of the recalled goods.

7.3. The MAH, manufacturer/importer or distributor should report to the MCA with relevant explanation and obtain its approval if the final report cannot be submitted within two weeks after commencing of the recall.

7.4. The report establishes the effectiveness of the recall. Unless satisfactory report is received, further recall action may have to be considered.

8. EVALUATION OF THE RECALL

8.1. 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.

8.2. The MCA shall evaluate the reports received from the recalling site and an assessment made of the effectiveness of the recall action. In some cases the MCA may contact a percentage of customers in the distribution list as a means of assuring the MAH, manufacturer/importer or distributor is carrying out its recall responsibilities.

8.3. The MAH, manufacturer/importer or distributor shall identify the root cause of the problem and implement the corrective and preventive actions accordingly.

8.4. On completion of a recall or during the process of a recall, the MAH, manufacturer/importer or distributor is requested to provide details of the corrective actions and time lines proposed to prevent a recurrence of the problem which gave rise to the recall.

8.5. Where the nature of the problem and appropriate corrective actions are not apparent, investigation and in some cases Pharmacovigilance and/or Good Manufacturing Practice inspections or audits may be necessary (refer to MCA *Guidelines for National Pharmacovigilance System* and MCA *Guideline for Inspections by the Medicines Control Agency*).

8.6. Apparent follow-up actions will be taken by the MCA. This might include a review of the medicine dossier by the MCA and any appropriate action instituted by the MCA based on the outcome of the review of the applicable dossier.

8.7. Once the recall has been handled satisfactory, the MCA will determine closure of the recall.

8.8. Where a recall is initiated following a report submitted by a foreign regulatory authority, the reporter should be provided with an outline of the results of investigation and a summary of the recall.

9. REINSTATEMENT OF SUPPLY

9.1. The quality of the products shall conform to specific requirements before resuming the supply to public. The MAH, manufacturer/importer or distributor must seek approval from MCA before **reinstatement of the medicines previously recalled**.

9.2. After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the MAH, manufacturer/importer or distributor shall submit analytical report(s) of the new batch tested to the MCA as a proof of product quality that will be evaluated by the MCA.

9.3. After evaluation the MCA will inform the MAH, manufacturer/importer or distributor whether the submitted reports are satisfactory.

9.4. The MCA may take samples of the first three batches of the product for testing and will inform the MAH, manufacturer/importer or distributor whether the analytical test was satisfactory.

10. FINAL PROVISIONS

10.1. This guideline is the second version published by the MCA and will become effective on 01 July 2020.

10.2. The guideline will be reviewed within 5 years of becoming effective.

11. DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	25 July 2017	New document
2	01 July 2020	Editorial changes

APPENDIX 1: FLOW CHART ON RECALL STAGES