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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Quality Defects and Product Recall

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Guideline for Quality Defects and Product Recall

1 INTRODUCTION

The Maldives Food and Drug Authority (MFDA) takes appropriate action to safeguard the public from defective, substandard, and falsified medicinal products which may potentially present a significant risk to the consumer. Defects in quality, safety, and efficacy of a product can occur during manufacture, storage, and transportation. These products pose an immense risk to public health. Hence, necessary actions are taken to remove a specific batch of a product or a particular product from the market. Recalls or withdrawals of products are necessary to ensure that unlicensed/unauthorized medicines and substandard and falsified medicines are removed from the market.

When a defective product in the distribution chain is identified, importers, distributors and retailers have to work in close collaboration with the MFDA. The responsibility for recall of a medicines lies with the Marketing Authorization holder/ Medicine Registration Certificate holder. Medicine importers, retailers, and manufacturers shall establish effective product recall procedures. MFDA has the authority to notify and instruct importers, distributors, retailers, or any appropriate person to immediately stop the distribution and sale of the medicinal products, and to notify and instruct health professionals and product users to stop the use of the particular medicinal products. The MFDA takes appropriate measures to ensure that product recalls and recall activities are undertaken in a timely and appropriate manner.

Definitions:

Falsified medicines: Products that deliberately or fraudulently mispresent their identity, composition, or source.

Recall: means the removal of specific batch/batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety or efficacy.

Substandard: authorized medical products that fail to meet quality standards and specifications.

Suspected Defective Products: Products with non-conformities.

Unregistered/ unapproved: products that are not authorized for sale in the Maldives and are not

included in the Approved Drug List published by MFDA.

Withdrawal: means the total withdrawal of a medicinal product from the market

2 PURPOSE

This guideline is intended to serve as a guidance for pharmaceutical manufacturers, distributors, and consumers regarding reporting quality defects in medicines, product recalls and withdrawals. This guideline aims to inform the stakeholders about the actions that will be taken by MFDA and outline the role of the stakeholders.

It is intended to ensure that in the event of a necessary recall or withdrawal, the operations are standardized, and effectively and efficiently carried out by MFDA and stakeholders in order to safeguard public health.

3 SCOPE

This guideline defines the actions and responsibilities for reporting quality defects, the handling of product recalls and withdrawals of suspected or evidently defective or unlicensed/unauthorized medicinal products from the market. It does not apply for reporting Adverse Drug Reactions, or incidents during the administration of medicines.

4 Defective medicinal products

4.1 What are defective, substandard, and falsified products?

4.1.1 Defective products are products that does not conform to its specifications and quality requirements defined by their marketing authorization. These non-conformities include defects in product integrity (e.g. crushed pills, solidified or crystallized syrups), defective packaging (e.g. broken blister packs), and labelling.

4.1.2 Product defects shall not be confused with Adverse Drug Reactions (ADR) where undesirable side effects are observed after consumption of a product conforming to its specifications.

4.1.3 Changes in efficacy and side effects may be observed when medicine brands or generics are

switched and consumers shall contact a medical health professional or a pharmacist if there are any concerns.

4.2 Who can report?

4.2.1 Anyone who recognizes or suspects a quality defect can report quality defects. These include:

- Consumers/patients/public
- Doctors
- Nurses
- Medicine Importers
- Pharmacists/ Pharmacies
- Manufacturers
- Distributors

4.3 Recognizing defective, substandard, and falsified products

4.3.1 The following table lists the nature of substandard and falsified medicines and some of the features of defective, substandard, and falsified products that can be recognized without extensive analysis.

Defective Products	Substandard Products	Falsified Products
What to look out for: ▪ Product mix up (product name and content do not match) ▪ Product contamination ▪ Falsified medicines ▪ Leakage/ lack of integrity of containers of liquids, cracks in vials, leaks in infusion bags, faulty container closure for sterile products, etc. ▪ Non-compliant	▪ Inadequate amounts of active ingredients ▪ Formulation different from registered formulation ▪ Contains ingredients that are not safe or harmful ▪ Impurities or contamination of products ▪ Fails to meet stability standards	▪ Deliberate and deceitful/ fraudulent misrepresentation of their identity (name, labelling, or packaging), composition (ingredients, component), and source (name, address, manufacturer, importer/distributor, etc.) ▪ Substitution, adulteration, reproduction of an authorized product ▪ Manufacture of a product that is not authorized **What to look out for:**

carton/label/leaflet (typos, or omission of words) ▪ Damaged cartons or containers or packaging ▪ Broken or crumbling tablets ▪ Missing tablets or units of medicines ▪ Missing labels or leaflets ▪ Products that are unapproved or unauthorized for sale in the Maldives (not listed in Approved Drug List) ▪ Tampered product packaging	**What to look out for:** ▪ Inadequate packaging design or quality ▪ Spelling mistakes in the packaging ▪ A patient fails to respond to treatment ▪ Unusual Adverse Drug Reactions occur ▪ Unusual appearance or smell	▪ Inconsistent documentation ▪ Unexpected stock levels ▪ Spelling mistakes, unusual batch numbers, unusual printing, unusual shelf life, unusual or unexpected or modified manufacturing or expiry dates, signs of repacking

4.4 What do you do if you find a defect?

4.4.1 Marketing authorization holders are obliged to report to MFDA any suspected product quality defects of medicines imported to or manufactured in the Maldives. This includes restrictions set by competent authorities of other countries where the product is marketed, or any other new information that will affect the risk-benefit assessment of the product.

4.4.2 If you suspect a medicine you are taking is defective, to ensure that you do not stop your treatment, see a doctor to continue the treatment or consult a pharmacist to clarify the issue. They can also guide you to differentiate between Adverse Drug Reactions (ADR) and product quality defects. For guidance on ADR reporting refer to the Guideline on Pharmacovigilance and ADR reporting.

4.5 How to report?

4.5.1 Suspected defects shall be reported to MFDA. You can report defective products via

- Completed Quality Defect Reporting Form (MTG/QA-QD/Fo 0054),
- Customer Complaint and Incident Form (ADM/QP-CI/Fo 0004),

- An email to mtg@health.gov.mv,
- Phone call to 3014322, 3014316
- In person to the head office of MFDA located at Roashanee Building, K.Male'; or
- A call to the hotline number (7200321) that is established for after office hour emergencies.

4.5.2 MFDA will promptly respond to quality defects, and within two weeks from the date of notification of the issue, inform the complainant of the actions taken.

4.5.3 The suspected defective product shall be retained and preserved as they may be required for analysis. More samples may also be taken from the same batch for analysis.

4.6 International Rapid Alert System

4.6.1 In addition to local reports of quality defects, MFDA as the competent authority in the Maldives receives international alerts regarding product defects generated by other competent authorities through the rapid alert system established by WHO (World Health Organization).

4.6.2 DDG, Pharmaceuticals of Medicine and Therapeutic Goods division (MTG), MFDA, is the designated focal point for Maldives for WHO rapid alert system.

5 MFDA's response to quality defect reports

5.1.1 MFDA will collect product and incident information required for assessment and investigation of the issues reported.

5.2 How do we assess and investigate quality defects?

5.2.1 Once a suspected defective medicine is reported to MFDA, the MFDA will carry out an assessment, investigation and if necessary, inspections of facilities.

5.2.2 **International Alerts:** Once an international alert is received, MFDA checks whether the product has been imported to the Maldives. All medicines imported/cleared for importation are monitored by the pharmaceutical units established at the ports of entry. If a medicine has been imported to the country, a recall or withdrawal as appropriate will be announced and publicized. The recall and withdrawal procedure is outlined in point 6.

5.2.3 **Local reports:** for locally reported defects, cases are dealt on a case by case basis according to the urgency indicated by the nature of the defect. Depending on the nature of the defect reported, MFDA assesses and identifies the root cause of the problem and take necessary corrective and preventive actions.

5.2.4 During this assessment and analysis of a defect, MFDA may conduct interviews, inspections of the pharmacies, warehouses, and health facilities, conduct laboratory testing of the products at the National Health Laboratory (NHL) or from referral laboratories and conduct a health hazard assessment.

5.2.5 Based on the nature of the root cause, and level of risk, appropriate action will be taken. If there is a quality defect in the product, actions could include disposal of the products kept at a particular location, or recall a particular batch or withdraw the particular type of product from the market all together. If a statutory requirement has not been met, legal actions as defined in the legislation will be taken against the perpetrators.

5.2.6 ☞ **Furthermore, based on the nature of the root cause, and level of risk, the manufacturer maybe suspended for a designated time or blacklisted. The decision shall be made through the National Pharmaceutical Board.**

5.3 Classification

5.3.1 On the basis of the nature, consequence or urgency of the quality defect, a decision on the recall action is made and the MFDA will assign the recall in accordance to the recall classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

5.3.2 Recalls are classified into a numerical designation (I, II, or III) to indicate the relative degree of health hazard presented by the product being recalled.

Class	Definition	Possible strategies
Class I	Reasonable probability that the use of, or exposure to, the product will cause serious	▪ Immediate nationwide product recall ▪ Public announcement/ Press release ▪ Recall letter to all distribution points

	adverse health effects and may even cause death e.g.: microbial or chemical contamination of sterile products, wrong active ingredient, etc.	▪ Product ban ▪ Legal actions
Class II	Use of, or exposure to, the product may cause temporary or medically reversible adverse health effects e.g.: lack of efficacy, improper closure, mislabeling, etc.	▪ Public announcement/ Press release ▪ Recall letter to all distribution points ▪ Nationwide/local product recall ▪ Product ban ▪ Legal actions
Class III	Use of, or exposure to, the product is not likely to cause adverse health consequences e.g.: faulty packing or labelling	▪ Public announcement/ Press release ▪ Nationwide/local/ wholesale/retail level product recall ▪ Legal actions

6 Product recalls and withdrawals

6.1 Who authorizes or initiates a recall?

6.1.1 Product recall and withdrawals shall always be authorized by MFDA in consultation with the National Pharmaceutical Board and Policy Executive level of the Ministry of Health.

6.1.2 MFDA is authorized to initiate a product recall (statutory recall) after analyzing quality defects or international rapid alerts reported to MFDA.

6.1.3 Medicine importers, retailers, and manufacturers can also initiate voluntary recalls due to issues related to quality, efficacy, or safety of the products. Voluntary recalls have to be informed to and authorized by MFDA prior to being recalled.

6.1.4 Medicine importers, retailers, and manufacturers shall establish effective product recall procedures to ensure risk to public health is minimized. Identifying the distribution chain is important for a product recall. Hence, medicine importers and pharmacies shall keep and maintain records of the details of the medicines supplied, in stock, and sold. The medicine

suppliers and distributors shall have procedures in place that outlines the actions to be taken when a recall notice is given and must inform all the customers that received the stock of the medicines being recalled.

6.1.5 Two-way communication channels and contact points should be established between MFDA and the medicine suppliers, distributors, or pharmacies. The MFDA will work with the marketing authorization holder, or with importers if parallel imports are allowed.

6.2 How is a product recall conducted?

6.2.1 Once the decision has been made to recall a product, in accordance to the recall classification, that is posing a significant health hazard, the product recall process is to be initiated.

6.2.2 Each recall is unique and requires its own recall process and will take into account the following factors as they apply to the individual circumstances of the particular recall.

a. Results of health hazard assessment
b. Ease in identifying the product.
c. Degree to which the product's defect is obvious to the consumer or user.
d. Degree to which the product remains unused in the market place.

6.2.3 Recall process will address the following elements regarding the conduct of the recall.

6.2.3.1 **Depth of recall**: depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend. For example, to the consumer level, or a certain storage location in case of defects related to storage, etc.

6.2.3.2 **Public announcement:** Based on the risk to consumers or public health, a public announcement will be issued. The purpose of this is to inform and alert the public and the prescribers that a product is recalled due to products quality defects which can pose a threat to the users.

6.2.3.3 **Effectiveness checks**: the method for effectiveness checks will be determined as appropriate for or corresponding to the depth of recall. The persons or establishments specified in the

depth of recall are contacted by personal visits (as inspections), telephone calls, letters, or a combination thereof to verify that they:

a. have received notification about the recall;
b. removed the products from sale;
c. Completed the recall action as specified in the notice;
d. Put a halt on the product in the storage; and
e. Put a halt on the further import of the product.

6.3 How do you know if a product is being recalled?

6.3.1 MFDA will publish all recalls on the MFDA's or Ministry of Health's website, or social media accounts, and on the earliest issue of government gazette to ensure that the public is warned about products that are hazardous to health.

6.3.2 **Press Release:** In case of nationwide recalls or withdrawals, a press release will be issued. Issuance of a press release will be the highest priority and it will be issued promptly. Unique situations will be handled on a case-by-case basis.

6.3.3 **Written Recall Notification Letters:** Written recall notifications in the form of official letters will be sent to the product importer/importers and distributors. The recall notification letter will include the following information:

a. product identification:
- Include an accurate and complete description of the product, e.g. lot/unit numbers, expiration date, dosage form, pack size, etc.

b. description of the problem:
- Identify the problem and any potential health hazard(s) associated with it;
- Necessity to identify and quarantine the product from further sale or supply

c. depth of the recall:
- The recall notification letter will clearly identify the depth to which the recall is to extend (e.g. wholesale, retail, or user level).
- If the product could have been further distributed, then instructions to sub recall will be included. Sub recall instruction will also include the depth of the recall, e.g. "If you have further distributed this product, you should notify your customers to the retail level."
- If importers are instructed to conduct sub recalls, it is advisable to provide the date range that the recalled product was distributed and also to give a time frame to collect the product

d. **Instructions to customers/distributors:** The recall instructions will be clear. For example:
   - Cease distribution (temporarily)
   - Sub recall (if appropriate)
   - Return product/ disposal

e. **Contact Details of MFDA:** focal points or hotline numbers to be contacted will be given.

6.4 What do we do during a recall?

6.4.1 Based on the class of the recall a decision on inspection of all pharmacies, go downs, etc. will be made and conducted by monitoring and surveillance unit of the Medicine and Therapeutic Goods division(MTG) of MFDA. Establishment inspection will, in addition to other activities, determine the root causes of the problem in case of storage or transport violations, and document these violations for possible regulatory action, and evaluate overall compliance.

6.4.2 Products will be removed from retails shelves after informing the store or pharmacy management of the recall to ensure that products in storage, in transit to the store, or returned by customers, are not offered for sale. Stock of recalled products located in pharmacies and warehouses or other -storage facilities shall and will be identified and clearly marked. These products shall be isolated from other stock to prevent distribution.

6.5 What happens to the recalled products?

6.5.1 All recalled items shall be disposed in a way that will ensure that unsafe products do not make their way back into the market place. For guidance on medicine disposal, refer to Guideline for Medicine Disposal (MTG/RE-MD/GLN-TE 004).

6.6 What happens after a recall?

6.6.1 A report will be written after the implementation of a recall. The purpose of this report is to establish the effectiveness of the product recall. The report will contain the following information:

a. The circumstances leading to the recall;
b. The consequent action taken;
c. The extent of distribution of the relevant batch in the Maldives;
d. The result of the recall- quantity of stock returned, disposed, outstanding, etc.;
e. Confirmation that customers have received the recall letter;
f. The method of destruction or disposal of recalled goods; and

g. The action proposed to be implemented in future to prevent a recurrence of the problem.

7 Related documents

- Medicine Regulation (Regulation No.: 2014/R-46)
- Guideline for Medicine Disposal
- Guideline on Pharmacovigilance and ADR reporting

Contact

- Hotline Number: 7200321
- E-mail: mtg@health.gov.mv