Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum
The Head of Medical Services in LNG Oman
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES
MARKETING AUTHORISATION HOLDERS

After Compliments,

Please find attached our Circular No.....73..... dated 23/09/15 regarding Guideline for Medicines & Pharmaceutical Products recall procedure.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU

dg-padc@moh.gov.om ص.ب رقم : ٣٩٣ مسقط - الرمز البريدي : ١٠٠ ، هاتف : ٢٢٣٥٧١١١ ، فاكس : ٢٢٣٥٨٤٨٩، البريد الإلكتروني :
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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Circular No. 73 / 2019

23-01-1441 H
23-09-2019

Guideline for Medicines and Pharmaceutical Products Recall Procedure Version 1, September 2019

Pharmacovigilance plays an important role in ensuring safety of medicinal products. Reporting, investigating and recalling suspected defective medicinal products are integral part of Pharmacovigilance. A guideline for Medicines and Pharmaceutical Products recall procedure is prepared to help healthcare professionals/MAH/Local agents/consumers and the public to understand the steps involved in the system.

Please follow the link in the Ministry of Health website –"Guideline for Medicines and Pharmaceutical Products recall procedure".

MAH & wholesalers are requested to adhere to the guideline, for any future recall process, effective from 01/10/2019. An Arabic version of the Guideline is also available.

For reporting side effects
Department of Pharmacovigilance & Drug Information
Phone No. +968 22357686, 7687
Fax: +968 22358489
website: www.moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs & Drug Control

Department of Pharmacovigilance & Drug Information

Guideline for Medicines & Pharmaceutical Products Recall Procedure

Version 1, September 2019

Content

1. Introduction

When medicines (human/herbal), vaccines, biologicals, medical devices-containing medicine and health 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 Department of Pharmacovigilance & Drug Information (DPV&DI).

Reports of suspected quality problems are received from different sources, such as healthcare professionals (doctors, pharmacists etc.), patients, pharmaceutical manufactures and the public. The Central Quality Control Lab (CQCL) in the Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC) may also report confirmed out of specification results from testing medicines on the market, as part of post marketing surveillance.

The DPV&DI asses the nature of product problem/defect and the adequacy of the recall of the product and monitor the progress and effectiveness of the recall.

This guideline is 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 the local agent in order to safeguard public health.

2. Definitions & Abbreviations

Definitions

Batch Recall:

The action of withdrawing specific batch/batches of a medicinal product from the distribution chain and users for reasons relating to deficiencies in the quality, safety or efficacy.

Depth of recall:

Level with the distribution channel from which a product is recalled, i.e. wholesale, retail, patient/consumer.

Abbreviations

cGMP: Current Good Manufacturing Practice
CQCLD: Central Quality Control Lab Department
DGPA&DC: Directorate General of Pharmaceutical Affairs & Drug Control
DPV&DI: Department of Pharmacovigilance & Drug Information
MOH: Ministry of Health

3. Recall Classification

Recall classification is based on the risk impact to patients/public. They are: **Class I**, **Class II** and **Class III**.

Class	Definitions & Examples
Class I	This recall occurs when products are potentially life-threatening or could cause a serious risk to health. **Examples:** • 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 threatening condition.
Class II	This recall occurs when product defects could cause illness or mistreatment, but are not Class I. **Examples:** • 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.

Class III	This recall occurs when product defects may not pose a significant hazard to health i.e. low risk to health but recall may be initiated for other reasons, due to quality, safety or efficacy concerns. **Examples:** • Faulty packaging e.g. wrong or missing batch number or expiry date. • Faulty closure. • Contamination, e.g. microbial spoilage, dirt or detritus, particulate.

Note:

1. Class I or **Class II recalls** are considered to be urgent safety-related recalls.

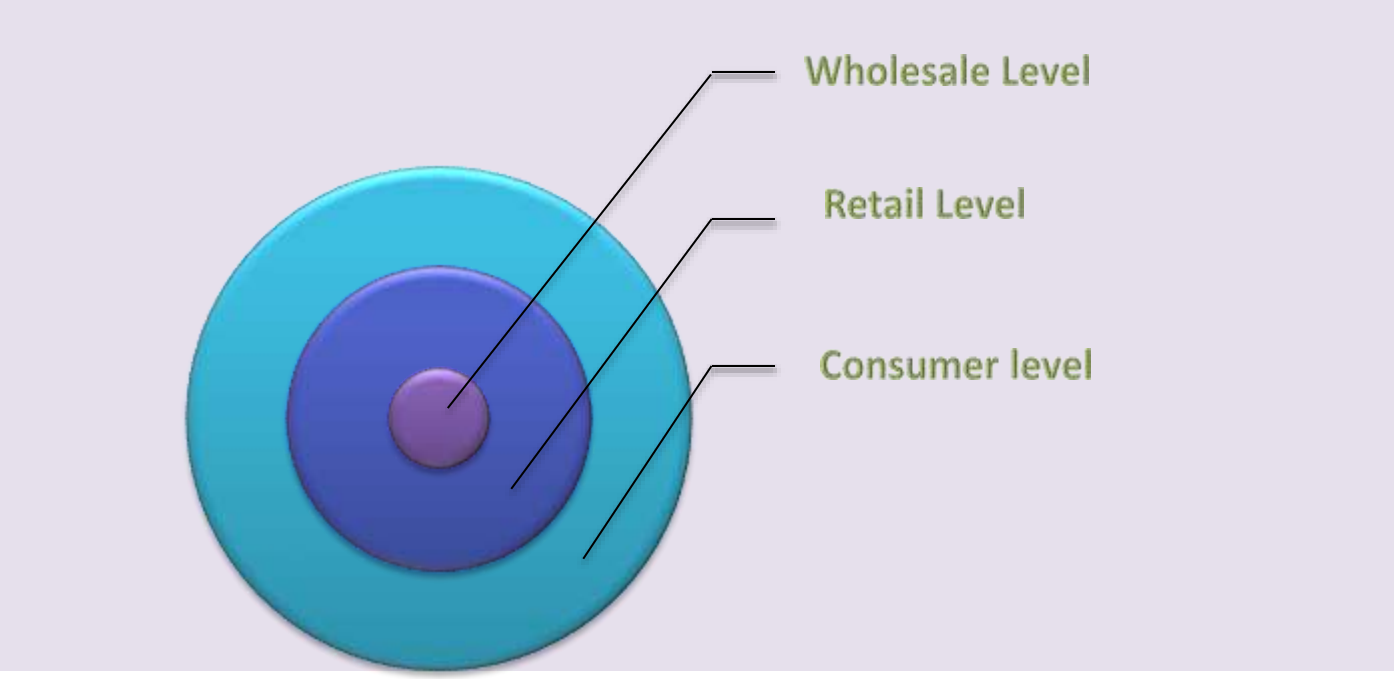
2. Class III recalls is considered to be routine non safety-related recalls.

3. Recall Levels

The main factors to be considered when determining the level (or depth) of a recall are the significance of the risk, and the channels by which the products have been distributed.

Level	Definition
Wholesale level	Includes all parties involved in wholesale distribution (medical stores) and suppliers.
Retail Level	Include: • All government and private health institutions • Community pharmacies • Healthcare professionals • May also include wholesales
Consumer Level	• Patients and other consumers • May include: wholesale and retail levels

The following diagram shows the levels of recall.



4. Recall Process

Recall Process describes actions that may be taken to protect the public when a defective or potential harmful product has been identified.

The recall process involves three stages:

Stage 1. Initiation of recall:

- Notification & Problem identification
- Hazard/risk assessment (classification and level) & decision to recall

Stage 2. Implementation:

- Recall Circular
- Media Release

Stage 3. Evaluation of the Recall

- Effectiveness of recall action
- Investigation of the reasons for recall and remedial action
- Completion of recall

Stage 1: Initiation of Recall

1. Notification & Problem Identification:

- Recall might be initiated as a result of reports or complaints on quality, safety or efficacy on a medicine (human or herbal), vaccine, or biological, medical devices-containing medicine, or health products referred to the DPV&DI from a variety of sources.
- The reports or complaints may be referred by healthcare professionals (doctors, pharmacist etc.), patients, public and pharmaceutical manufacturers.
- Recall might also be initiated as a result of analysis and testing of samples of medicinal products by the CQCLD for batch samples that do not meet specifications such as assay, impurities etc.
- Recalls of pharmaceutical products manufactured overseas might be initiated by the local or overseas health authorities, or from information received directly from such authorities, however, the recall circular will be issued by DGPA&DC.

2. Hazard/ Risk Assessment & decision to recall:

Certain information is essential to permit the assessment of the validity of the drug quality problem report. The DPV&DI should gather all relevant information on the recall before the initiation of the recall.

Stage 2: Implementation

1. Issue Recall Circular

The DGPA&DC will issue a recall circular **(Annex 1)** with a statement of the reason(s) for the recall, together with specific details that allow the product to be easily identified. The circular may be sent by email, facsimile to the client. Also the circular will be announced on the MOH website.

For Class I & Class II, In case the announcement is made on the social media, patients & consumers must be warned to stop taking the affected medicine (s) and seek for the replacement from the concerned health facility.

The recall circular should include:

a. **Description of the pharmaceutical product:**
   - Product name
   - Manufacturer
   - Pack size
   - Dosage form
   - Batch number
   - Expiry date

b. **Reason for the recall:**
   - The reason for the recall should be concisely explained.
   - It should be made clear that further distribution or use of the product should stop immediately.

c. **Instruction for recall of the product:**
   - Specific information on what should be done in respect of the recalled product.

2. Media Release:
   - The media release should contain sufficient and relevant details of the recalled product, together with a clear outline of the problem (without causing unnecessary alarm).

Stage 3: Evaluation of the recall

1. Effectiveness of recall action
    - It is the local agent responsibility to assure that the recall is effective.
    - The local agent should provide the DPV&DI with **Progress Report (Annex 2)**, generally within **seven** calendar days after initiation of the recall action, and other times as required.
2. Investigation of the reasons for recall and initiation of remedial action
    - On completion of a recall, the local agent is requested to provide the DPV&DI with **Final report (Annex 3)** on the problem and details of the remedial action proposed to prevent a recurrence of the problem that gave rise to the recall within **14** calendar days after commencing of the recall.
    - 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 DGPA&DC GMP 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.
3. Completion of the recall
    - The DPV&DI will terminate the recall when the local agent has completed all recall activity, including monitoring and final product disposition. The DPV&DI will notify the local agent by a letter the DGPA&DC considers the recall terminated **(Annex 4)**.

NB: Progress Report & Final Report should be submitted online (Submission Type "Recall")

Annex 1 Recall Circular Template

Ministry of Health letterhead

Circular No:

Date:

Recall Title

Class of Recall: ☒ Class I ☐ Class II ☐ Class III

Level of Recall ☐ Wholesale level ☐ Retail level ☐ Consumer level

Product Information:

Product name:

Active ingredient(s):

Affected batch number:

Manufacturer:

Manufacturing date:

Expiry date:

Issue:

Detail about the nature of the issue leading to the recall.

Action:

- Instruction to immediately stop prescribing/ dispensing/ distributing or using and quarantine affected stock.
- An instruction regarding the return of affected stock.
- Instruction for the local agent to complete the Progress and Final Recall report attached.
- A statement to all healthcare professionals to report ADR, quality problems and medication errors to the Department of Pharmacovigilance & Drug Information, phone no: 0096822357687, Fax: 0096822358489, website: www.moh.gov.om

Annex 2 Recall Progress Report

Recall Progress Report

Local agent/Distributer letterhead

To: Director, Department of Pharmacovigilance & Drug Information

Recall Progress Report for----------

Recall Circular No & Date	
Product name & strength	
Active ingredient(s)	
MOH registration number	
Dosage form	
Pack size	
Manufacturer	
BN	
Manufacturing date	
Expiry date	
Name of client to whom the defective product have been supplied	
The date and means of notifying clients of the recall	
The number of responses received from clients	
The names of the non-responders	
The quantity of stock returned	
The estimated time frame for the completion of the recall	
Any other relevant details	

Name of reporter:
Signature:
Date: **Stamp**

NB*:* The report should be submitted online (Submission Type "Recall") DPV&DI within 7 calendar days after commencing of the recall.

Annex 3 Recall Final Report

Recall Final Report

Details of the recalled product	
Product name & strength	
Active ingredient(s)	
MOH registration number	
Dosage form	
Pack size	
Manufacturer	
BN	
Manufacturing date	
Expiry date	
Reason for recall	
Extent of distribution	
Imported/manufactured quantity	
Exported quantity (for local companies)	
Countries of export	
Quantity distributed in Oman	
Action taken by	
Steps taken to prevent re-occurrence of the problem	
Result of Recall	
Quantity of stock returned	
Quantity of stock used or sold by the consignees	
Quantity of stock not located	
Method of disposal	
☐ Destroy ☐ Return to manufacturer ☐ Others (specify)	
Name of reporter: **Signature:** **Date:** **Stamp**	

NB: The report should be submitted online (Submission Type "Recall") to DPV&DI within 14-calendar days after commencing of the recall.

Annex 4 Recall Termination Letter Template

MOH letterhead

MH/DGPA&DC/DPV&DI/

Date:

RE: Recall No: /

To:

After Compliments,

This is to inform you that the DGPA&DC has reviewed your Progress and Final Recall Report, and conclude that the recall has been completed and there has been proper disposition of the recall product/batch. Therefore, DGPA&DC considers the recall terminated.

Your faithfully,

Director of Pharmacovigilance & Drug Information

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