الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Products Recall Guidance

Version 1.0

Date of publication	20 September 2023
Date of implementation	20 December 2023

Products Recall Guidance

Version 1.0

Saudi Food & Drug Authority

Drug Sector

For Inquiries	*pq.drug@sfda.gov.sa*
For Comments	*Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Drug Sector	27 December 2022	-
1.0	Drug Sector	20 September 2023	Final

Table of Content:

1. INTRODUCTION

A product might be subjected to recall if they were suspected of being potentially harmful to users due to their defective quality, safety or efficacy. All related information must be reported to the Product Quality Department (PQD) and National pharmacovigilance and drug safety center (NPC) at Saudi Food and Drug Authority (SFDA).

This guidance outlines the role and responsibilities of each party involved in the recall action. In addition, the guidance will help to understand and comply with articles of the Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products that relate to recalls action.

1.1. Objective

The Products Recall Guideline intended to ensure that in the event of a necessary recall, the recall operations are effectively and efficiently carried out by the responsible supplier.

1.2. Scope

This guidance covers the recall requirements and the procedure for the following products:

- Drug intended for use in human and animals
- Human herbal product
- Human health product

2. DEFINITIONS

Recall action is the term used to describe an action taken to resolve a problem with a product currently in use or available for use because of deficiencies in its quality, safety, or efficacy. There are two types of recall action:

- **Recall** means the removal of affected therapeutic products from supply or use for reasons relating to established deficiencies in the safety, quality, or efficacy.
- **Recall for Product Correction** advises of the responsible supplier/manufacturer's intention to, modify, adjust, re-label or provide updated instructions for use. This action would be for reasons relating to deficiencies in the safety, quality, or efficacy of the affected products.

  The corrective action may take place at the user's premises (field correction) or the responsible supplier's premises or any other agreed location and may involve a period of quarantine.

Responsible Supplier is the entity that initiate a recall process and has primary responsibility for the supply of products in Saudi Arabia. It includes manufacturers, marketing authorization holders, scientific offices, importers, agents, distributors, and retailers.

3. RECALL ACTION CLASSIFICATION

Recall action classified according to the following:

- Class 1: The defect presents a life-threatening or serious risk to health.
- Class 2: The defect may cause mistreatment or temporary harm to the patient, but the life-threatening or serious risk probability is remote.
- Class 3: The defect is unlikely to cause harm to the patient, and the recall carried out for other reasons.

The following table shows examples of recall action classification.

Recall Class	Example
Class I	• 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	• 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 (“rogues”) • Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products) • Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
Class III	• Faulty packaging e.g. wrong or missing batch number or expiry date • Faulty closure • Contamination- microbial spoilage, dirt or detritus, particulate matter • Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution

4. RECALL ACTION LEVEL

The depth of the recall action depends on the nature of the risk, the amount of time that has elapsed since the batch was first distributed, the type of product and the extent of distribution. The recall strategy will specify the level in the distribution chain to which the recall is to extend. The following table shows examples of recall action levels.

Recall Level	Definition
Wholesale level	• Include all parties involved in wholesale distribution.
Retail and hospital level	may include, as appropriate: • all public and private hospital pharmacies, community pharmacies • other general retail outlets e.g., supermarkets and health food store • wholesale level.
Consumer or patient level	• Patient and consumer • May also include retail and hospitals and wholesale level

5. REPORTING A PROBLEM OR THE SUSPECTED DEFECT

A Defective product may be identified by a number of different means, including (but not limited to):

- Detection by the responsible supplier undertaking the recall (voluntary recall) or by another supplier within the distribution chain
- A complaint from a healthcare professional or consumer
- A result of sample analysis and testing of products by SFDA through post marketing surveillance project
- International health regulators recall reports.

6. REACALL ACTION PROCESS

The Recall Action Process involves the following phases of activities

Phase 1. Initiation - Notification and problem identification, hazard/risk assessment, recall action assessment and agreement (strategy, classification and depth, and communication plan).

Phase 2. Implementation - responsible supplier is responsible for notifying the recall action to the agreed level. SFDA monitors the recall action process to ensure that all activities are carried out in an effective and timely manner by reviewing progress reports submitted by the responsible supplier.

Phase 3. Review / Close Out - monitor the effectiveness of the recall action and close out recall documents. This phase includes the identification of the root cause of the issue and whether the corrective and preventive actions (CAPA) implemented by the manufacturer are likely to reduce the likelihood of the same issue recurring.

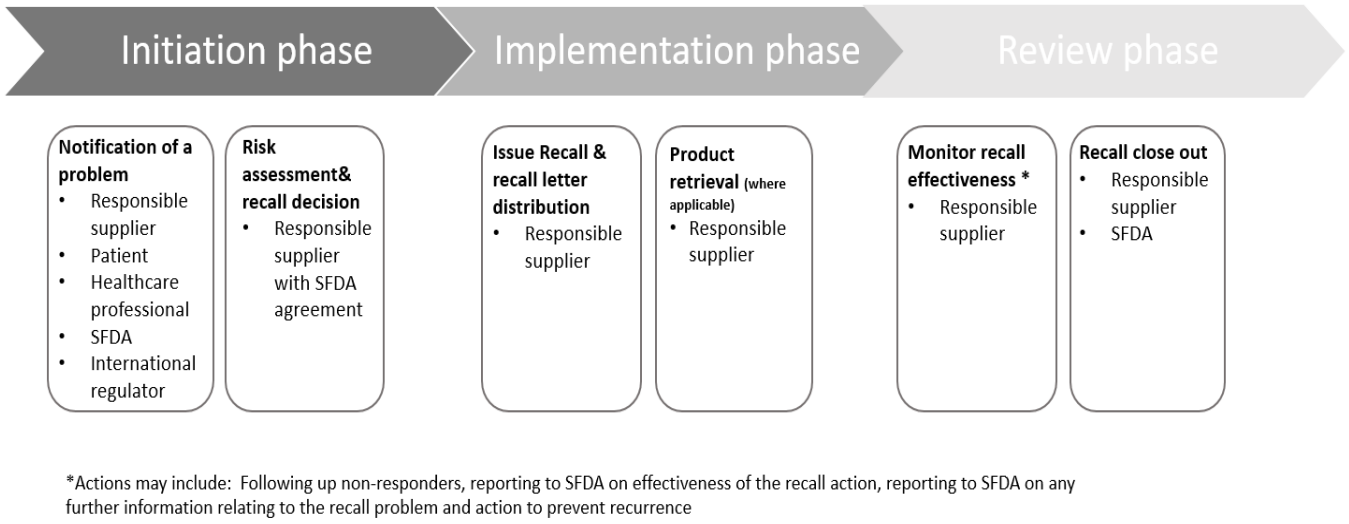

Figure 1: recall action process

7. ROLES AND RESPONSIBILITIES OF RESPONSIBLE SUPPLIER

a) Responsible supplier are responsible for identifying potential issues with their products

b) Responsible supplier should have in place a written recall procedure that describes how a recall action will be initiated and carried out, and should ensure that relevant staff members are appropriately trained in the procedure.

c) Assessing the risks of any identified hazards and mitigating the risks.

d) Maintain records for all the products manufactured or distributed.

e) Appointment of a person in charge of recall action and provide his/her contact information.

7.1 Initiation phase

Notification of a product problem

The responsible supplier should immediately notify SFDA when they become aware of a possible defect. SFDA should be supplied with as much information as possible during the initial contact. Responsible supplier should follow up the initial notification with the remaining information as soon as it becomes available.

Required information

The responsible supplier should submit the required information using their own recall reporting form or the product recall reporting form (see appendix 1). The reports must include the following information:

- Name and details of responsible supplier
- Name of the product
- Affected lot numbers
- Name and details of manufacturer
- Product distribution details
- Proposed recall classification
- Proposed recall level
- Reason for recall
- Proposed actions you will take to address the product's risk to health

SFDA also requests to provide the following items, where applicable:

- Any adverse reaction reports for the product
- Distribution records for the affected lots

- A health risk assessment
- A detailed investigation report identifying the recall's root cause, when available
- Availability of unaffected product
- Any additional information

The classification and level of recall action determined initially by the responsible supplier based on the assessment of the health hazard presented by the product. However, SFDA will review the classification and level of recall action and adjust it where appropriate. The criteria that will be used by SFDA for this assessment are described in Section 8.

7.2 Implementation phase

Communication and distribution of recall letter

The recall strategy should define the method and content for all communications associated with the recall. The goal in communicating a product recall is to ensure entities in the supply chain comply with the recall notification. Ensure the format, content, and extent of your communication is appropriate for the product's level of risk and for your recall strategy. The content of recall communication include:

• A description of the product, including:

o name

o lot number(s)

o registration number

o manufacturer name

• The reason for the recall.

• Actions to be taken by the recipient, including instructions to stop further distribution or use immediately

• Instructions for how to recall the affected product, including:

o specific steps for its return or correction

o a request for a response to confirm the recipients received the communication and understands any required action

• Instructions to all entities involved in the chain of distribution to notify their own customers of the recall and to provide instructions on how to proceed to recall the affected product.

• Instructions to retailers, pharmacists or health care practitioners to notify their consumers of the recall and provide instructions on the actions to take with the affected product, if end users need

to be notified of the recall.

• Expected recall action termination date (the maximum period for recall action is 12 weeks from the receipt of the recall letter)

Communication timelines

After receiving recall letter from SFDA, the responsible supplier should initiate recall action and contact with affected entities immediately.

Retrieval of the affected product

Responsible supplier is required to retrieve a defective products from all affected parties and prevent any further distribution of the affected product in the market place (where applicable). A responsible supplier should arrange for the retrieval of the product by establishing collection points across the distribution network.

7.3 Review phase

Progress report

Progress reports should be provided to SFDA during the course of the recall on the implementation of the recall action, the response rates, the investigation into the issue and any corrective and preventive actions (CAPA). The progress reports should be submitted daily.

Recall progress reports should normally specify:

- number of recipients notified of the recall and date and method of notification
- number of respondents and quantity of affected product(s) in their possession
- number of non-respondents
- next expected follow-up date with non-responders and method of communication, when applicable
- the quantity of stock returned or corrected
- Initial and updated information on the investigation into the root cause and the CAPA's
- Any other information that may be relevant.

Note: The recall strategy should define how to follow up with non-responders if recipients do not respond to the initial notification.

Final report

When the recall is complete, responsible supplier should provide SFDA a final report (close-out) that should specify the following

- An investigation report and detailed corrective action plan to address the recall's root cause and prevent its recurrence, using measures such as:
  - design changes
  - process validation
  - increased quality control
- In the case of a product recall, the intended destruction method of the product by a specialized medical waste company

Note: the responsible supplier should notify the SFDA about the proposed date and the site for product destruction to be witness by SFDA representative

- In the case of a recall for product correction, confirmation that the product correction has been applied to all units with customers.

8. ROLES AND RESPONSIBILITIES OF SFDA

- assessing the health hazard presented by a product that is being considered for recall action, SFDA will take the following factors into account (as well as any other factors that are relevant to the particular situation):
    - Whether any illness or injury has already occurred from use of the product
    - Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard
    - The hazard to individual groups within the exposed population (such as children, the elderly, consumers having surgery or those who are immunocompromised)
    - The degree of seriousness of the health hazard to which the population will be exposed and The consequence (immediate or longer term) of occurrence of the hazard
    - The likelihood of occurrence of the risk
    - Alternative treatment options, including the risk associated with providing no treatment if an alternative is not available.
- Review proposed risk classification and level of recall by responsible supplier and adjust it, where appropriate.
- Send a recall letter to the responsible supplier to initiate the recall process.
- Examine the progress reports sent by the responsible supplier and determine if the effectiveness of the recall action and CAPA are satisfactory.
- Where SFDA is satisfied with implementing the corrective actions of the recall, the investigation will be recommended for closure.

Publicising Recall actions

Based on the recall level and classification, type of health hazard on the patient, and the availability of the product, SFDA may issue:

- A recall circular to all healthcare institutions, if appropriate (it will be published on the SFDA website).
- A recall notification to healthcare professionals
- A public alert through appropriate channels if a recall action is to be conducted at the consumer level.

9. ROLES AND RESPONSIBILITIES OF HEALTH CARE PROFESSIONAL, HEALTH INSTITUTION, AND CONSUMER

Healthcare professionals, health institutions and consumer have an important role in reporting significant defects or concerns to SFDA through email, Saudi vigilance system or by phone (see Appendix 2 for contact details).

Note: this should not be confused with an adverse reaction where the product conforms to its specification but an adverse event or reaction is observed.

The following information will be useful if available:

- Product name, strength and dose form
- Manufacturer name
- Batch/lot number/serial number
- Expiry date
- Defect and details of any associated clinical incident
- Name, email address telephone and of the person reporting the problem
- A photo (if available)

Appendix 1: Product Recall Reporting Form

[1] Type of Report	
Initial Notification or Follow Up Information	○ Initial notification ○ Follow-up information

[2] Recall Information	
Product Brand / Trade Name(s)	
Product Type	○ Human drug ○ Biologic ○ Herbal/health product ○ Veterinary drug
Manufacturer name	
Manufacturer nationality	
Registration Number (If available)	
Risk Classification	• Class 1: The defect presents a life-threatening or serious risk to health. • Class 2: The defect may cause mistreatment or temporary harm to the patient, but the life-threatening or serious risk probability is remote. • Class 3: The defect is unlikely to cause harm to the patient, and the recall carried out for other reasons.
Recall Depth	
Reason for recall *Note: Add additional information as attachments.*	

[3] Recalling company's details *Note: Contact names provided should be available for contact by SFDA at any time. Complete all company information.*			
Recalling Company			
Contact Name			
Email			
Title			
Tel/mobile		Fax	
Alternate Contact Name			
Email			
Tel/mobile		Fax	
Regulated Activity	○ Manufacturer ○ Importer ○ Scientific Office ○ Distributer ○ Wholesaler ○ Marketing Authorization Holder		
Address			
City		Province	
Country		Postal / Zip Code	

[4] Product/Distribution Details *Note: Add additional information as attachments.*	
Product brand name /Generic Name of Drug/Medicinal Ingredient(s)	
Lot / Batch Number(s)	

Manufacturing Date(s)		Expiry Date(s)	
Dosage Form		Strength	
Package Size		Other identifier (GTIN)	
Quantity of drug manufactured or imported			
Quantity of the drug distributed			
Estimate amount remaining on the premises of the manufacturer, importer or distributor *(Additional distribution details may be attached in section 6.)*			
Any other action taken by the manufacturer/importer or distributor with respect to the recall *Note: Add additional information as attachments.*			

[6] Additional information (Attachments)
Please check the appropriate box if you are including attachments.
☐ Health risk assessment

☐ Recall strategy
☐ Distribution information
☐ Recall communication
☐ Determination of medical necessity of product
☐ Product label, product image

Any other relevant information about the recall *Note: Add additional information as attachments.*

Appendix 2: Contact details for SFDA

Contact SFDA to submit recall information, potential recall, or for general enquiries on the recall of drugs

Telephone	SFDA Call Center: 19999
E-mail	Product Quality Department pq.drug@sfda.gov.sa
Website	https://ade.sfda.gov.sa (to report product quality-related issue by consumers, healthcare professionals, health institutions)