Procedure for Pharmaceutical Product Recall

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Version 1.0

1. Introduction

This document is intended to ensure that the recall/withdrawal operations are effectively and efficiently carried out in order to protect the public health.

When an NHRA-regulated product is defective, potentially harmful, or mislabeled, recalling that product—removing it from the market or correcting the problem—is often the most effective means for protecting the public from products that violate the laws administered by NHRA.

2. Scope

This document applies to pharmaceutical product recall initiated voluntarily by the Marketing Authorization Holder or upon request by NHRA.

3. Recall level

Recall can be made to different levels through the distribution chain.

Recall levels include:

- Wholesale (Importer/Distributer) Level.
- Retail (includes pharmacies and general retail outlets) level.
- Consumer/Patient level.

4. Recall Submission to NHRA

It is recommended, to submit the information outlined in this document to NHRA as soon as possible, after the decision to recall is made and the agent notified. It is recommended , not to wait to submit this information until ALL applicable information is prepared and assembled prior to NHRA notification. This "early" notification will allow NHRA the opportunity to review and comment on written notification and to offer guidance and assistance in recall process.

1.Product information:

1. Product name (include brand name and generic name)
2. Description of the product
    - Include if product is powder, liquid, tablet, capsule, etc.
    - Include the intended use or indications.
    - Medicine registration Number
    - Indicate if prescription or OTC
    - Strength
    - Route of Administration
    - Include type of packaging
    - **labeling Include**:

- Product labeling
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

2. Batch Details (Production Identification Numbers):
    1. Lot/Unit Numbers
    2. Expiration date(s) or Use by date(s) or Expected shelf life of product.
3. Name of the responsible agent
4. Marketing authorization holder
5. Manufacturer:
    1. Company name, address.
    2. Site registration number , if applicable
6. Identify company responsible for the violation /problem
    1. Company name, address,
7. Reason for recall
8. Health hazard assessment

    Provide assessment of the health risk associated with the deficiency.

    NOTE: A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists are still in violation of the law and should be recalled.
9. Volume of recalled product:
    1. Total quantity produced
    2. Date(s) produced
    3. Quantity distributed
    4. Date(s) distributed
    5. Quantity on HOLD by Recalling company and its distribution centers.
    6. Indicate how the product is being quarantined
    7. Estimate amount remaining in marketplace
        - distributor level
        - retail level
        - pharmacy or hospital
    8. Provide the status/disposition of marketed product, if known, (e.g. used or destroyed).
10. Distribution pattern:
    1. Number of DIRECT accounts by type,
        - wholesale
        - retail pharmacy
        - Hospitals , clinics
        - Government consignees

11. Recall strategy:
    1. Report on what instructions were given to customers for the recalled product.
    2. Explain if this recall will create a market shortage that will impact on the consumer.
    3. Provide a proposed method of destruction or return, if applicable.
    4. To contact NHRA prior to product destruction and may choose to witness the destruction.
    5. The recalling company and customers keep adequate documentation of product destruction and whether or not destruction was witnessed by an NHRA investigator.

Public Notification

1. NHRA web site update:
   NHRA shall update the official website www.nhra.bh with the most update information on the safety, warning and recall of the product when deemed necessary.

2. Press release:
   In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued **promptly**. Unique situations will be handled on a case-by-case basis.

   NOTE: For those recalls where NHRA believes a public communication is warranted, the Authority will publish safety circulars on the website or if required ,issue a Press Release.
   Provide examples of ALL recall communications to NHRA

Evaluation of the Recall

1. Effectiveness of recall:
   It is the recalling company's responsibility to assure that the recall is effective.

2. Recall status report:
   A recall status report should be provided after initiating a recall to NHRA. The reports will include the following information:
   - Dates customers notified.
   - Number of customers notified.
   - Quantity of RECALLED product returned or accounted for.
   - Details of your recall effectiveness checks.

3. Root cause of the problem that resulted in recall:
   It is recommended to provide this information to NHRA once the root cause has been established. It is important to establish the root cause of the problem so that appropriate preventative measures can be taken.

4. Corrective actions to prevent future occurrences of the problem:
   It is recommended to explain the corrective actions planned or underway that will prevent a similar problem from occurring.

5. Termination of recall:
   We recommend to evaluate recall for termination when all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered or destroyed (if destroyed in Bahrain; a certificate of destruction from Bahrain waste company should be submitted to NHRA. If re-exported; an official letter from MAH declaring the re-export from the country should be submitted to NHRA). A final status report and documentation of recalled product disposition should be provided to NHRA . NHRA will then consider formal termination of the recall action.

General notes:

- All legal importers must have recall SOP and maintain records for the recalls.
- It is always the MAH responsibility to ensure the recall is effective and to inform the authority of any obstacles or difficulties where applicable.
- If the recalled product is centrally registered the MAH Company must address the recall letter to all GCC countries.