FOOD AND DRUGS AUTHORITY

GUIDELINES FOR PRODUCT RECALL

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1 INTRODUCTION

The Food and Drugs Authority (FDA) is established under the Public Health Act, 2012, Act 851 to ensure public health and safety by regulating the manufacture, importation, exportation, storage, distribution, use and advertisement of food, drugs, herbal medicinal products, cosmetics, medical devices and household chemical substances.

Recalls are an effective method for removing or correcting marketed products, their labeling, and/or promotional literature that violate the laws administered by FDA. Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or judicial actions, especially when the product has been widely distributed.

FDA regulated firms may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by FDA, in response to a formal request by FDA, as statutorily mandated or as ordered by FDA.

These guidelines are hereby made for information, guidance and strict compliance by all concerned.

1.1 **Scope**

To explain and standardize the procedure for product recall in order to ensure effective removal and disposition from the market products that violate requirements and that may present a health hazard to the consumer/user.

1.2 **Abbreviations**

In these guidelines:

FDA - Food and Drugs Authority
HCP - Healthcare Professional
MAH - Market Authorization Holder **QA** - Quality Assurance
CAPA - Corrective and Preventive Action

2 GLOSSARY

2.1 "**Product**" means any locally-manufactured or imported drug (allopathic, herbal, food supplements, biological & vaccines, veterinary), medical devices, cosmetics, household chemicals, investigational products and any Advertisement thereof as defined under the Public Health Act, 2012 Act 851.

2.2 "**Recall**" means a firm's removal from further sale, distribution or use, or correction, of a marketed product that does not meet regulatory requirements as specified in the Public Health Act and/or violates FDA guidelines.

The definition of "Recall" does not include a "product withdrawal" or a "stock recovery".

2.3 **"Voluntary Recall"** is when a firm requests a product recall after discovery of safety issues, product defects or non-compliance to regulatory requirements.

2.4 **Statutory (Non-Voluntary) Recall"** is when FDA requests/orders a product recall due to non-compliance to regulatory requirements.

2.5 "**Correction**" means repair, modification, adjustment, re-labelling, or inspection (including patient monitoring) of a product without its physical removal to some other location.

2.6 "**Recalling firm**" means the firm that initiates a recall. It is usually the firm that has primary responsibility for the manufacture/import and marketing of the product to be recalled.

2.7 "**Product withdrawal**" means a firm's removal from further sale or use, or correction of a marketed product that does not violate legislation administered by the FDA. It is not considered to be a recall.

2.8 "**Stock recovery**" means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm. It is not considered to be a recall.

2.9 "**Recall strategy**" means a planned specific course of action to be taken in conducting a specific recall, which addresses itself to matters such as the depth of recall, need for public warnings, and extent or effectiveness checks for the recall.

3 REQUIREMENTS

3.1 **Responsibility**

3.1.1 Initiation of Statutory (Non Voluntary) Recall: The Authority shall be responsible for requesting/ordering a product recall when the registration of a product is cancelled for safety reasons, or when the product does not meet regulatory requirements.

In such instances, the Authority shall monitor the effectiveness of the recalling firm's actions and provide scientific, technical and operational advice where necessary.

3.1.2 Initiation of Voluntary Recall - It is the recalling firm's sole responsibility to request and implement the recall process by contacting all companies to whom the recall products have been distributed and ensuring the physical removal of the products from the market to the level required.

In such cases prior notice should be given to the Authority.

3.1.3 If the recalling firm's actions are deemed inadequate the Authority will take appropriate actions to remove the product from sale or use. A firm's recall does not preclude enforcement actions being taken by the FDA, as deemed appropriate, either during or following the completion of a recall.

3.2 **Product Recall Trigger**

Any product / batch(es) not meeting the defined quality standards has to be recalled from the market. Recall can be of two types; Voluntary Recall and Statutory Recall.

3.2.1 Voluntary Recall

Voluntary recall can be triggered by any incident that affects the quality, safety and efficacy of the batch/product in question such as

a) Batch(es) not complying with regulatory specifications during the post marketing stability study
b) Batch(es) found to be defective during investigation of market complaint.
c) During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc.).

d) If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation.
e) If the post marketing surveillance reports /pharmacovigilance reports indicates that there is serious safety risk associated with the product

3.2.2 Statutory Recall (Non Voluntary)

Statutory recall of products or batch(s) from the market by the Authority may be triggered by the:

f) Product/batch identified to be in violation of requirements, such as substandard, falsification etc.
g) Serious reports of adverse drug reactions not included in the package insert
h) Unexpected frequency of adverse reaction stated in the package insert
i) Products banned by the Authority
j) Products for which the market authorization have been withdrawn/cancelled.
k) Labeling and / or Promotional materials that are considered to be in violation of regulations.

3.3 **Recall Classification**

The Authority shall assign numerical designation, i.e. I, II or III, to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. The following classifications shall apply:

Class I: A dangerous or defective product that could cause serious health problems or death.

Class II: A product that might cause a temporary health problem, or pose slight threat of a serious nature.

Class III: A product that unlikely to cause any adverse health reaction, but that violates FDA labeling or manufacturing laws

3.4 **Levels of Recall**

The level (or depth) of recall of a product/batch shall be determined based on recall classification and level to which distribution has taken place. There are three levels of recall namely, consumer/user, retail and wholesale

Table 1 – Recall Type, Depth and Action

Recall Type	Depth of Recall	Action
A Consumer or User Level	Recall is designed to reach all suppliers of medicines (all distribution points) i.e. wholesalers, hospitals pharmacies (private / public hospitals), retail outlets, and individual customers or patients through media release (TV, radio, print media, social media etc.)	Recall letter to manufacturer/importer to be initiated at all levels of distribution plus media release.
Recall Type	**Depth of Recall**	**Action**
B Retail Level / User facilities	Recall is designed to reach wholesalers, hospital pharmacies (private / public hospitals), retail outlets	Recall letter to manufacturers / importers and HCPs
C Wholesale Level	Recall is designed to reach wholesale level and other distribution points. This can be achieved by means of representatives calling on wholesalers and/or retail outlets. ***If it is known where the product in question had been distributed to, specific telephone calls or recalls letters to arrange for the return of the product could be made***	Recall letter to manufacturers, importers/wholesalers

a. All Class I recalls shall be executed to the levels of Wholesale/Distributors, retail, and consumer. In such cases, public announcements shall be made using print/electronic media aids viz. Newspapers, Television, Radio etc.

b. All Class II recalls shall be executed up to the levels of wholesale and retail.

c. All Class III recalls shall be executed up to the levels of wholesale.

3.5 **Timelines for Effective Recall System and Rapid Alert**

The following timelines shall apply to product recalls.

Table 2: The timeline for initiating and stopping sale/distribution of defective product

Recall Class	Initiation Timeline	Physical Recall Timeline
Class I	24 Hours	72 Hours
Class II	48 Hours	Up to 10 Days
Class III	72 Hours	Up to 30 Days

3.6 **Procedure for Rapid Alert and Recall System:**

The following steps shall be taken when a recall is initiated:

a) As soon as the product/batch(es) to be recalled is/are identified, Market Authorization Holder or local agent or QA in charge shall review the information related to the defective product/batch(es) and decide about recall as per the procedure established.

b) The decision on recall of the defective product/batch shall be made within 24 Hours up to maximum of 72 Hours for Class I recall upon receipt of the recall information.

c) Within 24 Hours of the decision taken for the recall of the product/batch(es), the communication shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, social media, text (SMS) etc. to the entire supply chain.

d) The MAH/Local Agent where the product is marketed shall inform the concerned regulatory authorities where the product batch(es) in question was distributed immediately after the decision of recall has been taken. Further actions on recall will be undertaken according to class of recall.

e) It is the responsibility of the recalling firm (Marketing Authorisation Holder (MAH)/ Local agent) immediately after discovering the problem to officially notify distributors to suspend sale and/or further distribution of the product in question. Details of notification shall include but not limited to:

- Name, strength, batch and any other pertinent descriptive information of the product
- Reason for the recall
- Suggested action to be taken and its urgency
- Provide specific instructions on what should be done with the recalled product

f) Follow-up communications should be sent to those who fail to respond to the initial recall communication

g) Records of the recall notice, available stock and returned stock from various outlets shall be maintained by the recalling firm and shall be made available for verification by FDA regulatory officers.

3.7 **Recall Communication**

3.7.1 General

A recalling firm is responsible for promptly notifying each of its affected distribution outlets about the recall. The format, content, and extent of a recall communication

should be commensurate with the hazard of the product and the strategy developed for that recall.

Recall communication should convey:

a) That the product in question is subject to a recall;
b) That further distribution or use of any remaining product should cease immediately;
c) Instructions regarding what to do with the product.

3.7.2 Implementation

As determined by the recall strategy, a recall communication can be accomplished by:

- Telephone, SMS, email, social media, fax, announcement on FDA website (see section 11.3)
- Special delivery letters may be conspicuously marked –e.g. “MEDICINE RECALL” in bold red on the letter and envelope and also “URGENT” for serious cases.

3.7.3 Alerting the Public

Public notification is generally issued when a product that has been widely distributed or poses a serious health hazard is recalled.

Not all recalls are announced on FDA website or in the news media. However, if a company does not issue public notification of a recall, FDA may do so if the Authority determines it is necessary to protect consumers.

Product recalls may also be communicated to consumers through their healthcare professionals using the “Dear Healthcare Professional Letters”.

3.8 **Effectiveness Checks**

The purpose of effectiveness checks is to verify that all affected distribution outlets identified have received notification about the recall and have taken appropriate actions. The level of effectiveness of the recall shall be conducted by the recalling firm as follows:

a) Level A - 100 percent of the total number of distribution outlets to be contacted;
b) Level B - Some percentage of the total number of distribution outlets to be contacted – greater than 10% but less than 100% - which percentage is to be determined on a case-by-case basis.
c) Level C - 10 percent or less of the total number of distribution outlets to be contacted, which percentage is to be determined on a case-by-case basis; or

d) Level D - No effectiveness checks.

The FDA, sometimes assisted by other health agencies, may carry out its own effectiveness checks as part of monitoring the recalling firm's performance. This is a separate exercise which must not be considered as part of, or supplement to, the recalling firm's responsibilities for adequate effectiveness checks.

If a recall is determined to be ineffective FDA will request the company to take additional actions.

3.9 **Post Recall Notification to FDA**

After initiating a recall, the recalling firm immediately on becoming aware of the problem shall notify the FDA in writing with the recall information including:

a) Name, strength, Batch(es), Manufacturing and Expiry Dates, manufacturing company and address and any other means of identification.
b) The total quantity of the product imported or manufactured.
c) The total quantity of the product being recalled originally in possession of the company
d) The total quantity of the product that had been distributed up to the time of the recall.
e) The total quantity of the product being recalled that had been distributed at the time of the recall
f) The distribution record of the recalled product.
g) The reason for initiating the recall – nature of defect.
h) Report on investigation conducted to identify root cause and relevant corrective actions.
i) Final disposition of the recalled products.

3.10 **Disposition of Recalled Products**

No person(s) shall dispose of any recalled product without permission and supervision from the FDA.

Refer to the "***Guidelines for Safe Disposal of Unwholesome Products***" on the FDA website.

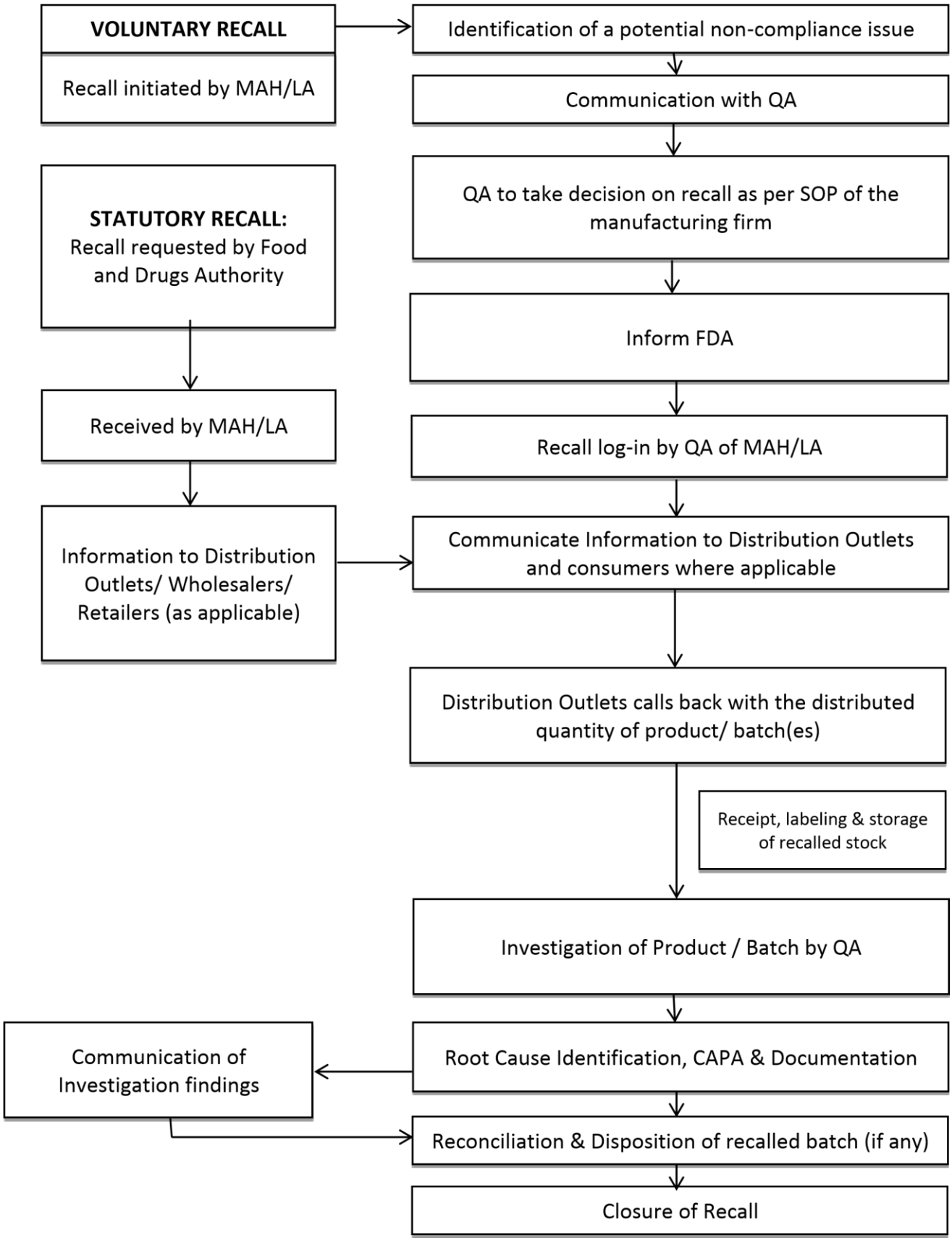
3.11 Termination of Product Recall

A recall will be terminated when the FDA and the recalling firms are in agreement that the product which is the subject of the recall has been removed from the market and proper disposition or correction has been made.

4 PENALTIES

Where non-adherence to these guidelines results in exposure of consumers to a safety risk, the FDA will impose Administrative Charges and Sanctions in accordance with Section 148, Sub-section 4 & 5 of the Public Health Act, 2012, Act 851.

APPENDIX I: OVERVIEW OF PROCESS FLOW FOR RAPID ALERT AND RECALL SYSTEM


VOLUNTARY RECALL
Recall initiated by MAH/LA
STATUTORY RECALL:
Recall requested by Food and Drugs Authority
Received by MAH/LA
Information to Distribution Outlets/ Wholesalers/ Retailers (as applicable)
Identification of a potential non-compliance issue
Communication with QA
QA to take decision on recall as per SOP of the manufacturing firm
Inform FDA
Recall log-in by QA of MAH/LA
Communicate Information to Distribution Outlets and consumers where applicable
Distribution Outlets calls back with the distributed quantity of product/ batch(es)
Receipt, labeling & storage of recalled stock
Investigation of Product / Batch by QA
Root Cause Identification, CAPA & Documentation
Communication of Investigation findings
Reconciliation & Disposition of recalled batch (if any)
Closure of Recall