REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

Guidelines for Product Recall or Withdrawal

Edition 1

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This document has been prepared to serve as a guide to pharmaceutical manufacturers and distributors regarding the recalls of medicines, and the Pharmacy and Poisons Board's current thinking on the safety, quality and efficacy of medicines. The Board reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine and may make amendments in keeping with the knowledge which is current at the time of consideration of data which has been submitted regarding any recalls.

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1. DEFINITIONS

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.

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

Medicine - means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man: or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

Parallel importation - means the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder.

Parallel importer - means a person who parallel imports a medicine into the Republic on authority of a permit issued in terms of regulation issued under the Pharmacy and Poisons Act, cap. 244 Laws of Kenya

Holder of a certificate of registration - means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration. This terminology will also include the agent/ distributor of a drug.

Stock recovery - means a firm's removal or correction of a product that has been released for sale and has not yet been despatched or has not left the direct control of the holder of a certificate of registration/ parallel importer (Refer to regulations under the Pharmacy and Poisons Act, cap. 244 Laws of Kenya).

2. ABBREVIATIONS

PPB- Pharmacy and Poisons Board
HRC- Holder of a certificate of registration

3. OBJECTIVE

To explain and standardize the procedure for classification and communications involved in a product recall or withdrawal

4. PURPOSE OF RECALL/WITHDRAWAL

To effectively remove from the market products that violate requirements and that may represent a health hazard to the consumer/user

5. RESPONSIBILITY

The Registrar and the Pharmaceutical Inspectorate secretariat will be responsible for initiation and supervision of product recall or withdrawal.
Most recalls are conducted on voluntary basis. The Pharmacy and Poisons Board can recall medicines when registration thereof has been cancelled, or when medicines are sold illegally in Kenya. If the recalling performance is deemed inadequate the Pharmacy and Poisons Board is prepared to take appropriate actions to remove the product from sale or use.
These guidelines serve to remind the holder of a certificate of registration/parallel importer that the Pharmacy and Poisons Board expects them to take full responsibility for medicines recalls, including follow-up checks to ensure that the recalls are successful. It is important to note that:

- During a recall, the primary role of the Pharmacy and Poisons Board is to closely monitor the effectiveness of the companies' recall actions and to provide scientific, technical and operational advice.
- If a recalling company's actions are deemed inadequate the PPB can take appropriate action to remove the product from sale/use.
- The recall action does not preclude enforcement actions being taken by PPB, as deemed appropriate, either during or following the completion of the recall.

6. WHAT MAY OCCASION A RECALL/WITHDRAWAL OF A PRODUCT?

The withdrawal/recall of a particular batch or batches of a product from the market may be occasioned by the company following:

- Serious reports of adverse drug reactions not included in the package insert
- Unexpected frequency of adverse reaction stated in the package insert
- Incorrect labeling of a product
- Incorrect formulation of a product
- Result of ongoing stability studies (unfavorable?)

7. RECALL CLASSIFICATION

It is necessary to assign/indicate the relative degree of health hazard presented by the product being recalled, namely

- Situation in which there is reasonable probability that the use of or exposure to a suspect product will cause serious adverse health consequences or death
- Situation in which the use of or exposure to a suspect product will cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- Situation in which the use of or exposure to a suspect product is not likely to cause any adverse health consequences

The following classification criterion is recommended:

Class I

Class I is for defective/dangerous/potentially life-threatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

Class II

Class II is for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Class III

Class III is for medicines that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements of Act 101 of 1965 in terms of the requirements of printed packaging material, product specification, labelling, etc.

Type A

A type A recall is designed to reach all suppliers of medicines (all distribution points) i.e. wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).

Action: Recall letter to all distribution points plus media release.

Type B

A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

Action: Recall letter to all distribution points.

Type C

A type C recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals) this can be achieved by means of a 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.

Action: Specific telephone calls, recall letters to/representatives calling at distribution points if known where the medicines have been distributed.

8. RECALL NOTIFICATION

- It is imperative that before or upon initiating a recall, the company immediately on becoming aware of the problem, notifies the Registrar, PPB or in his absence his designate
- If the notification fails and there is urgent need to recall the product then the company may proceed according to their discretion and follow up contact with the PPB to be pursued in the process.

9. BASIC INFORMATION REQUIRED FOR RECALL

- Name, strength, pack size, batch/lot number and any means of identification of the recalled product
- Total quantity of the recalled product originally in possession of the company
- The date distribution of the product began
- The total quantity of the recalled product that had been distributed up to the time of the recall should be indicated.
- Area of distribution of the product and, if exported, the country to where it was exported
- The quantity of the recalled product still in their possession
- The reason for initiating the recall; nature of defect
- Suggested action to be taken and its urgency
- Indication of the health risk together with reasons

10. HEALTH HAZARD EVALUATION

- Before initiating a recall, the company will gather, correlate and evaluate all known information on the nature and extent of the reputed health risk.
- An evaluation of the health hazard presented by a product being recalled or considered for recall will also be conducted by the PPB and will take into account, but need not be limited to, the following factors:
  - Whether any disease or injuries have already occurred from the use of the product
  - Assessment of hazard to various segments of the population e.g. children, surgical patients etc, who are expected to be exposed to the product, with particular attention to those individuals who may be at greatest risk
  - Assessment of the degree of seriousness of the health hazard to which the population at greatest risk would be exposed.
  - Assessment of the likelihood of occurrence of that hazard
  - Assessment of the consequences (immediate or long-term) of occurrence of the hazard.
- The recalling company is given every opportunity to contribute to the information on which the health hazard evaluation is made by the PPB, who, on the basis of this determination, classifies it based on the relative degree of health hazard posed by the product being recalled or considered for recall.

11. RECALL STRATEGY

Takes into consideration the following:

- Result of health hazard evaluation
- Ease in identifying the product
- Extent to which the product deficiency is obvious to the consumer/user
- Continued availability of essential products (risk: benefit)

12. ELEMENTS OF A RECALL STRATEGY

1. **Depth of recall**
   Depending on the product's degree of hazard and extent of distribution, the recall strategy has to specify the level in the distribution chain in which the recall is to extend, as follows:

   - Consumer or user level including any intermediate wholesale and/ or distribution or retail level, and or all government and military hospitals;
     OR
   - Retail level, including any intermediate wholesale and/ or distribution level;
     OR
   - Wholesale and/ or distribution level.

2. **Recall communication** from recalling company to all affected parties

13. RECALL COMMUNICATION

- A recalling company is responsible for promptly notifying involved parties about the recall
- Format, content, and extent of recall communication should be commensurate with the hazard of the product and the strategy developed for that recall.
- Should convey:
  - The product in question is subject to recall
  - Further distribution or use of any remaining product should cease immediately
  - Instructions on what to do with the product

14. IMPLEMENTATION OF RECALL COMMUNICATION

The following may be used:

- Telephone
- Telex
- Telegram
- Public media
- Special delivery
- Conspicuous marking e.g. "MEDICINE RECALL" in bold red on the letter and envelope, and also "URGENT" for serious cases
- Public warning for products that pose serious health hazards. However, this should be reserved for urgent situations where other means of preventing use of the recalled product appear inadequate. PPB to decide if necessary and who to issue such a warning
- Type of public warning to be specified in the recall strategy for the product:
  - General public warning in the general media as appropriate
  - Public warning through specialized news media e.g. professionals or to specific segments of the population such as physicians, hospitals etc.

15. CONTENTS OF RECALL COMMUNICATION

It should:

- Be brief and to the point
- Name the product, strength, pack size, and any other pertinent descriptive information of the product
- Indicate nature of the defect
- Specify urgency of the action
- Indicate reason for the action
- Indicate the health risk; and
- Provide specific instructions on what should be done with the recalled product
- Note: Where necessary, follow-up communication should be sent to those who fail to respond to the initial recall communication

16. POST RECALL PROCEDURES

- The PPB must be furnished with a report within a specified period (2 weeks) of the recall or withdrawal being instituted. The report to contain the following information:
  - Name of the product
  - Strength of the product
  - Pack size
  - Batch/ lot number
  - Nature of the defect
  - Action that was taken
  - Urgency of the action taken
  - Reason for the action
  - Indication of the health risk and reported clinical problems
  - Copies of all the recall correspondence; and
  - Steps taken to prevent re-occurrence of the problem
  - After termination of a recall and not later than 90 days after a recall has been instituted, a full reconciliation must be submitted.

- **A recall will be terminated when the PPB and the recalling company are in agreement that the non-compliant product has been removed and proper disposal or correction has been made.**

Annexure 1

RECALL ASSESSMENT FORM

*The information below could be provided verbally but should be confirmed in writing within **3 working days**

Recall information	**Information by the Holder of Certificate of registration/Distributor/Parallel importer**	**Comments by Pharmacy and Poisons Board(PPB)** *(for official use only)*
Origin of report		
1. Name of person/organisation reporting the problem		
2. Company		
3. Physical address		
4. Telephone number		
5. Facsimile number		
6. E-mail address		
7. Date of report		
8. Name of recipient at the Pharmacy and Poisons Board		
Product(medicine) details		
1. Name of product affected		
2. Registration number		
3. Dosage form		
4. Strength		
5. Pack size/type		
6. Batch number and expiry date		
7. Manufacturer/holder of the certificate of registration, address and contact details		
8. Date manufactured		
9. Date released		
10. Total quantity prior to distribution		
11. Quantity released for distribution prior to the recall		
13. Date of distribution		
14. Local distribution (give full details and quantity)		

Recall information	**Information by the Holder of Certificate of registration/Distributor/Parallel importer**	**Comments by Pharmacy and Poisons Board(PPB)** *(for official use only)*
15. Overseas distribution (give full details and quantity)		
Nature of defect		
1. Source of problem (e.g. patient/ hospital/pharmacy/manufacturer, etc)		
2. Details of problem		
3. Number of complaints received		
4. Name and address of any Medicines Regulatory Affairs notified of the problem		
5. Action taken so far (if any)/ Proposed action and its urgency		
6. Type of hazard/health risk and assessment of risk to the user		
7. Proposed recall classification and type		
8. Other relevant information		