



REPUBLIC OF KENYA
PHARMACY AND POISONS
BOARD

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Guidelines
for
Product Recall and
Product Withdrawal

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Guidelines for Product Recall and Product Withdrawal

This document has been prepared to serve as a guide to pharmaceutical manufacturers and distributors regarding the recalls of medicines, and reflects 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 medicinal product 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.

FOREWORD

Safety of medicines is a core responsibility of the manufacturers and distributors of medicines. The responsibility is shared with the Pharmacy and Poisons Board.

Recognizing that information obtained prior to first marketing is often inadequate to cover all aspects of drug safety and that tests in animals are at times insufficiently predictive of human safety; and taking into consideration that clinical trials may not completely replicate what happens in clinical practice, it is prudently expected that more information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions may emerge regarding drugs which are already authorized for use. These, combined with the fact that defects may emerge during manufacture or storage of the products make it necessary for stakeholders to be prepared to conduct product recall or withdrawal if and whenever need arises.

These guidelines have been prepared to assist stakeholders in dealing with such issues and define how the Pharmacy and Poisons Board would manage such eventualities as well as the role of the affected companies.

I trust that the cooperation and timely action by stakeholders, in this regard, will go a long way in upholding safety of medicines at all times.

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REGISTRAR

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TABLE OF CONTENTS

		Page
1.	DEFINITIONS	1
2.	ABBREVIATIONS	2
3.	OBJECTIVE	2
4.	PURPOSE OF RECALL/WITHDRAWAL	2
5.	RESPONSIBILITY	2
6.	WHAT MAY OCCASION A RECALL/WITHDRAWAL OF A PRODUCT?	3
7.	RECALL CLASSIFICATION	3
8.	TYPES OF RECALL	4
9.	RECALL NOTIFICATION	5
10.	BASIC INFORMATION REQUIRED FOR RECALL	6
11.	HEALTH HAZARD EVALUATION	6
12.	RECALL STRATEGY	7
13.	ELEMENTS OF A RECALL STRATEGY	7
14.	RECALL COMMUNICATION	8
15.	IMPLEMENTATION OF RECALL COMMUNICATION	8
16.	CONTENTS OF RECALL COMMUNICATION	9
17.	POST RECALL PROCEDURES	10
18.	ANNEXURE - RECALL ASSESSMENT FORM	11

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.

2. ABBREVIATIONS

- 2.1. PPB- Pharmacy and Poisons Board
- 2.2. 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 Pharmacy and Poisons Board 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?

- 6.1. The withdrawal/recall of a particular batch or batches of a product from the market may be occasioned by the following:
- 6.2. Serious reports of adverse drug reactions not included in the package insert
- 6.3. Unexpected frequency of adverse reaction stated in the package insert
- 6.4. Incorrect labeling of a product
- 6.5. Incorrect formulation of a product
- 6.6. Result of ongoing stability studies (unfavorable?)

7. RECALL CLASSIFICATION

- 7.1. It is necessary to assign/indicate the relative degree of health hazard presented by the product being recalled, namely
- 7.2. 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

- 7.3. 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.
- 7.4. 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:

7.5. 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.

7.6. Class II

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

7.7. Class III

Class III is for medicine that is defective and is unlikely to cause any adverse health reaction or which do not comply with the requirements of the Pharmacy and Poisons Act, cap 244 Laws of Kenya, in terms of the requirements of printed packaging material, product specification, labelling, etc.

8. TYPES OF RECALL

8.1. 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.

8.2. 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.

8.3. 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 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.

9. RECALL NOTIFICATION

It is imperative that before or upon initiating a recall, the company immediately on becoming aware of the problem, notifies the Registrar, Pharmacy and Poisons Board 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.

10. BASIC INFORMATION REQUIRED FOR RECALL

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

11. 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, assessment of the following factors:

- 11.1. Whether any disease or injuries have already occurred from the use of the product

- 11.2. 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
- 11.3. The degree of seriousness of the health hazard to which the population at greatest risk would be exposed.
- 11.4. The likelihood of occurrence of that hazard
- 11.5. The consequences (immediate or long-term) of occurrence of the hazard.

The recalling company will be 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.

12. RECALL STRATEGY

In formulating a recall strategy, the following should be taken into consideration:

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

13. ELEMENTS OF A RECALL STRATEGY

13.1. 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:

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

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

14. RECALL COMMUNICATION

A recalling company is responsible for promptly notifying involved parties about the recall and the same information notified to the Board.

The format, content, and extent of recall communication should be commensurate with the hazard of the product and the strategy developed for that recall.

Recall communication should convey:

- 14.1. That the product in question is subject to recall
- 14.2. That further distribution or use of any remaining product should cease immediately
- 14.3. The instructions on what to do with the product

15. IMPLEMENTATION OF RECALL COMMUNICATION

The following may be used in a recall communication:

- 15.1. Telephone
- 15.2. Telex
- 15.3. Telegram
- 15.4. Public media
- 15.5. Special delivery

15.6. Conspicuous marking e.g. “MEDICINE
RECALL” in bold red on the letter and envelope,
and also “URGENT” for serious cases

15.7. A public warning may be necessary 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

The type of public warning should be specified in the recall
strategy for the product e.g.

15.7.1. General public warning in the general
media as appropriate

15.7.2. A public warning through specialized
news media such as professionals or to
specific segments of the population like
physicians, hospitals etc.

16. CONTENTS OF RECALL COMMUNICATION

A recall communication should:

16.1. Be brief and to the point

16.2. Name the product, strength, pack size, and any
other pertinent descriptive information of the
product

16.3. Indicate nature of the defect

16.4. Specify urgency of the action

16.5. Indicate reason for the action

16.6. Indicate the health risk; and

16.7. 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. This should be done within a reasonable
time depending on the urgency of the recall.

17. POST RECALL PROCEDURES

The Pharmacy and Poisons Board 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:

- 17.1. Name of the product
- 17.2. Strength of the product
- 17.3. Pack size
- 17.4. Batch/ lot number
- 17.5. Nature of the defect
- 17.6. Action that was taken
- 17.7. Urgency of the action taken
- 17.8. Reason for the action
- 17.9. Indication of the health risk and reported clinical problems
- 17.10. Copies of all the recall correspondence;
and
- 17.11. Steps taken to prevent re-occurrence of the problem
- 17.12. 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 Pharmacy and Poisons Board 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		

Recall information	Information by the Holder of Certificate of registration/Distributor/Parallel importer	Comments by Pharmacy and Poisons Board(PPB) (for official use only)
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)		
15. Overseas distribution (give full details and quantity)		
Nature of defect		
1. Source of problem (e.g. patient/hospital/pharmacy/man)		

Recall information	Information by the Holder of Certificate of registration/Distributor/Parallel importer	Comments by Pharmacy and Poisons Board(PPB) <i>(for official use only)</i>
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		

The form should be signed and dated appropriately