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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Guidelines for Recall and Withdrawal of Medical Products and Health Technologies

January 2022

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HPT/PDS/VMS/GUD/030	Guidelines for Recall and Withdrawal of Medical Products and Health Technologies	Revision No: 1	Effective date 01/02/2022 Review Date: 31/01/2027

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Abbreviations

FBOs:	Faith Based Organizations
CEO:	Chief Executive Officer
IVDs:	Invitro Diagnostics
INN:	International Non-Proprietary Name
MAH:	Marketing authorization holder
MEDS:	Mission for Essential Drugs and Supplies
PPB:	Pharmacy and Poisons Board
WHO:	World Health Organization
PMS:	Post market surveillance
QSE:	Quality, Safety and Efficacy
UDI:	Unique Devices Identifier

Definitions of terms

Recall The removal of specific batch(es) of a medical product and health technologies from the market for products that do not meet marketing authorization requirements including reasons relating to deficiencies in the quality, safety, efficacy or effectiveness

Recall classification Recall Classification is the numerical designation, i.e., I, II, or III, assigned to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

Recall strategy Recall strategy is a planned specific course of action to be taken in conducting a recall, which addresses the depth, need for public awareness, and extent of effective checks/follow-up for the recall.

Withdrawal The total removal of medical product and health technologies from the market for reasons relating to deficiencies in the quality, safety, efficacy leading to cessation of its market authorization.

Medical Product For purposes of this guideline, medical product includes medicinal products and medical devices.

Health risk Reasonable probability that the use of or exposure to a product may cause serious adverse health consequences or death; use of or exposure to the product may cause temporary or medically reversible adverse health consequences; or the outcome where the probability of serious adverse health consequences is remote.

Health technology Is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives (WHO).

Parallel importation Means the importation into Kenya by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical representative.

Parallel importer A person who is licensed to carry out the business of parallel importation.

Market Authorization Holder An agency/company which has been granted marketing authorization for medical product (s) and health technologies in the Kenya. The company is responsible for all aspects of quality, safety, efficacy/effectiveness and compliance with conditions of registration.

Voluntary recall A recall initiated by the market authorization holder or their agent as a result of abnormal observation in any product quality, safety and efficacy during periodic review or investigation of a market complaint or any other failures.

Statutory recall A recall directed by the Pharmacy and Poisons Board upon notification of deficiencies in the quality, safety, efficacy of a medical product and health technologies.

Voluntary withdrawal A withdrawal initiated by the market authorization holder or their agent as a result of abnormal observation in any product quality, safety and efficacy during periodic review or investigation of a market complaint or any other failures.

Statutory withdrawal A withdrawal directed by the Pharmacy and Poisons Board upon notification of deficiencies in the quality, safety, efficacy of a medical product and health technologies.

Product quality defect An attribute of a medical product and health technology or its component which may affect the quality, safety and efficacy of the product, and which is not in line with the approved Product Authorization or other marketing authorization.

Wholesaler An entity licensed by PPB to carry out the business of a wholesale dealer

Procurement agencies Central procurement agencies of medical products and health technologies including Kenya Medical Supplies Agency and Mission for Essential Drugs Supply (MEDS)

Medicines distribution outlets They include hospital pharmacies, clinics, medical canters

General sales outlets Include shops, supermarkets and other vendors of general sales medical products and health technologies

Research institutions Academic or scientific research institutions

Donations Medicines not registered in Kenya and imported to Kenya as donations

Investigational products Medical products and health technologies applied in clinical trials and other clinical studies

Clinical investigational institutions Institutions conducting clinical trials or clinical studies

Qualified person A person designated as responsible for recalls by the MAH

Consignee Means anyone who received, purchased or used the product being recalled.

Direct Lifting Recalled products are taken off the shelf and the MAH or persons responsible for recall collects them directly from the premises where the product is stored or kept

Acknowledgements
The Pharmacy and Poisons Board wishes to express its appreciation to all individuals and organizations who made contributions towards development of this guideline on market surveillance of medical products and technologies in Kenya

1. Preface

Post-marketing quality surveillance of medical products and health technologies is a critical function of the PPB and it is useful in monitoring and assuring quality of products circulating in the Kenyan market. Recalls and withdrawal of medical products based on the health risk that may occur to the population is one of the regulatory actions that are implemented following market surveillance activities.

Recalls are effective methods for removing or correcting marketed products, their labeling and / or promotional literature that violate the requirements administered by the Pharmacy and Poisons Board. Recalls enable the Board to protect safety and health of the public and prevent health risks that may be presented from substandard and falsified medical products or safety issues. It is an efficient and timely method especially when products are widely distributed.

The Market Authorization Holders and importers regulated by the Board may initiate recalls in consultation with the Board to fulfill their responsibility to protect public health and safety. The entities may also initiate recalls following notification of quality defect or safety issue from the Board, and in response to a formal requirement from the Board, as statutory recall.

The guidelines are made for information and guidance by all concerned players and stakeholders.

CHIEF EXECUTIVE OFFICER

2. INTRODUCTION

2.1 Background

The Pharmacy and Poisons Board is National Medicines Regulatory Authority for Kenya established by an act of parliament to that regulates both the pharmacy practice and trade in medicines and health technologies. To achieve this, the relevant act of Parliament, CAP 244, gives it mandate to regulate the trade and manufacturing of medical products and health technologies.

The Board's mandate therefore encompasses appropriate regulatory mechanisms to ensure the highest attainable standards of quality, safety and efficacy of medical products and health technologies are met. To ensure public safety, the Board strategies shall include but not limited to recalls and withdrawals of defective products.

Defective medicinal products and health technologies pose a serious health threat as they may have various effects on the wellbeing of a given population. There are many potential causes for a recall. These potential causes include, but are not limited to, any circumstance where the safety, identity, strength, purity, quality, or fitness for use or performance of a marketed product or device is in question.

Product defects shall include but not limited to deviations in quality attributes, potential contamination, failure to meet, product related market complaints, adverse drug reactions or adverse events and non-conformities from Good Manufacturing Practice inspections. All these factors may lead to product recall or withdrawa from the market.

A recall is an action taken to remove a particular batch or several batches of medical products and health technologies from distribution chain or use, for which deficiencies in quality, efficacy or safety have been reported. These products include substandard and falsified medical products, products reported to cause adverse drug reactions or those that fail to meet regulatory requirements.

The level (depth) of recall shall be based on the class of the recall and extent of the level to which distribution has taken place.

Consumer/End user level recall; To the level of individual consumer, patients an physician.

Retail level; Recall action to the level immediately preceding consumer/end user level. It includes retail pharmacies, hospital pharmacies, clinics and nursing homes.

Wholesale level; All distribution levels between the manufacturer and retailer.

A Withdrawal generally involves the total removal of a product (all batches) or health technology from the market due to either quality defects, a safety or efficacy issue or due to non-compliance to a market authorization.

Reports of quality defects shall be received by the Pharmacy and poisons Board from different sources and the defects shall be classified according to their potential threat to patients and public health in general.

Recalls/withdrawals shall be performed promptly and should result in the effective removal of the batch or product in question from the market to the extent agreed with Pharmacy and Poisons Board.

Marketing authorization holders (MAH) are required to take full responsibility for their medical products recalls, to ensure successful execution.

This guide takes into account classification of recalls, recall notification requirements, specific roles for different stakeholders in the recall process and the basic requirements expected by PPB in relation to recalls

2.2 Legal Mandate

This guideline draws its mandate from CAP 244 which is an act of parliament that regulates the practice of pharmacy, manufacture and trade in medical products and health technologies in Kenya.

The Constitution of Kenya 2010, section 43 (1) states that every person has the right to highest attainable standard of health, which includes right to healthcare services including reproductive healthcare.

The Pharmacy and Poisons Act, Cap 244, Section 3 A (d) section 63 (1) (c) empowers the Pharmacy and Poisons Board to recall medical products and health technologies from the market. The act also empowers the Board to formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products, grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary and investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products.

2.3 Scope

This guideline shall apply to recall of all medical products and health technologies in the Kenya throughout supply chain including public, private, faith-based organizations (FBOs) and institutions in which clinical investigations are performed. It shall apply to all medical products and health technologies marketed in Kenya by the MAHs and parallel importers including investigational products.

3. RECALLS OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES

3.1 Classification of recalls

3.1.1. A recall may be voluntary by the MAH or statutory requirement by PPB and may be classified according to the reasons for recall.

3.1.2 For any recall, the MAH is required to fill a notification form (Annex I) and notify PPB.

3.1.3 For statutory recalls, PPB shall make a recall communication to the MAH who shall be required to fill the recall form and submit it within 24 hours of the communication.

3.1.4 For statutory recall, Health risk evaluation will be done by PPB and initiate recall action on case-by-case basis.

3.1.5 Recalls are usually classified in relation to the level of seriousness of the issues leading to the recall and their impact on the health of patients or the public.

3.1.6 In this regard, three classes of recalls shall be identified; classes I, II and III, and each recall classification determines the extent of the recall and method/communication by which the recall notification shall be issued.

3.2 Class I

This is where there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death.

Examples of such quality defects:

3.2.1 Wrong product (label and contents are different products).

3.2.2 Correct product but wrong strength, with serious medical consequences.

3.2.3 Microbial contamination of sterile injectable or ophthalmic product and medical devices.

3.2.4 Chemical contamination with serious medical consequences.

3.2.5 Mix up of products within a pack.

3.2.6 Implantable pace maker with a defect that results in a loss of pacing output, which for pacemaker dependent patient may lead to serious injury or death

3.2.7 Wrong active ingredient in a multi-component product with serious medical consequences.

3.2.8 Serious adverse reactions which are batch or product related false result on IVD test for a medicine with narrow therapeutic index that may lead to overdose, causing permanent injury.

3.3 Method and extent of recall to be considered for Class I recalls:

3.3.1 Recall of the batch(es) of products to patient or user level may be necessary. If so, this can be done via announcements by the MAH or PPB or both using public means (national radio and television and/or by newspaper notifications).

3.3.2 Medical practitioners, pharmacists, retailers and wholesalers should be contacted by the MAH or designee within 24 hours, where possible, notifying of the recall action, asking them to quarantine the product immediately and providing the required instructions. If initial communication is by a source other than by letter, there should be a follow-up letter issued to the above persons to confirm this notification.

3.3.3 Direct uplifting of stock, rather than allowing the return of the affected product via wholesalers, is the method of choice for retrieval of product in the case of Class I recalls.

3.4 Class II

This is where the use of, or exposure to a defective product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote.

Examples of such quality defects are:

3.4.1 Mislabeling e.g., wrong or missing text or figures.

3.4.2 Missing or incorrect information e.g., leaflets or inserts.

3.4.3 Microbial contamination of non-injectable, non-ophthalmic sterile product with serious medical consequences.

3.4.4 Chemical or physical contamination (significant impurities, cross-contamination, particulates).

3.4.5 Mix up of products but not within a pack.

3.4.6 Non-compliance with specification (e.g., assay, stability, fill/weight).

3.4.7 Insecure closure with serious medical consequences (e.g., cytotoxic, child-resistant containers, potent products).

3.4.8 Software error in radiation treatment planning tool that could lead to therapy being miscalculated and incorrectly administered

3.5 Method and extent of recall to be considered for Class II recalls:

3.5.1 All target parties should receive a recall letter from the MAH or their agent instructing them to quarantine the product and the next course of action.

3.5.2 In general, such recalls should be carried out to wholesaler, retail pharmacy, and hospital pharmacy, medical practitioners, or general sales outlets level as appropriate. In some cases, telephone or email contact by the MAH with certain groups may be necessary.

3.5.3 The recall notification period to all stakeholders shall be within 72 hours from the time PPB and the MAH agree on the recall action.

3.6 Class III

This is where the use of, or exposure to a defective product is not likely to cause adverse health consequences. Examples of such quality defects are:

3.6.1 Faulty packaging e.g., wrong or missing batch number or expiry date.

3.6.2 Faulty closure of products

3.6.3 Contamination, for example, microbial spoilage, dirt or detritus, particulate matter.

3.6.4 Outer packaging of a consumable medical device indicates a different size to that which is actually supplied in the box, it would be obvious to the user that the consumable was the incorrect size.

3.7 Method and extent of recall to be considered for Class III recalls:

3.7.1 Such recalls may be carried out to wholesale, retail, hospital and/or medical practitioners' level.

3.7.3 In most cases however, a recall to wholesaler level may be sufficient.

3.7.3 Class III recalls shall be notified by letter to appropriate target groups by the MAH.

3.7.4 The recall notification period to all stakeholders shall be within 72 hours from the time PPB and the MAH agree on the recall action.

3.8 Medical alerts/cautions

3.8.1 The nature of the product quality, safety, efficacy and effectiveness defect may be such that a product recall/withdrawal may not be considered necessary or appropriate.

3.8.2 However, consideration should be given to the need to alert healthcare professionals who may prescribe use of, or who may distribute, dispense or administer the product, bringing to their attention details of the product defect.

3.8.3 The issuing of a medical alert (Caution in use notification) may be appropriate in this case. The alert can also be given to consumers.

3.8.4 Like all notification, "Caution in use notification", shall submitted to PPB for review and approval before the alert is sent out. The Pharmacy and Poisons board shall have the prerogative to reclassify the defect and may order for recall-based quality risk assessment or justifiable reasons.

3.8.5 The notification period for these kinds of alerts shall be within 5 days from the time the MAH and PPB agree on the caution in use notification.

Class	Level/extent of recall	Method of Communication channels	Timelines of communication	Method of recall	Duration of Recall
I	Consumer, Hospital Pharmacies, retailers, wholesaler, medical practitioners, patients	Phone, email, Radio, TV, press announcements. All these shall be followed by letter	24 hrs.	Direct uplift of stocks	14 days
II	Retailers, Hospital Pharmacies, wholesale, medical practitioners	Letter, email, phone	72 hrs.	Via wholesaler	21 days
III	Wholesalers, possibly Hospital pharmacies and other retailers	**L**etter, email, phone	5 days	Via wholesaler	28 days
Caution in use notification	Hospital Pharmacies, medical practitioners, wholesalers	letters	5 days	NA	

Figure 1; *summary of recall class and communication*

N/B The above timelines are for guidance but may change depending on specific cases

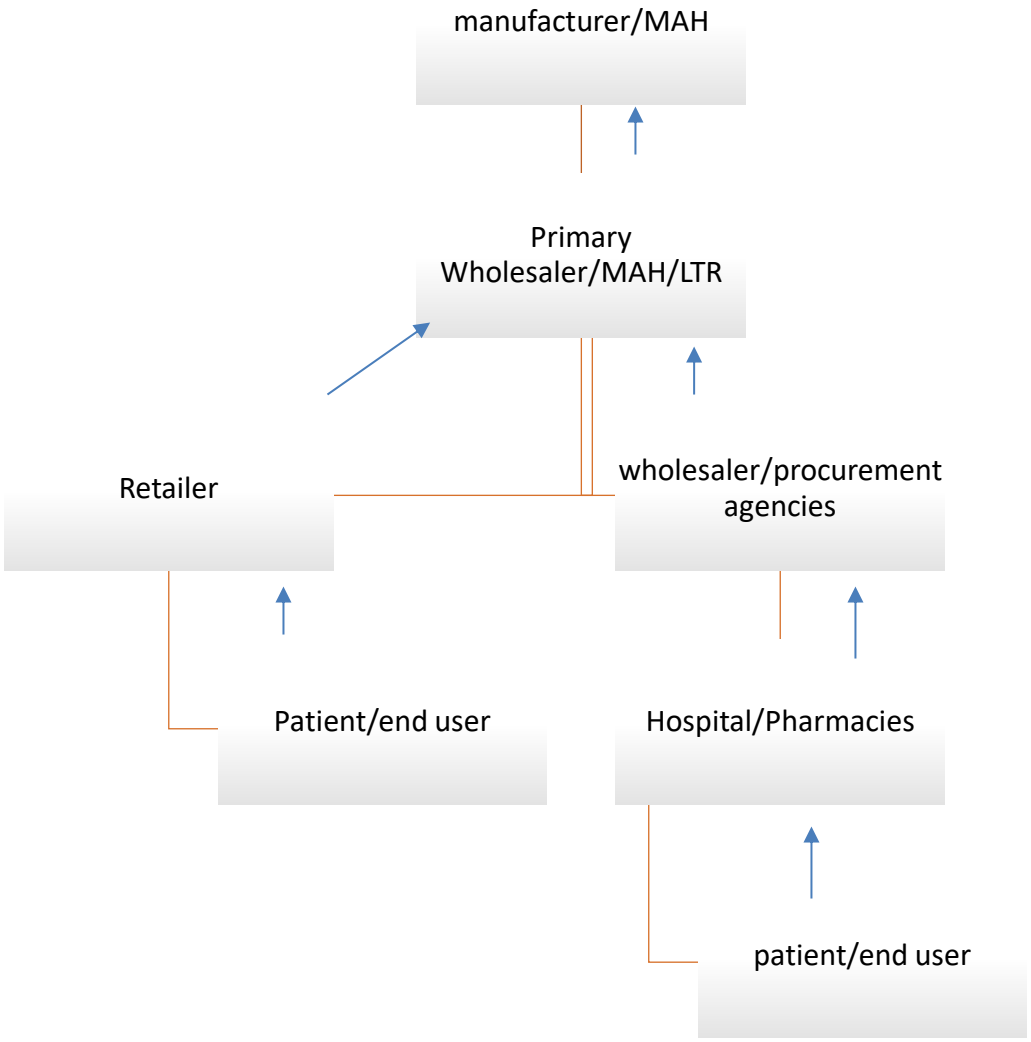

Figure 2; Flow chart of distribution, recall and withdrawal chain

3.9 Withdrawal of medical products and health technologies

3.9.1 A withdrawal may be voluntary by the MAH or statutory requirement by PPB and may be classified according to the reasons for withdrawal. For any withdrawal the MAH is required to fill a notification form (Annex II) and notify PPB.

3.9.2 For statutory withdrawal, PPB shall make a withdrawal communication to the MAH who shall be required to fill the withdrawal form and submit it within 24 hours of the communication.

3.9.3 For statutory withdrawal Health risk evaluation will be done by PPB and initiate withdrawal action on case-by-case basis.

3.9.4 Reasons for withdrawal:

a) Quality, Safety, Efficacy concerns

b) Issues of concern touching on the quality, safety, efficacy and effectiveness for medical products may lead to withdrawal of products from the market.

3.10 Recall and Withdrawal Communication

3.10.1 Recall and withdrawal communication may be initiated by MAH or PPB depending on available information and circumstances.

3.10.2 All communication from PPB shall be in line with the Organizational Communication Strategy.

Figure 3: Recall Communication Flow Chart

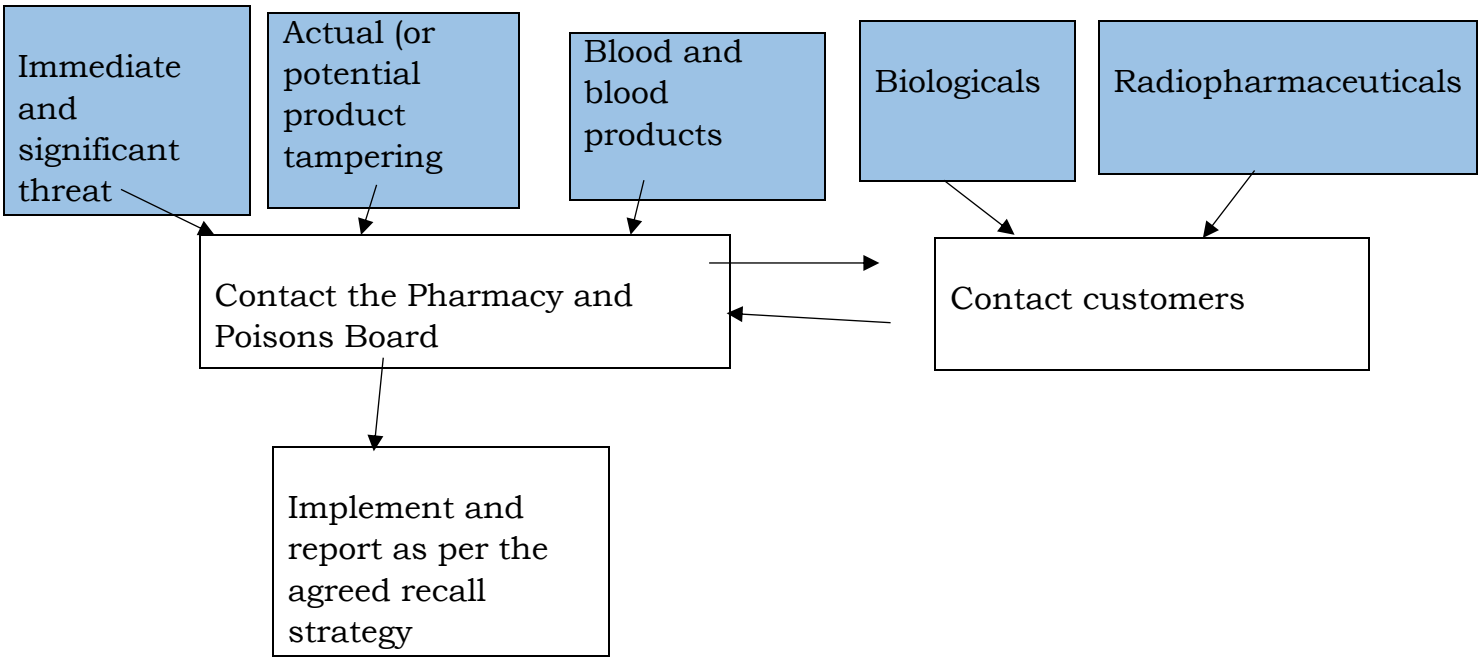

Figure 3; Communication Flow

3.10.3 Recall and withdrawal Notification from MAH to PPB

a) The MAH/manufacturer or designate shall formally notify the Pharmacy and Poisons Board through a letter, email or telephone, with accompanying notification form (Annex II) immediately on becoming aware of a product defect.

b) Notifications for any intended recall or withdrawal action shall be made to PPB within 24 hours of the discovery of product defect.

c) A formal letter of notification shall follow any telephone communication.

d) The MAH shall notify PPB of a product defect and any intended recall or withdrawal even if some of the required information in Annex II is not available at the time of reporting.

3.10.4 Recall and withdrawal communication from MAH to other stakeholders

a) The MAH shall establish a communication mode in consultation with the Pharmacy and Poisons Board following a recall or withdrawal notification.

b) The Recall communications may include; emails or registered letter, telephone calls may be used in addition.

c) Whichever the mode of communication adopted, the information contained, depending on the target audience, must be accurate, factual and approved by PPB.

d) There shall be maintained verifiable records of communication to the clients and stakeholders.

e) The communication shall be monitored and resulting records may be subjected to audits.

f) It is the responsibility of the MAH/manufacturer or designate agencies to notify their clients of an intended recall or withdrawal.

g) Recall/withdrawal communications should be brief and to the point;

h) Clearly identify the product(s) to be recalled, such as the product name, pack size, unit, INN, brand name, serial numbers(s), potency, strength, dosage form, type, model, series, lot number(s), product registration number, Universal Product Code, Unique Device Identifier (UDI) if

applicable, and any other pertinent descriptive information to enable accurate and immediate identification of the product;

i) It shall contain a concise statement of the reason for the recall, known or potential hazard(s), and instructions for consignees to follow in handling the recall. The MAH has the ultimate responsibility of notifying the consignees of any recall.

3.10.5 Recall letters

a) The recall letter should be on a company letterhead, dated, with the name and signature of authorized person **(Annex II: Model Recall Letter)**

b) The text of recall letter shall include:

i. Instruction for recall of the product,
ii. The method of return, Disposal or Correction (for medical devices)
iii. A response from consignee to confirm receipt and understanding of the action to be taken e.g., use of pre-addressed cards, telephone replies or a form to complete and return by facsimile or e-mail.
iv. The MAH should clearly identify a hotline for enquiry.
v. Information to be given to patient concerning product under recall
vi. For retail level recall, the MAH should have confirmation for stock at hand that is returned from the consignees
vii. If the health risk of the product is high and distribution is limited, the MAH may contact clients and provide the information listed above by telephone then follow up by a recall letter.
viii. A press/media release may be done by the MAH with approval from the Board

3.10.6 Recall and withdrawal communication from PPB to MAH

a) The Pharmacy and Poisons Board shall be responsible for initiating recall and withdrawal.

b) The Board shall promptly inform the MAH of any product defect and the requirement for recall or withdrawal, and require that the MAH develop

a recall or withdrawal strategy and share with PPB for concurrence and approval.

3.10.7 Recall and withdrawal communication from PPB to stakeholders

a) PPB shall be responsible for initiating all recalls and withdrawal in collaboration with the MAH.

b) The communication methods shall include letters, email, and press release, as it may be appropriate.

c) Note: Press/media release is a responsibility of the Pharmacy and Poisons Board. Market authorization holders shall refrain from issuing press/media release at any stage of recall.

3.10.8 Press/media Release

a) These are rapid alerts to the public usually reserved for hazards classified as Class I, and where appropriate Class II, or in situations where other means for controlling the hazard appear inadequate.

b) Rapid alert to public may only be issued through appropriate channels, which may include press, and media release through respected and popular newspapers and media houses.

3.10.9 Minimum Information for Recall /Withdrawal Action

a) Complete description of the quality defect/reason for the proposed recall.

b) Brand name of the affected product, INN name of the product, active pharmaceutical ingredient, product strength, pharmaceutical form (e.g. tablets, solution for injection, etc)

c) Description of package, batch numbers, manufacturing date ad expiry date information for each batch

d) Finished product manufacturer's name and address

e) Name and address of MAH holder, and other contact details

f) The total quantity of the medical product that had been distributed up to the time the recall was initiated.

g) List of customers to whom the product was issued.

h) Area of distribution of the product, if exported, country where it was exported.

i) Indication of health risk, together with reasons

3.11 Responsibilities in relation to recall/withdrawal

3.11.1 The Pharmacy and Poisons Board shall be responsible for:

a) Hear and determine appeals on recall (appeal timelines should be stated)

b) Investigating the recall processes

c) Establishing an updated database of all products recalled or withdrawn from the Kenyan market. The list of recalled/ withdrawn products shall be published on PPB website.

d) Reviewing recall strategy for both statutory recall and voluntary recalls and suggest appropriate changes.

e) Take over the implementation of recall actions, where there is sufficient reason to believe that the MAH is unable to conduct the recall as per the strategy and that the recall action is ineffective.

f) Establish a Quality, Safety, Efficacy and Effectiveness Committee. The committee shall be comprised of C.E.O as the Chair,

3.11.2 Quality Safety Efficacy (QSE) Committee shall

a) Determining if regulatory action is a recall process and initiate recalls, both voluntary and statutory recalls.

b) Terminate recall actions

c) PPB shall determine when a recall should be terminated and, upon such determination, it shall provide written notification of termination to the MAH/ Manufacturer

d) Notifying the MAH on the mandated recalls (Timelines within 48 hours)

e) Notifying the procurement agencies on mandatory recalls where applicable.

f) Taking appropriate regulatory actions or other measures when the MAH fails to recall a product, when recall action is not effective, the MAH fails to complete recall action in timely fashion, when PPB has a reason to believe the MAHs recall strategy is not effective

g) The sanctions shall include but not limited to suspension or revocation of marketing authorization, registration or licenses, disciplinary action, fines, blacklisting, prosecution
h) Seeking and providing scientific advisory to assist in preparation of media releases/ media alerts (SOP)
i) Seeking and reviewing information on all product recalls, this includes contact with other medicines regulatory agencies and organizations (WHO).

3.11.3 Recall Committee:

The recall committee is a technical committee of the QSE and its responsibilities shall be;

a) Conducting health hazard/ risk evaluation
b) Carrying out classification of recalls
c) Reviewing recall strategy and provide recommendations
d) Monitoring and auditing effectiveness of the recall strategy
e) Monitoring and auditing recall actions
f) Evaluating the effectiveness of recall actions
g) Instituting sanctions where MAHs/ Manufacturers refuse to recall, incomplete recall, ineffective recall, recalls not completed within stipulated timelines.

3.11.4 MAH/ Manufacturer

The MAH/Manufacturer shall be responsible for;

a) Establishing and maintaining a system which includes procedures to effectively and promptly recall products. The system shall be subject to audit by PPB
b) Designating a person(s) responsible for recall actions.
c) Informing PPB of recall action in other jurisdiction of similar products marketed in Kenya (timelines)
d) Keeping an updated list/ database of all their products and clients with a clear and effective batch/lot tracking/tracing system.
e) Filling the recall notification form and submitting to PPB for both voluntary and mandatory recalls (refer to recall notification form)
f) Submitting progress reports to PPB as per the prescribed timeline

g) Ensuring that mandated recall is implemented comprehensively and completed expeditiously
h) Performing reconciliation of quantities returned on the recall with the quantities dispatched.
i) Reconciliation shall include accurate batch recording, together with properly kept distribution records of distributors, wholesalers and retail pharmacies
j) Reviewing the effectiveness of the recall actions
k) Ensuring all recall products are put under quarantine, and clearly marked not for sale or distribution, shall be stored separate from the rest of the products.
l) Providing recall notification (Refer to recall notification form) to all the distribution outlets as per prescribed timelines through appropriate communication channels (Refer to communication strategy)
m) Challenging their recall systems at least once a year unless the MAH has executed an actual recall within that period.
n) The recall procedure shall be challenged to ensure its effectiveness; it shall involve verifying the accuracy of contact names and numbers, and challenging the company's product traceability and batch reconciliation procedures. The MAH shall include the whole distribution chain in the challenge, where possible.
o) The recall challenge records shall be kept and shall be subject to audit by PPB.
p) Keeping recall documents and records for a minimum of 5 years. (Refer to archives act, PPB guide, and other guides
q) Destruction of recall products under supervision of PPB
r) Communicating the recall/ withdrawal alert to all the relevant stakeholders
s) Conducting root cause analysis of the quality defect and determine the corrective and preventive actions (CAPAs). This shall be communicated to PPB (timelines)
t) Carrying out recall classification in consultation with PPB

3.11.5 Distribution chain (Importers, exporters, wholesalers, procurement agencies)

They shall be responsible for;

a) Keeping an updated list/ database of all their products and clients with a clear and effective batch/lot tracking/tracing system.
b) Maintaining a system which includes documented procedures for recalls
c) Quarantine of stocks of recalled batch(es) at hand
d) Receiving and quarantine of returned products received back from consignees
e) Assisting the MAH in execution of the recall- Shall facilitate the MAH by contacting the retailers and other suppliers to whom the product was supplied.
f) When a potential recall action is as a result of a quality defect that occurred at a wholesaling facility, the wholesaler is required to contact the MAH and PPB to discuss whether recall action is necessary.

3.11.6 Parallel Importers

Formal agreements between the parallel importer and the wholesaler from the importing country must be established to ensure the parallel importer is notified of any potential product defects, recalls or withdrawals of the product in another country.

The parallel importer shall be responsible for;

a) Ensuring an effective recall process.
b) Keeping PPB informed on the progress of recall provide updates and final report on completion of the recall to PPB.
c) Maintaining records of all imported products and where they have been distributed to ensure traceability of the products in case of a recall/withdrawal
d) Establishing mechanisms to ensure reimbursement/refund for recalled/withdrawn product.
e) Tracking the progress of the recall and generate stock reconciliation data for the recall.
f) Ensuring safe disposal of the recalled products as per the destruction/ disposal guidelines

3.11.7 Retail Pharmacies/ Research institutions/ other medicines distribution outlets

They shall be responsible for;

a) Quarantine of stocks of recalled batch (es) at hand
b) Receiving and quarantine of recalled products from consumers/ patients
c) Quarantine and return the recalled products to the wholesaler/ MAH
d) Adhering to the instructions provided in the recall notification by MAH, manufacturer, wholesaler or PPB.
e) Maintaining records of all products dispensed to patients and contact the patients/ end user to return recalled/withdrawn products where necessary
f) Communicating with the wholesaler/MAH and PPB where a potential recall situation is the result of a quality defect at a retail pharmacy,
g) Assisting the MAH in execution of the recall- Shall facilitate the MAH by contacting the consumers/ patients and other organizations where the medical products and health technology was supplied
h) Providing professional advice to consumers/ patients as and when needed

3.11.8 Consumers

Consumers shall be responsible for;

a) Return of recalled medical products or health technologies to the facility from where the product was obtained.
b) Seeking professional advice from registered health care facilities and healthcare professionals
c) Donations
d) Donation guideline should have a clause stating that the recipient (consignee in Kenya) shall be responsible for implementation of regulatory actions, such as recalls and withdrawals
e) The consignee of medical products and health technologies donations in Kenya shall be responsible for implementation of all regulatory actions including recalls and withdrawals.

3.11.9 Clinical trial/ Clinical investigation Institutions

a) The sponsor of a clinical trial and the principal investigator shall be responsible for implementation of regulatory actions, such as recalls and withdrawals.

3.12 RECALL STRATEGY

3.12.1 Each recall is unique and must have its own recall strategy.

3.12.2 Recall strategies are based on the individual recall circumstances and may not necessarily be dependent on recall classification.

3.12.3 A recall strategy assures the effectiveness of mitigating the risk posed by a product under recall. It shall address the actions taken by the MAH to ensure the product is successfully removed from the market.

3.12.4 The Board will review recalling MAHs, recall strategy.

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

a) Class of recall: class I, II, III

b) recall communication:

c) From the recalling firm to its affected accounts. (Consider section on communication)

3.12.6 Public warning

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. In urgent situations, consideration should be given to the need for a press release that could be nationwide or to affected geographical areas only.

3.12.7 In some cases, special communication with specific segments of the population as discussed under recall communication section.

3.12.8 Effectiveness Checks

a) The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

b) The recalling MAH is responsible for conducting effectiveness checks.

c) The MAH's recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted by the recalling MAH.

d) PPB shall carry out independent effectiveness checks as part of monitoring the recall performance. This is a separate exercise which must not be

considered as part of, or supplement to, the MAHs responsibilities for adequate effectiveness checks.

3.12.9 Extent/Level of the recall:

a) The recall may extend to the consumer or user level, the retail level, or the wholesale level. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

b) Consumer or end user level, which may vary with product, including any intermediate wholesale or retail level; (indicate recall spots, operation hours and duration) or Retail level, including any intermediate wholesale level; or Wholesale level.

3.12.10 Health risk evaluation

a) Before initiating a recall, the MAH shall collect, correlate and evaluate all known information on the nature and extent of the reported health risk.

b) An evaluation of the health risk 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:

c) Whether any disease or injuries have already occurred from the use of the product.

d) The health risk to various segments of the populations e.g. children, surgical Patients and pregnant women, who are expected to be exposed to the product, with particular attention to those individuals who may be at greatest risk.

e) The degree of seriousness of the health hazard to which the population at greatest risk would be exposed.

f) The likelihood of occurrence of that health risk.

g) The consequences (immediate or long-term) of occurrence of the health risk.

h) Availability of alternative products

i) The MAH will be given every opportunity to contribute to the information used by PPB to evaluate risk. PPB shall classify the recall based on the

relative degree of health risk posed by the product being recalled and the implications for other products, for the supply chain, and for patients / users.

j) A statement on and the reasons for recommending the desired option under each of the elements shall be included. The recall strategy should consider the disposition of recalled products (e.g., carcinogenic products) when normal disposition means, landfill, crushing, denaturing, etc., are inadequate.

k) The MAH shall submit to PPB all relevant/applicable recall information as and when it becomes available at different stages of recall process.

l) The MAH shall submit the information outlined in this guidance to PPB as soon as possible after the decision to recall is made while considering the annexed checklist.

3.13 POST RECALL/WITHDRAWAL PROCEDURES

3.13.1 Recall reports

a) Weekly progress reports shall be sent to the PPB by the MAH/Manufacturer. By the 30th day from the recall notification, a final report of the details of the recall, and recall actions that were taken must be submitted to PPB for review.

b) The determination by the MAH/Manufacturer that a recall is complete can only be made by reconciliation of quantities dispatched vs quantities returned. This reconciliation can only be accomplished through accurate batch recording together with properly kept distribution records.

3.13.2 Marketing authorization holder recall reports shall include;

a) Mechanism of recall notification and communication (e.g., by letter, telephone or email)

b) he extent of recall (e.g., to distributor or level, wholesale, retail pharmacy level or end user/consumer level), extent of product distribution(territory), total quantity of the product manufactured for the affected batch(es)

c) Total quantity distributed in Kenya, for the affected batch(es), date when recall was closed-out.
d) Reconciliation report (should include physical address of the location (s) where returned quantities have been stored).
e) Root cause analysis/investigation report
f) Corrective and preventive actions (CAPA) and measures taken to prevent future occurrence of the same defects
g) Timelines for each of the corrective actions identified
h) Specific action steps for disposal of the recalled product

3.13.3 Timeframes for reports

a) Initial report (1 week)

i. Submit your initial report at the agreed time, one week after the start of the recall which shall include;
ii. Dates when parts of the recall strategy were implemented, e.g., when you sent the recall letter to customers, number of customers notified.
iii. Descriptions of any major impediments, such as the recall or corrective actions not progressing according to agreed timelines.
iv. Implications of the initial investigation findings for the scope of the recall, (e.g., whether you or the manufacturer have identified any additional goods with the same issue.) Whether you notified overseas suppliers of exported goods about the recall in Kenya.

b) Follow-up report (2 week)

Submit your follow-up report at the agreed time, two weeks after recall implementation that shall include:

i. Percentage of customers you contacted who have responded to your recall
ii. the amount of affected goods held (including none)
iii. Percentage of customers who returned or destroyed their affected goods,
iv. Identity of customers with goods requiring correction

v. Descriptions of any major impediments, such as the recall or corrective

vi. actions not progressing according to agreed timelines.

c) Final report (4 Weeks)

i. Submit your final report at the agreed time, at 4 weeks after

ii. implementing the recall that shall include:

iii. Percentage of returned goods

iv. Percentage of returned goods destroyed or disposed. Include a certificate

v. of destruction for destroyed goods.

vi. Percentage of customers with goods that have been corrected, or

vii. supplied with the correction

viii. Details of recall effectiveness checks including percentage recall achieved

ix. Root cause analysis that led to the recall

x. Proposed CAPA to prevent recurrence of the issue that led to the recall.

d) Destruction/ Disposal of recalled products

Destruction of recalled products shall be as per PPB guidelines on safe management of pharmaceutical waste.

3.14 TERMINATION OF A RECALL

This shall be determined after the PPB has reviewed the final report submitted by the MAH. The recall shall be terminated upon submission and review of the following:

3.14.1 Reconciliation report for all the stocks under recall

3.14.2 Detailed investigation report leading to the recall

3.14.3 Corrective action preventive action plan and report

3.14.4 Concise GMP report from PPB where necessary

3.14.5 Destruction certificate issued by PPB

3.15 Appeals

Any person aggrieved by the decision of PPB to institute a recall/withdrawal may appeal through the Boards appeal mechanism.

3.16 Costs of recall/withdrawal

Where an MAH or their agents has failed to satisfactorily carry out a recall such that the recall process is then taken over by PPB, the MAH shall be required to reimburse all costs incurred by PPB to undertake the recall.

4 References

a) Product recall procedures, Health products and Food branch, Health Canada

b) Guidance for Industry: Product recalls, including removals and corrections (FDA, 11/03/2003)

c) Guideline for recall / withdrawal of medicines, medical devices and IVDs, Medicines Control Council, November 2015

5. Revision History

Pharmacy and Poisons Board	**Revision History**			Rev No. 1
Revision No:	**Date**	**Prepared by**	**Section (s) revised**	**Description of change**

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7. Annexes

Annex I: Recall / Withdrawal Notification Form

RECALL COMPLETION FORM	
Part I: Company Details	
MAH Name:	
Manufacturer's name:	
Manufacturing Site Address:	
LTR Details	
LTR Name and address:	
Contact mobile no:	
Email address:	
Part II: Recall responsibility	
Responsible officer for recall	
Mobile Number	
Hotline(s) for enquiry mobile number	
Part III: Product details	
Product Name	
All Batches and Quantities of the product within the shelf life Imported to the Kenyan Market	
(For Local Manufactures;) All Batches and Batch size of the product that is within the Shelf life released to the Kenyan Market.	
Unused stock subject to recall (currently in quarantine):	
Other similar complaints received by yourself	
Other complaints regarding different batches for which complaints NOT received by PPB	
Part IV: Proposed Action	
Nature of Complaint	
Proposed recall classification	

Recall start date	
Recall end date	
Proposed recall level	
Location of recall spots (For Consumer level recall only)	
Operating hours and duration of the recall spots (For Consumer level recall only)	
Proposed recall strategy (use separate sheet)	

I declare that the information provided is complete and true to the best of my knowledge. I commit to carry out the recall as agreed.

Name: _____ Signature: _____ Date: _____

Annex II: Product Recall Closure Form

1 Details of company

1.1 Name of company : _____

1.2 Address of company : _____

1.3 Name of reporting person : _____

1.4 Designation : _____

1.5 Office tel. : _____

1.6 Mobile tel. : _____

1.7 Fax : _____

1.8 Email : _____

1.9 Signature of reporting person: _____

1.10 Date : _____

3 Product details

Additional products can be provided as an attachment.

3.1	Name of product	:	_____
3.2	Product license number or other reference number *(please indicate relevant reference number for unregistered therapeutic product)*	:	_____
3.3	Active ingredient(s)	:	_____
3.4	Batch no: _____		Expiry date:_____
	Batch no: _____		Expiry date:_____
	Batch no: _____		Expiry date:_____
3.5	Quantity imported or manufactured in Singapore	:	_____
3.6	Quantity remaining in warehouse	:	_____
3.7	Quantity sold#	:	_____
3.8	Quantity recalled^	:	_____

2 Details of recall

2.1	Class of the recall	:	_____
2.2	Level of the recall	:	_____
2.3	Date of recall initiation	:	_____
2.4	Date of recall completion:		_____

Please attach sales record.

^ Please provide names and addresses of purchasers and quantities recalled.

4. Action(s) taken on affected stock(s)

4.1 I confirm that the above recall has been completed on *(date)*_____and all recalled stocks have been planned for:

- ☐ Destruction*.
- ☐ Re-introduction into the market upon approval by the Authority.
- ☐ Other actions upon approval by the Authority. Please specify the actions to be taken:

_____

_____

* Approval is not required. Documentary proof of action taken is required to be submitted once the recalled products are destroyed.

Attachment – Product details

		1	2	3	4	5
3.1	Name of product					
3.2	Product license number or other reference number					
3.3	Active ingredient(s)					
3.4	Batch number(s) affected and expiry date(s)					
3.5	Quantity imported or manufactured in Singapore					
3.6	Quantity remaining in warehouse					
3.7	Quantity sold					
3.8	Quantity recalled					

3.9	Action taken (pls specify: destruction / re- introduced / others)					

Annex III: MODEL RECALL LETTER

Company
Letterhead Date
(Month, Day, Year)

URGENT
[Insert FOOD, DRUG, MEDICAL DEVICE, BIOLOGIC, COSMETIC, TOBACCO] RECALL
[ ]
Contact Name or
Department Firm Name
Street Address
City, State, Zip Code

Dear [Insert Customer/Distributor/Manufacturer, etc.], This is to inform you of a product recall involving

[Insert: PRODUCT NAME, BRAND NAME, DESCRIPTIONS, UPC CODES, LOT NUMBERS AND ETC.]

See enclosed product label [for ease in identifying the product at retail/user level]. This recall has been identified due to [problem]. Use of [or consumption of] this product may [include any potential health hazard].

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or [Enclosed is a letter you should use in notifying your customers].

[Your notification must include instructions on what customers should

do with the recalled product.]

This recall should be carried out to the [wholesale], [retail], [consumer], [user] level.

Your assistance is appreciated and necessary to prevent [i.e. consumer Please complete and return the enclosed response form as soon as possible. If you have any questions, call [name, email and telephone number].

This recall is being made with the knowledge of the Pharmacy and Poisons Board.

Enclosures: Name: (Print)

Signature:

Title:

Annex IV: checklist for a recall strategy

Indicate the level in the distribution chain to which you are extending the recall. (i.e., wholesale/retail/pharmacy/medical user) If your recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to retail/pharmacy level.	
Indicate the method of notification (i.e., mail, phone, facsimile, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.	
Indicate how letters will be sent to customers (e.g., overnight mail, first class mail, certified mail, facsimile)	
If you have a web site, you should consider posting the recall notification on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)	
Report on what you have instructed customers to do with the recalled product.	
It is helpful for recalling firms to know the name and title of the Recall Contact for each of its consignees. Addressing a recall notification letter to a recall contact will expedite the recall process and reduce the potential for the notification letter to get misdirected.	
f product is to be returned, explain the mechanics of the process.	
Explain if this recall will create a market shortage that will impact on the consumer.	

Report on recall **effectiveness check** strategy. Include your actions for non- responders.	
Determine and provide your course of action for out-of-business distributors.	
Provide a proposed method of destruction, if applicable.	
If the product is to be "reconditioned", explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your local PPB District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable CGMPs	
Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.	
You contact your local PPB District Recall Coordinator prior to product destruction. PPB will review your proposed method of destruction and may choose to witness the destruction	
The recalling firm and customers keep adequate documentation of product destruction (and whether or not destruction was witnessed by an PPB investigator).	
Field corrections (i.e., product relabeling), be performed by recalling firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For Drug Recalls: Misbranded drugs for re-labeling should be returned to the recalling firm.	
You contact your local District Recall Coordinator prior to release of reconditioned goods.	

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