Guidelines for the Recall or Withdrawal of a Medical Product

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01: Writing, Reviewing, Checking, Approval and Authorization of this Guideline.

This guideline was written by the National Drug Authority Secretariat and extensively reviewed by the concerned departments and authorized by the Director, Inspectorate and Enforcement.

	Authorized by
Title	Director, Inspectorate and Enforcement
Name	Nahamya David
Signature	
Date	16 August 2017

0.2 Responsibility for Implementation

0.2.1 The Director, Inspectorate and Enforcement shall be responsible for the effective and consistent implementation of this Guideline.

0.2.2 All inspectors are responsible for reading and understanding this Guideline in order to know their responsibilities.

0.2.3 The Head Quality Management and the Manager GMP shall be responsible for coordinating the updating/revision of this Guideline.

0.3 Abbreviations and Acronyms

DIE	DIRECTORATE OF INSPECTORATE AND ENFORCEMENT
GMP	GOOD MANUFACTURING PRACTICES
LTR	LOCAL TECHNICAL REPRESENTATIVE
NDA	NATIONAL DRUG AUTHORITY
IVDs	IN VITRO DEVICES

1.0 INTRODUCTION

The guidelines for recall/withdrawal of medicines, medical devices and In Vitro Devices (IVDs) is the result of an agreement between the holder of the product registration certificate /parallel importer/distributor of the medicine/medical device/IVDs, and the National Drug Authority (NDA) in Uganda. Its purpose is to define the action to be taken by the Directorate of Inspectorate and Enforcement and the holder of the product registration certificate /parallel importer of the medicine/medical device/IVDs, when medicines/medical devices/IVDs for reasons relating to their safety, quality and efficacy/performance are to be removed from the market.

The Directorate of Inspectorate and Enforcement under the supervision of Director Inspectorate and Enforcement is responsible for recall/ withdrawal, and will monitor closely the effectiveness of the holder of the product registration certificate /parallel importer's/distributors recall actions and provide a scientific, technical and operational advice.

The holder of a product registration certificate /parallel importer/distributor should inform the Director Inspectorate and Enforcement of all the quality defects that may result in a recall of a medicine/medical device/IVD and the holder of the product registration certificate /parallel importer/distributor together with the medicines regulatory authority may decide if there is a need to recall or not.

Each holder of a product registration certificate /parallel importer/distributor should advise the medicines regulatory authority of the names, after hours and telephone numbers of two persons who have authority to discuss and, if necessary, implement a recall.

These guidelines serve to remind the holder of a product registration certificate /parallel importer/distributor that National Drug Authority expects them to take full responsibility for medicines/medical devices/IVDs recalls, including follow-up checks to ensure that the recalls are successful and that corrective actions are taken.

1.1 DEFINITIONS:

Recall: the complete removal from circulation of a specific batch or batches.

Withdrawal: the total removal of a product from circulation

Stock recovery: the removal or correction of a product which has been released for sale but has not yet been dispatched or left in the control of the LTR.

Note: Throughout the rest of the text the term 'recall' will be used to include 'withdrawal' and 'stock recovery'

1.2 PURPOSE OF RECALL, WITHDRAWAL OR STOCK RECOVERY

These procedures are intended 'To protect the health of the consumer from harmful effects which may be caused by the use of unsafe, ineffective or poor quality medicines and other medical products' (National Drug Policy 2000 sec.
3.6).

1.3 AUTHORISATION OF RECALLS

All recalls will be authorised and classified by the NDA after full assessment of any health risks.

1.4 REASONS FOR RECALLS

Withdrawal of a product from circulation or recall of a particular batch(es) of a product may be proposed by the importer in consultation with the Local Technical Representative (LTR) because of inter alia:

- Verified reports of serious adverse reactions not stated in the package insert
- Unacceptably frequency of adverse reactions which are mentioned in the package insert
- Incorrect labelling
- Incorrect formulation

Withdrawal may be initiated by the NDA as a result of verified reports of serious adverse reactions.

2. PROCEDURES TO BE FOLLOWED

2.1 Notification of the problem

Immediately upon becoming aware of a problem, the importer of the product must notify the Secretary to Authority, NDA (or in his/her absence, his/her nominated representative). Such notification should be initially by the most rapid means available (e.g. direct verbal

communication, telephone, fax, or email) but should be promptly followed up in writing.

The notification must provide the following information:

a) Trade name
b) Generic name
c) Strength
d) Pack size
e) Batch/lot number
f) Any other means of identification
g) Total quantity originally in the importer's possession (i.e. prior to distribution)
h) Details of distribution: date of start of distribution, recipients of distributed stocks and quantities distributed to each (including any exported stocks) (see note 2)
i) Quantity still in importer's possession
j) Reason for wanting to initiate recall, i.e. nature of the product defect.
k) Suggested action to be taken and level of urgency
l) Indication of health risk involved with reasons (see note 1).

Notes:

1) Before proposing a recall, the importer (in liaison with the LTR) should obtain and evaluate all available relevant information on the nature and extent of the health risks expected to result from use of the defective product.
2) A brief summary of the product distribution maybe given in the initial notification but full details should be made available as soon as possible after this.

2.2 NDA ASSESSMENT OF HEALTH RISK

Following notification and prior to making any decision on a recall, the NDA will, through review of relevant available documentation and in consultation with external experts as required, make a careful assessment of the health risks presented by the product in question. This will take into account inter alia the following factors:

a) Whether any disease or injury has already occurred from use of the product.
b) Assessment of the risk to various population groups, e.g. children, surgical patients, etc. expected to be exposed to the product with particular attention paid to high-risk individuals.
c) Assessment of how serious the health risk is to which the population at risk would be

exposed.

d) Assessment of how likely the risk is to occur.
e) e) Assessment of the consequences (immediate and long-term) of exposure to the risk.

In reaching any conclusion, the affected importer/LTR will be given every opportunity to contribute to the information required for this assessment.

2.3 CLASSIFICATION OF THE RECALL BY NDA

Based on the above risk assessment and the perceived likely outcome of use of or exposure to the defective product, the NDA will then classify and authorise the recall as follows,

Class A: risk of serious health problems or death
Class B: risk of temporary or minor health problems but very low risk of serious health problems
Class C: unlikely to cause any health problems

2.4 DETERMINATION OF RECALL STRATEGY BY NDA

Based on this classification and on the specific circumstances involved, the NDA will decide on an appropriate recall strategy. In making this decision the following factors will be considered:

a) The ease of identifying the product in circulation
b) The extent to which the product deficiency is obvious to the consumer/user
c) The need for continued availability of essential products (risk-benefit ratio)

2.4.1 Elements of a Recall Strategy

The recall strategy developed by NDA will address the following elements regarding how the recall will be conducted:

a) Depth of recall
This will depend on the degree of risk (Recall Classification) and extent of distribution of the defective product.

The recall strategy will specify the level in the distribution chain to which the recall will extend, as follows:

i) Consumer/user level (includes any intermediate wholesale/distribution/

retail levels and all hospitals, clinics, surgeries and health facilities)
ii) Retail level (includes intermediate wholesale/distribution levels)
iii) Wholesale/distribution level

b) Recall communication

The format, content and extent of the communication will be defined by NDA depending on the health risk associated with the defective product and the strategy developed for the recall. In general the communication will convey:

i) That the defective product is subject to a recall
ii) That further distribution, sale or use of any remaining product should stop immediately
iii) Instructions on what to do with the product.

2.5 AUTHORISATION BY NDA TO COMMENCE RECALL

Having classified the recall and determined the appropriate strategy, NDA will authorise the importer (in liaison with the LTR) to immediately implement the recall by notifying all parties involved. This authorisation will be initially by the most rapid means available (e.g. direct verbal communication, telephone, fax or email but will be promptly followed in writing.

2.6 IMPLEMENTATION OF THE RECALL

Upon receiving recall authorisation from NDA, the importer (in liaison with the LTR) must immediately implement the recall by notifying all parties involved.

2.6.1 Method of communication

Depending on the selected recall strategy, this communication may be by telephone, fax, email, telegram, public media or special delivery letter marked 'MEDICINAL RECALL' in bold red type on the letter and envelope.

Notes:

1. For Class A and Class B recalls, the letter should also be marked 'URGENT'
2. All telephone or other verbal contacts must be confirmed in writing.

2.6.2 Contents of a the recall communication

The recall communication should be brief and to the point and should contain:

a) Name of the product

b) Strength of the product
c) Pack size
d) Any other relevant descriptive information
e) Nature of the defect
f) Urgency of the recall
g) Reason for the recall
h) Indication of the (degree of) health risk
i) Specific clear instructions on what to do with the product to be recalled

2.6.3 Follow-up to initial communication

The importer should actively follow-up those who do not respond within a reasonable time*** to the initial recall communication. This may be initially by telephone, fax or email but should be followed by further written communication.

2.7 ISSUE OF PUBLIC WARNING BY NDA (THROUGH MASS MEDIA)

In the case of urgent recalls (ie. Class A recalls and occasionally Class B recalls) where other means for preventing use of the product would be inadequate, the NDA may decide to issue public recall announcement/warning.

The purpose of this is to alert the public that a product being recalled presents a serious health hazard.

According to the recall strategy decided, the type of public warning may be either:

a) **General:** through national and or local news media as appropriate
b) **Specific:** through specialised news media, e.g. professional or trade publications, or to specialised target audience, e.g. physicians, hospitals, etc

2.8 POST-RECALL PROCEDURES

2.8.1 Recall Report

Within 30 days of the recall authorisation being communicated, the importer or LTR must submit to NDA a report containing the following information:

a) Name of the product
b) Strength of the product

c) pack size
d) Batch/lot number
e) Nature of the defect
f) Action taken
g) Urgency of the action taken
h) Reason for the action taken
i) Indication of the (degree of) health risk and reported health problems
j) Copies of all recall correspondence
k) Steps taken to prevent a recurrence of the problem

2.8.2 Termination of recall by NDA

NDA will terminate the recall when it is fully satisfied that all stocks of the defective product have been completely removed from circulation and that appropriate corrective measures have been instituted to prevent a recurrence of the problem. NDA will accordingly notify the relevant importer/s of the termination. Initially this may be by the most rapid means available (e.g. direct verbal communication, telephone, fax, or email) but in any case will be followed by official written notification.

2.8.3 Reconciliation Report

The importer must submit a full stock reconciliation report to NDA within 14 days after termination of a recall.

3.0 NOTES

3.1 MONITORING OF THE RECALL PROCESS BY NDA

The NDA (Inspectorate Department) will closely monitor the effectiveness of recall procedures authorised by NDA and instituted by the relevant importer and will provide relevant scientific, operational and technical advice.

3.2 UNSATISFACTORY IMPLEMENTATION OF RECALL PROCEDURES BY THE IMPORTER

If implementation of the authorised and recommended recall procedures by the importer is deemed to be unsatisfactory, the NDA will take prompt and appropriate steps to remove the product from sale or use.

3.3 NDA ENFORCEMENT ACTIONS

Authorised recall by a company will not preclude NDA taking any enforcement actions it deems appropriate, either during or after completion of the recall.

3.4 COSTS OF RECALL IMPLEMENTATION

All costs associated with the recall of a product will be for the account of the importer. Any costs associated with NDA recall-related activities (eg. recall announcements, storage, disposal/destruction, etc) will be invoiced to the importer.

Where such activities are in relation to multiple products being recalled, such costs will be apportioned on a pro-rata basis according to the wholesale value of each item.

REFERENCES

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
25 Sep 2017	0	INS/GDL/037	Author Kaleebu Frank Mwesigwa Denis Reviewers Ssali Peter	First issue