GUIDELINES ON RECALL OF MEDICINES, MEDICAL DEVICES AND BORDERLINE PRODUCTS

JUNE 1, 2020

NATIONAL MEDICINE REGULATORY AUTHORITY
Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINES ON RECALL OF MEDICINES, MEDICAL DEVICES AND BORDERLINE PRODUCTS

CONTENTS

1. BACKGROUND AND OVERVIEW

The National Medicines Regulatory Authority Act No. 05 of 2015 empowers the National Medicines Regulatory Authority (NMRA) to recall and dispose of medicine, medical devices, borderline products or investigational medicinal products. The Act further provides NMRA with powers to cancel or suspend registration or license issued to a medicine, a medical device, or a borderline product.

Under the collective provisions listed under Chapter VI of the Act, NMRA has the authority to ban or withdraw from use any medicine, medical device, or a borderline product which does not meet the required standard, or which could cause serious health problems to the person using. The Act stipulates heavy fines and or imprisonment to offenders of relevant provisions after a summary trial.

The Act prohibits dealing with illegal, counterfeit, or smuggled medicine, medical device, or borderline product. The NMRA takes stern actions against such dishonest dealing. At the same time, defects may be detected in products manufactured, imported and distributed lawfully due to various errors that could happen during manufacture, storage, or transportation.
These guidelines define the actions to be taken by the NMRA and various stakeholders in the distribution channel when a hazardous situation relevant to a medicine, medical device, or borderline product is reported or suspected. The hazardous situation can be a non-conformity to standards, an adverse event, and a need to temporary remove a product for a corrective action such as an error in labeling, or a counterfeit or a smuggled product circulating in the market.

The guidelines will assist both officers in the Pharmacovigilance Division as well as Authorized Officers including those working in the periphery to effectively carry out relevant duties.

2. SCOPE

Recall procedure is a method of removing or correcting a distributed medicinal product that violates the provisions of the Act or its regulations. A recall may be undertaken in response to formal directive by NMRA. A manufacturer or its authorized local agent also shall request for a voluntary recall, if they identified a related defect in an item produced or marketed by them.

In addition, NMRA may make a temporary directive to suspend or withhold from use of an item until its safety is established.

3. OBJECTIVES

When a product is suspected of being potentially harmful to its users due to defective quality, efficacy or safety, it may be necessary to recall such item from the distribution channels in order to prevent its further use.

These guidelines are intended to ensure that recall operations are efficiently and effectively carried out by the marketing authorization holder with the support of other relevant stakeholders in order to safeguard public health, and report back related information to the NMRA.

4. DEFINITIONS

A) A product defect

A non-conformity to a specification confirmed by laboratory analysis or a suspected deficiency which may produce an impact either directly or indirectly on the continuing safety, efficacy or quality of the product.

B) Recall

A permanent removal of the affected product from the market or temporary removal for product correction after which the corrected product may be returned back to the market.

C) Withhold

Temporary suspension of sale or use of a product without recall from the market, until its quality, efficacy, or safety is established

D) Voluntary recall

A recall initiated by a market authorization holder as a result of a defective report from the manufacturer, market complaints etc.

E) Rapid alert system

A system that is used to transit alerts on recalls to relevant stakeholders, and whose urgency and seriousness cannot permit delay in transmission than given in respective timelines.

5. PROCESS

5.1 Initiation of a recall

- NMRA shall initiate a recall of any medicine, medical device, or borderline product manufactured, sold, stored or distributed in, or imported into Sri Lanka and which is not safe for public health or which has any defect in quality, efficacy or safety. Annexure 1 – Recall Notification
- NMRA may recall any medicine, medical device, or borderline product
  (a) on a report or certificate issued by an additional approved analyst or by the approved analyst as specified in the Act.
  (b) on the recommendation of the Medicines Evaluation Committee (MEC), Medical Devices Evaluation Committee (MDEC) or the Borderline Products Evaluation Committee (BPEC)
  (c) on the recommendation of the Safety of Medicines and Risk Evaluation Sub Committee
  (d) on safety alerts issued by the World Health Organization or any other National Regulatory Agency
- NMRA shall temporarily withhold a product from being sold or used as a precautionary measure if there is a doubt whether the product is defective. (E.g. In an event of a death of a patient where the causality has not been established)
- The recall shall be enforced on part of the product, e.g. any specifically identified batch (es), or on the whole product, depending on the extent of the defect. If only a part of a batch or

consignment has been affected (e.g. due to poor storage), NMRA shall recommend discontinuation from use such affected part only.

- It is the responsibility of the marketing authorization holder to recall every batch or every product of defective medicine from the circulation within Sri Lanka.
- NMRA shall issue a drug alert notice via suitable channels and publish the relevant notice in the website of the NMRA. If deemed necessary, such notices shall be broadcast and or published to the general public through mass media.
- The marketing authorization holder for any medicine, medical device, or borderline product shall voluntary recall a product if any evidence appears casting doubts on its quality, efficacy or safety. The marketing authorization holder shall inform the Authority within 24 hours of initiating such voluntary recall.
- Every marketing authorization holder shall inform the Authority of any such facts relevant to recalls which are requested by the Authority
- The recall shall be carried out by the marketing authorization holder within the timeframe specified for respective defective classes.

5.2 Assessment of a recall

A recall will be classified according the potential hazard of the defect.

Class	Definition	Time frame for recall
I	The defect presents a life threatening or serious risk to health	Within 24 hours up to maximum of 72 hours
II	The defect may cause mistreatment or harm to the patient, but it is not life threatening or serious	Up to maximum of 10 days
III	The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorization or regulations	Up to maximum of 30 days

The timeline for ceasing sale/distribution of defective products under Class I shall be ensured within 24 hours and the physical recall being completed within 72 hours. Class II and Class III recalls shall be ensured within 10 and 30 days respectively.

5.3 Level of recall

A recall will be assigned an appropriate level depending on the nature of the defect, the distribution network of the product, and the extent of distribution.

(a) Wholesale level

Every distribution between the manufacturer and distributor including state purchasing agencies and stores [Includes: State Pharmaceuticals Corporation (SPC), Medical Supplies Division (MSD), Regional Medical Supplies Divisions (RMSDs) and warehouses]

(b) Retail level

Government and private hospitals, pharmacies including Rajya Osusala outlets and franchises, campaigns and clinics, medical, dental and other healthcare practitioners

(c) Consumer level

Patients and other consumers including hospitals and clinics

5.4 Responsibilities of the marketing authorization holder

- Enter the details relevant to recall in the Annexure 11- Recall Log and assign a unique recall reference number.
- Collaborate with the Authority on action taken to avoid or reduce risks posed by the specific batch, batches or product.
- Ensure that every recall is carried out effectively within the given timeframe in levels specified above.

  -The purpose of the effectiveness check is:

  - To verify that the Annexure 1- Recall notification letter is received by the customer,

  - The customer read and understood the recall notification, and recall instructions are followed.

  - Also, whether the recall notification reached the appropriate level in distribution chain should be verified.
- Inform Medical Supplies Division and State Pharmaceutical Corporation to ensure recall from the state sector circulation
- Inform relevant stakeholders down the distribution chain (e.g. wholesale distributors, retailers) and obtain the stock position of the recalled product in their procession.
- Verify that the recall reached appropriate level in the distribution chain and that they followed the recall instructions.
- Reconcile the stocks of the recalled materials against the total quantity of distributed materials and fill the Annexure 111" Summary report of product/batch recall".
- Ensure that the authorized officer (e.g. Food and Drugs Inspector) of the area relevant to the distributor/retailer is informed.
- Liaise with the manufacturer of the product to investigate the reasons for the reported health risk or defect and to carryout corrective and preventive actions.
- Have standard operating procedures and designated staff for the purpose of monitoring and implementing recalls.
- Store any stock of recalled drugs in a separate demarcated area, under lock and key, for inspections by the NMRA.
- Dispose recalled drugs according to the guidelines issued by the NMRA and regulations made in respect thereof. Prior approval of the NMRA should be obtained for destruction of recalled products and such action should be witnessed by an authorized officer of the NMRA.
- Obtain approval of NMRA before reintroducing temporarily recalled products
- Rectify issues that lead to the defects if intend to reinstate a product that had its registration cancelled due to permanent withdrawal of the product.
- Provide analytical certificates for fresh batches if requested by NMRA
- Facilitate GMP inspection if requested by NMRA

5.5 Responsibilities of NMRA

- Issue a recall alert notice and publish or broadcast such notice in any mass media and NMRA website. If the nature of the defect is serious risk to public health and an urgent action is required as given in "GL-023-Guideline on Rapid Alert System"
- Monitor the progress and effectiveness of a recall by verifying returned product disposition.

- Ensure that any recalled product shall not enter the Sri Lankan market through different market authorization holders.
- Suspend or cancel the marketing authorization of the product in terms of chapter III, part IV, No. 65 of the NMRA Act, after giving the marketing authorization holder sufficient time to respond, if the recall decision is applicable to the whole product
- Carryout a GMP inspection of the manufacturing site if deemed necessary by the Authority
- Suspend the manufacturer for a specific period if quality defects and or health risks are persistently reported or if it is proved beyond doubts that the defects are due to negligence or deliberate omissions of the manufacturer or if the GMP inspection report is not satisfactory.
- Constitute legal proceedings against offenders, in terms of chapter VI, part I, No. 108 (3) of the NMRA Act if administrative measures alone are not sufficient in comparison to the magnitude of the offence
- Reinstate such manufacturer if the Authority is satisfied that adequate corrective and preventive actions has been taken by the manufacturer, which shall be confirmed by a satisfactory GMP inspection of the manufacturing site

6 RELATED LEGISLATION ,DOCUMENTS AND FORMS

- National Medicines Regulatory Authority Act No. 05 of 2015
- Annexure 1 – Recall Notification
- Annexure 11- Recall Log
- Annexure 111- Summary Report of Recall
- Annexure 1V – Recall Alert Notification of a quality defect

7 REFERENCES

- Guidelines on product defect reporting and recall procedure, HSA, Singapore
- Procedure for handling rapid alerts and recalls arising from quality defects, PI 010-5, 1 July 2017, PIC/S
- Uniform recall procedure for therapeutic goods, v 2.0, 3 October 2017, TGA, Australia

8 FEEDBACK

Staff and customers may provide feedback about this document by emailing Pathmaperuma.a@nmra.gov.lk

9 APPROVAL AND REVIEW DETAILS

	NAME	SIGNATURE

Prepared by	Mr.ArjunaPathmaperuma	
Reviewed By	Mrs. DeepikaBulathsinhala	
Recommended By	Mr.Gopi Krishantha	
Approved by	Dr.KamalJayasinghe	

Next Review Date	

Annexure-1
Recall Notification

---------- (Market Authorization Holder)

Recall of Batch/Batches/Product Due to a Quality Failure/Defect

With reference to NMQAL report/adverse reaction on failing samples No. …… dated …… / Voluntary Recall by Market Authorization holder / Inspector's observations during inspections of your facility.

NMRA notifies the recall from the following batch/batches/product:

Manufacturer:

Batch No:

Date of Manufacture:

Date of Expiry:

Marketing Authorization Holder:

Failure/Defect:

Those having stocks of the above batch in their possession are advised to keep such stocks in a demarcated place until disposed. Also take necessary steps to inform the consignment details of any batches pertaining to above product in stock to Director, National Medicines Quality Assurance Laboratory, in order to facilitate further sampling, if required.

Chief Executive Officer
National Medicines Regulatory Authority

Copies:

1. Director, Medical Supplies Division – to inform all relevant government sector institutions
2. Chairman, State Pharmaceutical Corporation - to inform all SPC outlets
3. All authorized officers – to monitor recall in private sector intuitions in your area

Annexure 11

RECALL LOG

(To be filled by Licensee/Representative of licensee)

Recall Ref No.	Time & Date of recall Initiation	Product Name	Batch /lot No.	Mfg Date	Exp. date	Reason for recall	Recall Classification	Batch size	Unsold/ undistributed Qty in possession	Quantity distributed	Qty Returned	Closing date & sign.	Remarks

Annexure – 111

Summary Report of Product/Batch Recall

(To be filled by distributor/retailer as appropriate)

Recall ref. No.			**Date:**	
Product Name:				
Batch No.			**Mfg. Date:**	
Reason for recall				
Name of customer	**QTY. received on purchased invoice**	**Qty. sold**	**Qty. undistributed/stock in hand**	**Qty. received from customer in response to recall**
Total Quantity				
Quantity Available in warehouse after recall				
Justification of any deviations during reconciliation				
Stock/sale license No				
Prepared by:		**Signature/Date**		

Annexure IV

Recall Alert Notification of a Quality Defect
National Medicines Regulatory Authority

1. Product Recall Class of Defect
2. Name of the Product:
3. Brand name:
4. Dosage form: Strength:
5. Batch number: Expiry date: Date manufactured:
6. Pack size:
7. MA holder:
8. Manufacturer:
9. Details of defect:
10. Action taken by issuing Authority

Signature: Date:
Chief Executive Officer