



Guidelines on Recall of Medicines, Medical Devices and Borderline Products

Pharmacovigilance Division

National Medicines Regulatory Authority

Sri Lanka

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Introduction

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 wishes to take 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. The NMRA needs have an internal mechanism to ensure that unintentional defects are resolved through administrative measures without going to courts.

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, 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.

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Scope

Recall procedure is a method of removing or correcting a distributed drug 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.

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.

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) Statutory recall

A recall initiated by NMRA after a notification that a batch, batches or a product is identified as defective or in violation of the law.

E) Voluntary recall

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

F) Rapid alert system

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

Initiation of a recall

1. 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.
2. 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
3. NMRA shall temporarily withhold a product from being sold or used as a precautionary measure if there is a doubt whether the product is actually defective. (E.g. In an event of a death of a patient where the causality has not been established)
4. 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.
5. 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.
6. 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.
7. The marketing authorization holder for any medicine, medical device, or borderline product shall voluntarily 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.

8. Every marketing authorization holder shall inform the Authority of any such facts relevant to recalls which are requested by the Authority
9. The recall shall be carried out by the marketing authorization holder within the timeframe specified for respective defective classes:

Assessment of 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 10days
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

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.

- (i) Wholesale level
Every distribution between the manufacturer and distributor including State purchasing agencies and stores
- (ii) Hospital level
Medical Supplies Division (MSD), Regional Medical Supplies Divisions (RMSD), Government and Private Hospitals, Pharmacies, Clinics, Medical, Dental and other Healthcare Practitioners
- (iii) Retail level
Hospitals, Pharmacies, Clinics, Medical, Dental and other Healthcare Practitioners

- (iv) Consumer level
Patients and other consumers including Hospitals and Clinics

Responsibilities of the marketing authorization holder

- (i) ensure that a recall is carried out effectively within the given timeframe in levels specified above.
- (ii) Inform Medical Supplies Division and State Pharmaceutical Corporation to ensure recall from the state sector circulation
- (iii) collaborate with the Authority on action taken to avoid or reduce risks posed by the specific batch(es) or product.
- (iv) 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.
- (v) have standard operating procedures and designated staff for the purpose of monitoring and implementing recalls.
- (vi) store any stock of recalled drugs in a separate demarcated area, under lock and key, for inspections by the NMRA.
- (vii) dispose recalled drugs according to the guidelines issued by the NMRA and regulations made in respect thereof.
- (viii) obtain approval of NMRA before reintroducing temporarily recalled products
- (ix) 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.
- (x) provide analytical certificates for fresh batches if requested by NMRA
- (xi) facilitate GMP inspection if requested by NMRA

Responsibilities of the NMRA

- (i) issue a drug alert notice and publish or broadcast such notice in any mass media or website in the Authority.
- (ii) monitor the progress and effectiveness of a recall.
- (iii) ensure that any recalled product shall not enter the Sri Lankan market through different market authorization holders.
- (iv) 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

- (v) carryout a GMP inspection of the manufacturing site if deemed necessary by the Authority
- (vi) 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 .
- (vii) 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
- (viii) 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

References:

- 1.
- 2.