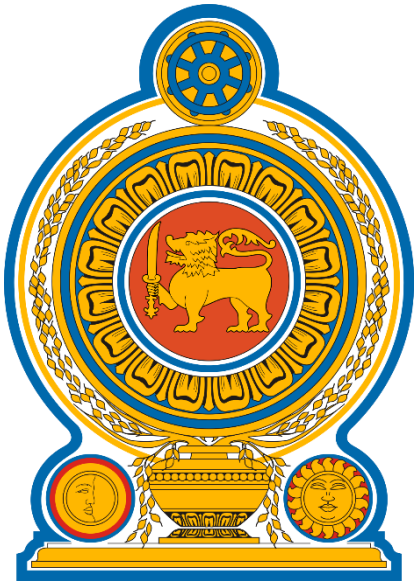

GUIDELINE ON RAPID ALERT SYSTEM

OCTOBER 15, 2019

NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINE ON RAPID ALERT SYSTEM

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1. INTRODUCTION

Effective implementation of rapid alert system is useful to protect public in a risk situation of using a

medicine such as a recall of one or more defective batches of a medicinal product during its marketing period.

Procedure can apply for an investigational product also during a quality failure in its clinical trial stage

2. PURPOSE

To cover transmission of information to relevant parties if the nature of the defect is a serious risk to public health and urgent action is required to protect public health.

This information covers such as,

- Quality defects identified by NMQAL (Product withhold, Product withdrawal, discontinue to use)
- WHO alerts of finished products and API regarding safety issues
- Follow up action to rapid alert notification

3. SCOPE

The scope of the rapid alert system is to transmit alerts which cannot permit any delay in transmission. Less urgent information should not be transmitted to ensure its effectiveness.

4. DEFINITIONS

NMRA – National Medicines Regulatory Authority
NMQAL- National Medicines Quality Assurance Laboratory
API - Active Pharmaceutical Ingredients
WHO - World Health Organization
SPC - State Manufacturing Corporation
MSD - Medical Supplies Division
RMSD- Regional Medical Supplies Division

5. RESPONSIBILITIES

The officer in charge appointed by the NMRA identified and investigates the defect and head of the relevant division issue the rapid alert.

6. PROCEDURE

6.1 Receiving Information
(From NMQAL, Government and Private Hospitals, WHO, National regulatory Authorities)
6.2 Assessment by Pharmacovigilance team

6.3 Classification of seriousness of the defect, quality issue (class I, II, III)
ANNEXURE II
6.4 Inform to relevant parties (Appendix I)
Class I – within 24 hours (telephone, SMS, fax, Email)
Class II – within 24 hours up to maximum of 72 hours
(telephone, SMS, fax, Email)
Class III- No need to send through rapid alert system
6.5 All alerts should be published in NMRA website.
6.6 All follow up actions to rapid notification should be informed to pharmacovigilance team by the relevant parties including Medicines regulatory division, using standard formats as per form I

7. ANNEXURES

ANNEXURE 1

Rapid alert contact list

1. Wholesale license holders
2. Retail license holders
3. Government Health Institutions (Chief Pharmacists)
4. Private Health Institutions (Chief pharmacists)
5. SPC
6. Food & Drug Inspectors
7. Market Authorization Holders
8. MSD
9. RMSD
10. Focal Point Medicine Regulatory Division /NMRA

ANNEXURE 2

CLASSIFICATION OF URGENCY OF DEFECTIVE MEDICINAL PRODUCT ALERTS

Class I

Class I defects are potentially life threatening or could cause a serious risk to health.

These must be notified through the Rapid Alert System in all cases.

Examples:

- Wrong product (label and contents are different products)

- Correct product but wrong strength, with serious medical consequences
- Microbial contamination of sterile injectable or ophthalmic product
- Chemical contamination with serious medical consequence
- Mix-up of some products (rogues) with more than one container involved
- Wrong active ingredient in a multi-component product, with serious medical consequences.

Class II

Class II defects could cause illness or mistreatment, but are not Class I. A rapid alert notification should be sent to all contacts of the rapid alert notification list as it might be difficult to know where a batch has been distributed. If the product distribution is known, the notification should be only sent to the contacts concerned.

Examples:

- Mislabeling, e.g. wrong or missing text or figures
- Missing or incorrect information (leaflets or inserts)
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- Chemical/physical contamination (significant impurities, cross-contamination, particulates)
- Mix up of products in containers (rogues)
- Non-compliance with specification (e.g. assay, stability, fill/weight)
- Insecure closure with serious medical consequences (e.g. cytotoxic, child resistant containers, potent products).

Class III

Class III defects may not pose a significant hazard to health, but withdrawal may have been initiated for other reasons. If deemed relevant by the issuing authority, the rapid alert system may be used.

Examples:

- Faulty packaging, e.g. wrong or missing batch number or expiry date
- Faulty closure
- Contamination, e.g. microbial spoilage, dirt or detritus, particulate

8.0 FORMS

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT

Reference number
(add letter head of sender)
1.To : (see list attached, if more than one)
2.Product Class of Defect I II (Circle one)
3. Name of the product
4.Brand Name
5.Strength
6.Dosage form
7.Batch number
8.Date of manufacturing
9.Date of expiry
10.Name & Address of the manufacturer
11.Market Authorization Holder
12.Details of defect
13.Information on distribution including exports
14. Action taken by Issuing Authority
15.From (Issuing Authority)
16. Contact person details
17.Signature & Date

Form II

FOLLOW UP AND NON URGENT INFORMATION

(add letter head of sender)
1.TO :
2.Rapid alert reference number assigned:
3.Product Name
4.Brand name
5.Dosage form:
6.Strength
7.Batch number
8.Date of manufacturing
9.Date of expiry
10.Name & Address of the manufacturer
11.Market Authorization Holder
12.Subject title
13.From (Issuing Authority)
14.Contact person details
15.Signature

9.FEEDBACK

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