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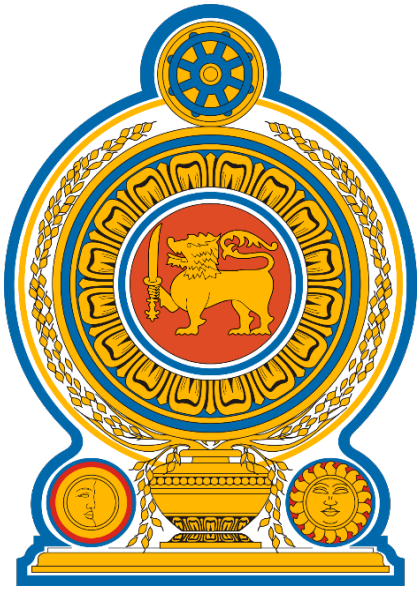


GUIDELINE ON COMPLAINTS RELATED TO THE NMRA ACTIVITIES AND PRODUCTS REGULATED UNDER NMRA ACT

FEBRUARY 11, 2022

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

GUIDELINE ON COMPLAINTS RELATED TO THE NMRA ACTIVITIES AND PRODUCTS REGULATED UNDER NMRA ACT

CONTENTS

1. INTRODUCTION

National Medicines Regulatory Authority (NMRA) considers complaints as an opportunity for improvement in products, services and processes. The Authority has procedures in place to ensure that all complaints are subject to a full and comprehensive investigation, receive a response and are examined for corrective and preventive actions.

An effective and efficient complaints handling process reflects the needs and expectations of both the organizations supplying products and services and those who are the recipients of those products and services. The handling of complaints through a process as described in this document can enhance customer satisfaction. Anyone who receives, requests, or is affected by our services can make a complaint.

NMRA takes particular care to identify complaints that might be considered critical, as these may require particular action or raise critical issues that need senior management's direct input. Critical complaints should normally be handled immediately.

2. PURPOSE

The formal complaints handling procedure is intended to ensure that all complaints are handled fairly, consistently and wherever possible resolved to the complainant's satisfaction. NMRA's responsibility will be to: deal reasonably, sensitively and timely with the complaint; take action where appropriate.

A systematic, standardized and effective approach to complaint handling is required in order to:

- Identify a complaint from all stakeholders of NMRA (public, healthcare providers and from the industry).
- Investigate complaints promptly and action any necessary remedial, corrective and preventive actions with the appropriate priority.
- Ensure that all complaints are recorded at the time they are received, that pertinent information (including samples) is gathered and evaluated, and that reports are issued through established channels in a timely manner.
- Identify any associated Human Safety Information (HSI), and report these in accordance with regulatory requirements and timelines
- Identify and investigate possible trends or patterns of complaints in order to take appropriate action.
- Identify and escalate serious human safety issues, associated with a single complaint or safety signals raised through trend analyses.

This guideline is used to ensure that complaints received are reported, logged, assessed and managed properly until closure. Also, to ensure that communication and escalation routes are defined all across the process steps.

3. SCOPE

These Guidelines apply to handling of complaints filed by stakeholders of NMRA activities regarding alleged non-compliance with relevant legislations, regulations, guidelines and required standards. These Guidelines apply to complaints of non-compliance with;

1. Activities regulated & carried out by the NMRA
   Complaints which is directly reported to NMRA for investigations and actions regarding alleged non-compliance with relevant legislations, regulations, guidelines and required standards

2. Products regulated under NMRA Act
   Complaints from public or healthcare providers or from the industry relating to the quality, safety or efficacy of any registered product including suspected SF products.
   & Investigational medicinal products (clinical trial products) and named patient supplies
3. NMRA Decisions & Regulatory practice

Complaints against NMRA decisions or practice with respect to regulatory functions conducted as per NMRA act.

4. DEFINITIONS

Complaint - expression of dissatisfaction made to an organization, related to its product or service, or the complaints -handling process itself, where a response or resolution is explicitly or implicitly expected

Complainant - A party, person or entity, making a complaint to NMRA

Critical Complaint- Complaint associated with life threatening effect.

Major Complaint - Complaint associated with serious non-compliance with specification & regulation but are not life threatening.

Efficacy- the ability to produce a desired or intended result.

Risk - Combination of the probability of occurrence of harm and severity of the harm.

Adverse Event (AE) –Any untoward medical occurrence in a patient or clinical investigation subject or consumer, temporally associated with the use of a medicinal product, whether or not considered related to the product

Safety signal - Information on a new or known adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature.

5. ROLES AND RESPONSIBILITIES

5.1 Responsibilities of the Quality Manager (QM)

- It is the responsibility of QM of Quality unit to receive complaints, monitor & follow investigations, follow up the final report preparation & ensure that appropriate decisions are taken & feedbacks & acknowledgment are communicated properly to complainants.
- Maintain records and complaint register.
- Raise the complaint investigations & final report to an Ad hoc committee for further decisions.

5.2 Role of the Regulatory and Quality Divisions

The Organization's regulatory and quality divisions responsible for implementation of NMRA's policies and procedures will be responsible for providing advice to QM in the initial review of complaints. This will include, but not be limited to:

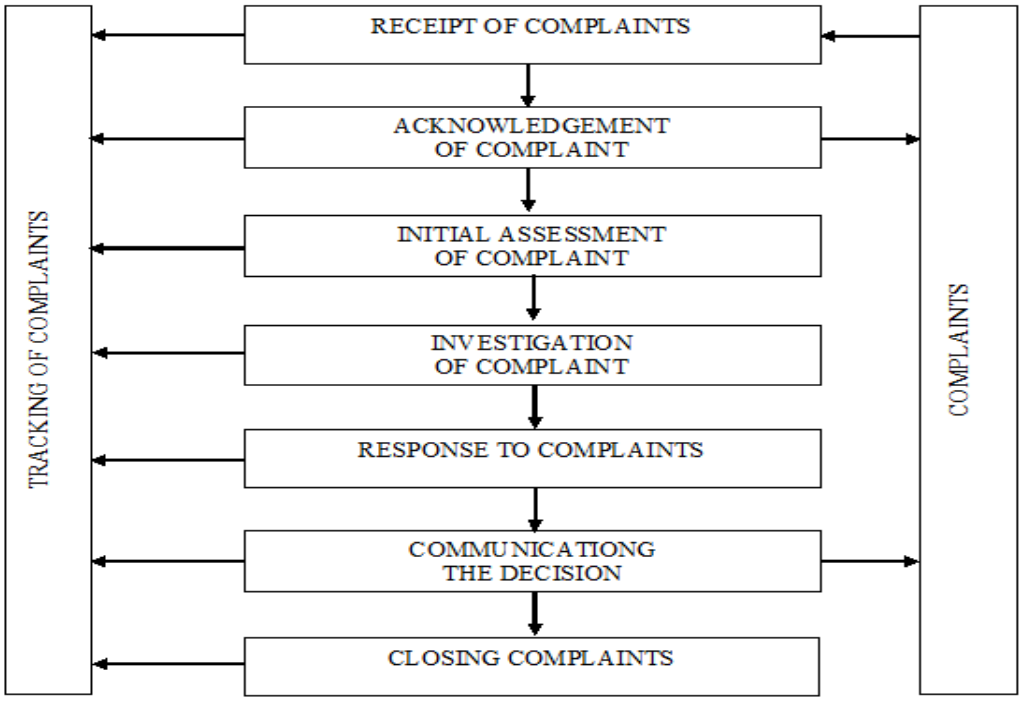
- Identifying whether or not there is a possible causal link between the NMRA activities and

the harm identified in the complaint;

- Identifying which, if any, NMRA regulations may have violated, in addition to those identified in the complaint;
- Providing technical support and expertise, where needed, in the identification and selection of independent expert consultants to carry out on-site visits during the investigation phase of the compliance review process;
- Assist in the monitoring of the implementation of recommendations through contacting project staff and other interested parties;
- Provide all other technical assistance as may be necessary for the compliance review process.

6. COMPLAINT HANDLING PROCESS

Complaints – handling flowchart



6.1 Receipt & Assessment of complaints

Any person, group, or representative of a person or group, who is potentially directly affected by a NMRA Activity or a product registered with NMRA, is permitted to file a complaint.

Complaints are received by QM of Quality unit through different ways;

-By courier or mail: 120, Norris Canal Road, Colombo 10

-by confidential fax: 0112689704

-by email: complaints.nmra@gov.lk

- The format given in the Customer complaint form (Annexure 1I) should be used in making complaint.

- All such complaints should be recorded in a register (Annex I- Complaint register) by the QM or an assigned person by QM and acknowledge the receipt of all complaints immediately within one day through post, phone or email.
- Anonymous complaints are not accepted.
- Personal information concerning the complainant should be available where needed, but only for the purposes of addressing the complaint within the organization and should be actively protected from disclosure, unless the customer or complainant expressly consents to its disclosure or disclosure is required by law.
- Complainants may amend complaints by providing additional information or alleging new instances of non-compliance at any time before the eligibility of the complaint is determined.
- Quality Manager of NMRA will further notify all complainants whose filings are inadmissible pursuant to these Guidelines of said fact within 5 days thereafter.
- Quality Manager of NMRA will refer complaints above to the relevant NMRA's divisions for preliminary assessment for risk impact, and the need and possibility of immediate action.
- After receiving the response of the relevant division, Quality Manager of NMRA may consult with the Complainant, NMRA staff, and other interested parties, as well as review any relevant documents before making a final determination on eligibility.
- If a complaint is determined to be ineligible, Quality Manager of NMRA (QM) will provide the complainant with an explanation of the reasons for the determination.
- Applications that are duplicative will be declined.
- All complainants admitted to participate will have 10 days from being notified of the decision on their request to make any initial comments they may have about the complaint.
- Adverse drug events can be reported to the NMRA by completing the relevant forms available in NMRA website. These reports are evaluated by the Safety and Risk Evaluation Sub-Committee (SAFREC) which consists of multidisciplinary staff (Pharmacologists, Immunologist, Physician etc.) to detect safety signals and to monitor drug safety. As a result, the NMRA may take regulatory actions to improve product safety and protect the public health, such as updating a product's labeling information, or re-evaluating an approval decision and also product recall.

6.2 Investigation

- Review and Evaluate complaints with all the risks that may reasonably be expected to occur to determine whether an investigation is necessary.
- Upon determining that a complaint is eligible, and upon the closure of the application and initial comment periods, QM will initiate an investigation.
- All participants, including the Complainant, will be informed that an inspection has begun. Inspections may include:
  -Interviews will relevant witnesses;
  - Collection and analysis of relevant documentation and product samples; and
  - Onsite visits.
- After completion of the interviews and onsite visits and receiving the analytical results and after performing the documentation-based investigation, the QM is able to finish the complaint investigation. QM will provide compliance review report to all individuals or entities admitted to participate in the process.
  Compliance review report will include:
  -A discussion of the procedural steps taken to address the Complaint;
  -Any factual findings, including any findings of non-compliance;

- Recommendations to bring NMRA into compliance with social and environmental commitments or to mitigate harm to the Complainants, if applicable;

- A proposed plan for monitoring implementation of any recommended actions that NMRA decides to take in response to the Complaint & further follow up, if applicable.

6.3 Managing Complaints related to NMRA regulated products received by NMQAL,

- Samples and relevant documents directly submitted to the National Medicines Quality Assurance Laboratory (NMQAL) with the completed form. (Annex III- Submission of product complaint to NMQAL).
- Technical investigation including documents review and laboratory analysis is carried out by the laboratory in accordance with the Laboratory procedure for complaint handling.
- After completion of the analysis any out of specification results will be handled in accordance with the NMRA's regulations, recall guideline and laboratory procedure for Quality Control of Medicines.

6.4 Response to complaints

- QM will issue a final compliance review report within 15 days, including findings and recommendations, and input from Complainants and other participants.

- An Ad hoc committee may be established by QM to discuss the complaint based on the type of the raised complaints, and further decisions will be taken by committee.

- The report relevant to critical complaints will be submitted to Ad hoc committee & further decisions will be raised to the Chief Executive Officer (CEO) of NMRA or his delegate and a copy provided to the Complainant and other participants. QM will record the decision in the complaint register.

- If the response is anticipated to be delayed by unforeseen circumstances the delay will be communicated to the Complainant and participants. Then it should be dealt with in a manner intended to lead to its effective resolution as soon as possible specially for critical complaints.
- After receipt of the final compliance review report, the CEO, or his delegate, will expeditiously make a final decision regarding what steps, if any, NMRA will take to bring the project or program or process or a product into compliance and/or mitigate any harm to the Complainants or other affected persons, as appropriate, taking into account relevant circumstances and subject to availability of resources.

6.5 Communication of decisions

- This decision will be sent to the Complainants and other participants, as soon as the decision or action is taken.

6.6 Complaint Register and archiving

- NMRA should maintain a complaints register and relevant documents should be retained according to the NMRA Document Control procedure.

6.7 Management review of the complaints-handling process

Top management of the organization should review the complaints handling process on a regular basis in order to :

- ensure its continuing suitability, adequacy, effectiveness and efficiency;
- identify and address instances of nonconformity with health , safety, environmental , customer statutory, regulatory and other relevant requirements ;
- identify and correct product and service deficiencies ;
- identify and correct process deficiencies ;
- assess risks and opportunities and the need for changes to the complaints -handling process and products and services offered;
- evaluate the effectiveness of the actions taken in relation to risks and opportunities ;
- evaluate potential changes to the complaints -handling policy and objectives

7. FEEDBACK

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

8. RELATED FORMS AND DOCUMENTS

Annex I – GL-011-RC01- Complaint Register
Annex II – GL-011-F01- Customer complaint form
Annex III- GN-PR-01-F03-Submission of Products complaints to NMQAL-
Annex IV-Suspected Adverse Reaction to Medicines/Borderline Products: Case Reporting Form (NMRA website)

9. REFERENCES

i) BS ISO 10002:2018- Quality management — Customer satisfaction — Guidelines for complaints handling in organizations

ii) Quality Management System-Requirements. International standard ISO 9001:2015. International Organization for standardization 2015

iii) WHO GMP Guidelines –TRS 986 annex 2 – Section 2 Complains.

10. APPROVAL AND REVIEW DETAILS

	NAME	SIGNATURE
Revised by	Deepika Bulathisnhala	
Reviewed By	Amara Pinnawala	
Recommended By	Ajith Priyadarshana	
Approved by	Dr. Saveen Semage	

12. DOCUMENT HISTORY

Document History				
Revision No.	Change	Name and Title		
		Author	Reviewer	Approving Official
00	Initial release	Chula Edirisinha Pharmacist/NMRA	Gopi Krishantha Pharmacist/NMRA	Dr.Kamal Jayasinhe CEO/NMRA
01	1)Changes to reflect Flow of the handling of complaints regarding products and services 2. Relevant annexures were included	Deepika Bulathsinhala Senior Pharmaceutical Analyst Head/Microbiological Division/ NMQAL	Amara Pinnawala Deputy Director/NMQAL	Dr. Saveen Semage CEO/NMRA

Annex I – Complaint Register GL-011-RC01

Date	Complaint reference	Complainant	Details of complaint	Nature of Complaint (Critical/Major/others	Corrective Action	Preventive action	Remarks	Closing date of complaint

Annex II- Customer complaint form GL-011-F01

1. Details of complainant
   Name/organization ____
   Address ____
   ____
   Phone ______________________
   Fax ________________________
   Email ____

   Details of person to be contacted (if different from above) ______________________________
   ____

2. Product description / Service description
   ____
   ____
   ____
   ____
3. Problem encountered
   Date of occurrence ____
   Description ____
   ____
   ____
   ____
4. Remedy requested
   Yes No
   ____
   ____
   ____
   ____

5. Date ____________________ Signature ____________________

List of attached documents
____
____
____

Annex III

Submission of Product complaints to NMQAL

GN-PR-01-F03

Director,
National Medicines Quality Assurance Laboratory,
120 Norris Canal Road,
Colombo 10.

DRUG SAMPLE FOR QUALITY TESTING (COMPLAINT / SURVELLIANCE)

LABEL

1. Name of the product.
   a) Generic Name : …….....
   b) Brand Name (if any) : ……...
2. Dosage form : ……...
3. Specifications (state whether B.P.,U.S.P.,N.F., etc.): …….....
4. Strength/s of the product (i.e., active ingredients): ……...
5. Composition of the drug product (i.e. Each enteric coated tablet contains…/ or each….etc):……
   ……
6. Batch number / Lot number: …….
7. Date of manufacture (if any): ……
8. Date of expiry: ……..
9. Manufacture's name and full address: …….
10. Description of the original container / pack: ……
    (If different from the submitted pack)
11. Quantity submitted Defective (Yes / No) Quantity: ……
    Unopened packs (Yes /No) Quantity: ……
12. Stock available at the institution of the drug product of the same batch: ……
    Different batch:…….
13. Storage requirements stated on the label:…….
14. Storage condition at the source: ……..
15. Nature of the problem / complaint with all relevant details:
    ……..
16. Any other remarks: ……..
    ……..

…… ……
Name, Address and designation Head of the institute /
Of the Officer making the request. Decentralized Unit