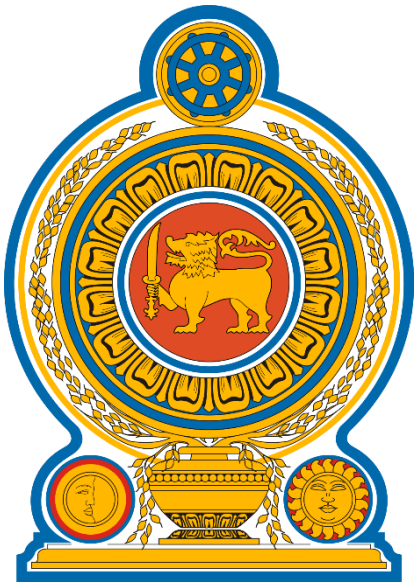

GUIDELINE ON COMPLAINTS RELATED TO THE NMRA ACTIVITIES AND PRODUCTS REGULATED UNDER NMRA ACT

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NATIONAL MEDICINE REGULATORY AUTHORITY
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GUIDELINE ON COMPLAINTS RELATED TO THE NMRA ACTIVITIES AND PRODUCTS REGULATED UNDER NMRA ACT

CONTENTS

1. INTRODUCTION

These Guidelines apply to the 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 carried out by the NMRA
2. Products regulated under NMRA Act

One of the objectives of the *National Medicines Regulatory Authority Act, No. 5 of 2015* (NMRA Act) is to ensure that all activities related to registration, licensing and importation storage, transport, distribution, sale, advertising and disposal of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner (Chapter 1, Part 1, 3 C). It indicate that NMRA is committed to ensuring that its programs and processes are implemented in accordance with the relevant legislations, regulations, guidelines and required standards.

"Ensure the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices" is one of the key objective of the NMRA Act (Chapter 1, Part 1, 3 C).

An effective complaint procedure helps organizations deal with complaints quickly, fairly and consistently and is an important part of an equal opportunity policy.

Incidents reported as product related complaints have the potential to adversely affect the health or safety of patients and damage the good reputation of the medicine regulatory system of the country.

The mechanism set out in these guidelines is designed to be independent, transparent and effective so as to provide stakeholders of NMRA with a means to have their complaints resolved and to keep them informed of what is being done to address their concerns throughout the compliance review process.

Compliance Reviews under these Guidelines are administrative in nature. In all cases, NMRA has the ultimate decision-making authority on remedies in response to Complaints. Complaint Reviews do not create any legally enforceable rights for Complainants, or any liabilities of NMRA.

Any aspect of the handling of Complaints under this mechanism is without prejudice to the privileges and immunities of NMRA and is not open to review by any court of law.

2. PURPOSE

The formal **complaints procedure** is intended to ensure that all **complaints** are handled fairly, consistently and wherever possible resolved to the complainant's satisfaction. ALT'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 and consistent with the principles of Good Distribution Practices (GDP).

- 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

The scope of this SOP is described as follow:

Applies	Does Not Apply to
• Serious critical complaints which is directly reported to NMRA for investigations and actions	• Internal complaints within the NMRA
• Communications either from public or healthcare providers or from the industry confirmed as a complaint relating to the quality, safety or efficacy of any registered product including samples	• Banned substances and illicit narcotics
• Investigational medicinal products (clinical trial products) and named patient supplies.	

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4. DEFINITIONS

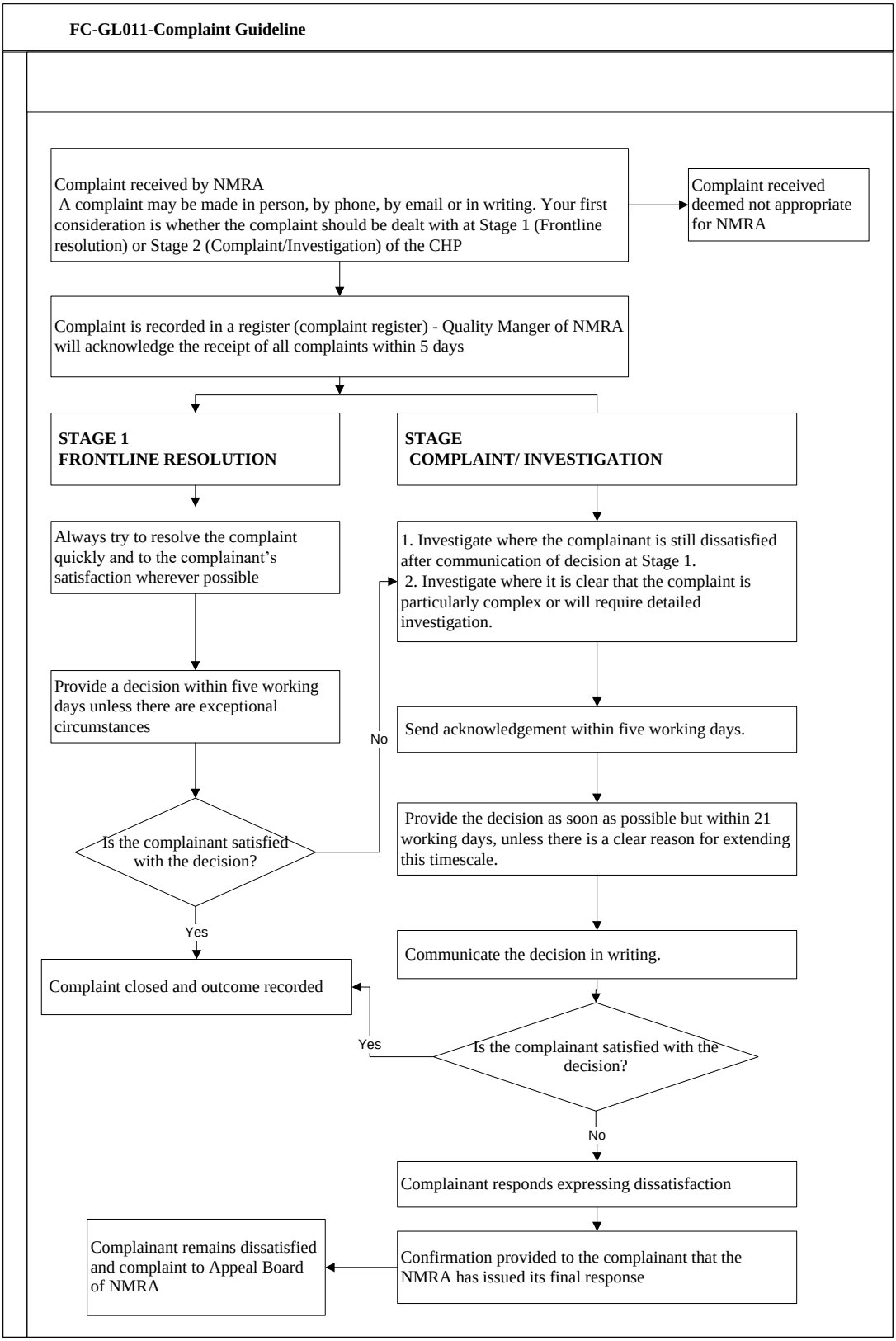
Word/Acronym	Definition
Activity related Complaint	is any allegation, claim, concern or information reported verbally, in writing or electronically to NMRA, indicating possible non-compliance with relevant legislations, regulations, guidelines and required standards.
Product related Complaint	any claim reported verbally, in writing or electronically to NMRA by or on behalf of a public that expresses dissatisfaction with a product released to market relating to product quality, stability, reliability, performance or usage or batch identity. Complaints may be associated with adverse events.
Serious Critical Complaint (Priority)	Product complaint with fatality
Critical Complaint (Priority 2)	Product complaint associated with Human Safety Information Or product complaints that are associated with major technical discrepancies regarding the identity, safety, quality, purity, or strength of the product that may have serious patient safety,

	medical, technical specification, or regulatory implications
Non-Critical Complaint (Priority 3)	Any other product complaint regarding impairment of product quality.
Complainant	a party, person or entity, making a complaint to NMRA
Lack of Efficacy (LoE)	The lack of expected or desired effect related to a therapy.
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 that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

5. THE PROCESS

Submission

Basic Complaint Handling Procedure (CHP) of NMRA



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 in person, and by mail, email, telephone and facsimile.

All such complaints should be recorded in a register (complaint register).

Anonymous complaints are not accepted. However, the complainant's name will be kept confidential if he or she so requests.

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 acknowledge the receipt of all complaints within 5 days.

Quality Manager of NMRA will further notify all complainants whose filings are inadmissible pursuant to these Guidelines of said fact within 21 days thereafter.

Notwithstanding anything above or below, if at any time after receiving a complaint, Quality Manager of NMRA believes significant, irreversible harm to the complainants or other affected people is imminent, NMRA may recommend to the Head of the relevant division of the NMRA to take interim measures pending completion of the compliance review.

Quality Manager of NMRA will refer complaints above to the relevant technical unit for preliminary comment. The technical unit will advise Quality Manager of NMRA on whether or not it believes the issue is eligible for further review.

After receiving the response of the technical unit, 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.

Applicants will be informed of the decision on their request within 10 days after the deadline to apply has closed.

All applicants 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.

Inspection

Upon determining that a Complaint is eligible, and upon the closure of the application and initial comment periods, QM will initiate an inspection.

All participants, including the Complainant, will be informed that an inspection has begun. Inspections may include:

(a) Interviews will relevant witnesses;

(b) Collection and analysis of relevant documentation; and

(c) Onsite visits.

After completing its compliance review, QM will provide a copy of the draft compliance review report to the Complainant(s), and all other individuals or entities admitted to participate in the process. Comments on the draft report must be submitted within 20 days after the date of issuance. The draft compliance review report will include:

(a) A discussion of the procedural steps taken to address the Complaint;

(b) Any factual findings, including any findings of non-compliance;

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

(d) A proposed plan for monitoring implementation of any recommended actions that NMRA decides to take in response to the Complaint, if applicable.

Within 25 days of the closure of the comment period for the draft report, QM will issue a final compliance review report, including findings and recommendations, and input from Complainants and other participants.

The report will be submitted to the CEO of NMRA and a copy provided to the Complainant and other participants. QM will notify, in the same locations as the public posting of the complaint, that this has been done. If this process is anticipated to be delayed by unforeseen circumstances the delay will be communicated to the Complainant and participants.

Decision by the CEO

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.

This may comprise or include confirmation of steps already proactively taken by the Organization in response to the complaint. This decision will be sent to the Complainants and other participants, and then released publicly in the same locations as the public posting of the complaint. How to File a Complaint

Complaints containing allegations that there has been a breach of the NMRA's environmental and social standards must be made in writing and communicated to QM by mail, courier, email or fax, directly or via any FAO office. All complaints should ideally provide, as a minimum, the following information:

- What happened? Describe the events with as much relevant detail as possible.
- When did it happen? Dates, time, how many times, etc.
- Where did it happen?
- Who do you think was involved? Who was implicated?
- The complainant's name and contact information;

The addresses to file a written complaint are:

- By courier or mail: 120, Norris Canal Road, Colombo 10
- by confidential fax: 0112689704
- by email: complaints-hotline@nmra.gov. com

QM will be responsible for the following:

(a) Receive Complaints and determine eligibility of requests for a compliance review;

(b) Conduct thorough comprehensive information gathering to provide for a factual determination of the issues raised, including where necessary in-country inspections, interviews of people reportedly affected by MRA activities, and reviews of documentation;

(c) Provide draft reports for comment to Complainants and other participants;

(d) Receive comments from, and, as appropriate, consult with those who have been alleged as not complying, including NMRA personnel, and officials of nongovernmental organizations, contractors and government entities affiliated with NMRA projects and activities;

(e) Submit final reports to the Director General with findings and recommendations;

(f) Report in its annual report to the Director General, which becomes public in accordance with OIG report disclosure policy, on the functions, operations and results of the compliance review process;

(g) Issue, when appropriate, Lessons Learned reports on compliance related issues covered by these Guidelines in accordance with OIG's Charter; and

(h) Explain through various means the process contained herein to potentially affected persons.

Role of the Technical Units

The Organization's technical units 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:

(a) Identifying whether or not there is a possible causal link between the a NMRA project and the harm identified in the complaint;

(b) Identifying which, if any, NMRA policy a project may have violated, in addition to those identified in the complaint;

(c) Providing technical support and expertise, where needed, in the identification and selection of independent expert consultants to carry out on-site visits during the inspection phase of the compliance review process;

(d) Provide feedback on draft compliance review reports for review by QM together with those supplied by the complainant and other participants;

(e) Assist in the monitoring of the implementation of recommendations through contacting project staff and other interested parties;

(f) Provide all other technical assistance as may be necessary for the compliance review process.

6. FEEDBACK

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