MDA/GD/0011

JUNE 2020

First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

COMPLAINT HANDLING

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following:

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012*;* and

c) Medical Device (Duties and Obligation of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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COMPLAINT HANDLING

0 Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

The Medical Devices (Duties and obligations of establishment) Regulations 2019 detailed out requirements for post-market surveillance and vigilance as provided in Chapter 3 of the Medical Devices Act 2012 (Act 737). These regulations are imposed to ensure licensees carry out their responsibilities to monitor and continuously ensure the safety and performance of their devices in the market.

This document is made pursuant to Medical Device Act 2012 (Act 737) Section 39 and Regulation 4 of Medical Device (Duties and Obligation of Establishments) Regulations 2019 to describe and define the framework and procedures on management and handling of medical device complaints by the establishment.

1 Scope and application

This guidance document specifies the requirements on complaint handling for all medical devices. This document is applicable to establishments including exporters dealing with medical devices.

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

2.1 complaint

Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed in the market.

2.2 harm

Injury or damage to the health of people or damage to property or the environment.

2.3 hazard

Potential source of harm.

2.4 incident

An event that causes, or has a potential to cause, unexpected or unwanted effects involving the safety of any person who use a medical device or any person associated with the use of a medical device.

Note. Incident is referred to as adverse event in ASEAN Medical Device Directive.

3 Requirements

Establishments are required to establish and maintain the following requirements for medical devices relating to complaint handling.

Complaints on any medical device can come from users of medical device such as patients, home users, healthcare practitioners, maintenance providers, or the general public. Establishments shall provide a standard form to users of medical device or any person to submit any complaints relating to their medical device (refer Annex B for a sample of the medical device complaint/ incident form). The establishment shall provide instruction on where to submit the complaint form.

3.1 Complaint handling procedure

For all medical devices placed in the market, establishments shall have in place a system to handle complaints received by the establishment. The establishment shall appoint dedicated personnel to handle all complaints. The elements of the complaints handling system shall include the following;

a) Receiving and recording of complaints. All complaints received shall be recorded and tracked.

b) Assessing the complaint. The criteria to determine whether the complaint is a reportable event shall be established which is based on the nature of the complaint, including but not limited to the following:

   i. whether there is a health hazard associated with the medical device;

   ii. whether the medical device fails to conform to any claim made by the manufacturer relating to its safety, quality and performance characteristics;

   iii. whether the medical device fails to meet any legislative requirements; and

   iv. failure of device, labelling or packaging to achieve the intended purpose of the device;

   If the complaint is a reportable event,

   i. The complaint shall be communicated to the AR or manufacturer if the complaint was received by the distributor or importer; and

   ii. a report shall be made by the AR or manufacturer to the Authority within the specified time (Please refer to MDA/GD/0014 on Mandatory Problem Reporting).

c) Investigating the complaint. An investigation to determine the root cause of the complaint is carried out when necessary. If investigation is not required, justification shall be prepared and recorded.

d) Implementing corrective and preventive action (CAPA). The need to implement CAPA is determined by the root cause of the complaint that has been concluded in the investigation. If CAPA is not required, justification shall be prepared and recorded. If FCA is required as CAPA for the complaint, please refer to MDA/GD/0013 on Field Corrective Action (FCA).

e) Communicating with the complainant. The establishment may communicate with the complainant on the outcome of the investigation or the action taken to overcome the problem.

f) Recording complaints. All records pertaining to complaint, investigation, justifications and communication to the complainant, the Authority and relevant parties shall be recorded (refer 3.1.1).

g) Closing the complaint. A complaint may be closed as a result of the following:

   i. Invalid complaint; or

   ii. All necessary actions have been carried out and problem(s) resolved.

These explanations are summarized in a process flow for handling a medical device complaint shown in Annex A.

Note: Attention should also be given by the establishment to identify the development of patterns or trends in problems related with the affected medical devices.

3.1.1 Records of complaints

a) The records on complaints related to a medical device shall include the following information:

   i. product information: product name, product identifier, serial/ lot/ batch number, expiry date and any other means of identification of the medical device;

   ii. complaint/ incident description and history;

   iii. reporter's details such as full name/ establishment name, contact information and establishment license number where applicable;

   iv. any other records pertaining to the problem investigation.

b) All actions taken by establishment in response to the complaints shall be recorded. These actions include, the assessment and investigation of the complaint, action taken to correct the problem or to prevent the recurrence of the problem, and communications with the complainant and/or Authority.

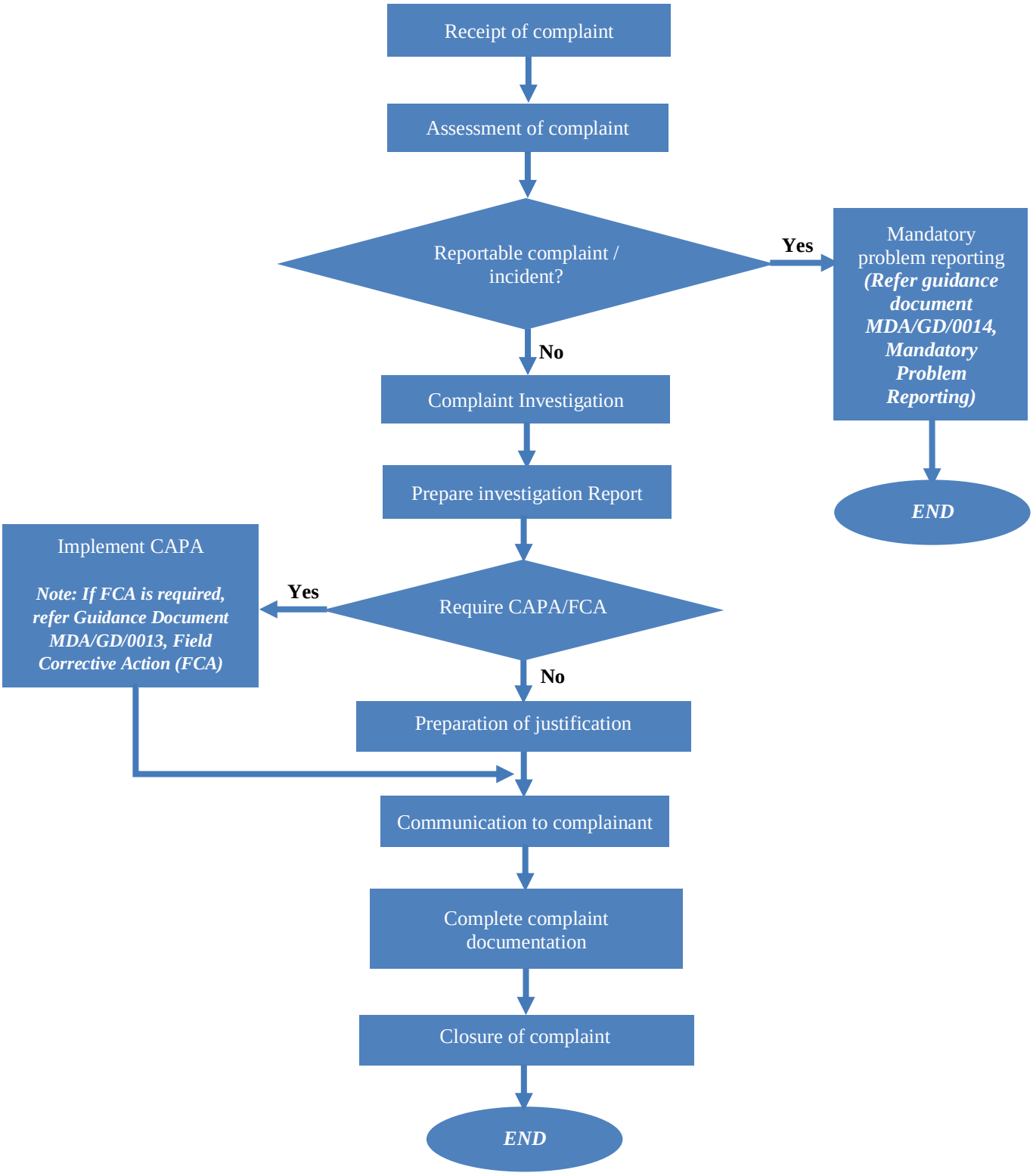
c) It is important that all oral complaints are documented.

3.1.2 Retention of complaint records

Complaint records maintained with respect to a medical device shall be retained for a period of 5 years on top of the projected useful life of the medical device as determined by the manufacturer (for example, if the projected useful life of the medical device is one year, the complaint records should be kept for six years).

Annex A
(informative)

Process flow for handling medical device complaints



Annex B
(informative)

MEDICAL DEVICE COMPLAINT FORM

This form may be used by the establishment to provide to users of medical device or any person to submit any complaints relating to a medical device. The establishment shall provide instruction on where to submit the complaint form.

Complainant	☐ Government ☐ Private ☐ Individual		
Institution	☐ Hospital ☐ Clinics ☐ Others: _____		
A. Device Particulars			
Device name			
Brand name			
Description of medical device (as appeared on label)			
Intended use (as appeared on label)			
Batch/ Lot/ Serial no.		Expiry date	
Establishment Particulars			
Name of manufacturer (if local device) / Name of authorized representative (if imported device)			
Manufacturer's / Authorized Representative's address			
Contact person			
Job title			
Telephone no.		Fax no.	
Email			
Name of distributor			
Distributor's address			
Contact person name			
Job title			
Telephone no.		Fax no.	
Email			
Complaint Information			
Description of complaint/ incident			

History of complaint/ incident			
Is there any injury involved?	☐ Yes ☐ No		
Complainant Information			
Name			
Position/ Occupation		Department/ Unit	
Address			
Telephone no.		Fax no.	
Email			

Other Information

I attest that the information submitted is true and correct.

Signature : _____

Name of reporting person : _____

Date of reporting : _____ (dd/mm/yyyy)

Organization stamp : _____

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