MDA/GD/0013
JUNE 2020
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

FIELD CORRECTIVE ACTION (FCA)

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 event 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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FIELD CORRECTIVE ACTION (FCA)

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. This document is made pursuant to Medical Device Act 2012 (Act 737) Section 41 and Regulation 6 of Medical Device (Duties and Obligation of Establishments) Regulations 2019 to describe and define the framework on establishment and management of medical device field corrective and preventive action by the establishment.

Manufacturers or their representative may need to undertake corrective or preventive action in relation to their medical devices. FCA can arise from post market surveillance information such as product complaints, incidents, market survey, research and development activities and others. These include safety related field corrective actions taken by the manufacturer to reduce the risk of harm to patients, operators or others and/or to minimise the recurrence of the event.

FCA might also be required by the Authority in cases coming from mandatory problem reporting and for medical devices that are no longer in the market or has been discontinued but could possibly still be in used (e.g. implants).

FCA is refered to as field safety corrective action (FSCA) in Asean Medical Device Directive (AMDD).

1 Scope and application

This guidance document provides guidance to the establishments (as defined in Section 2 of Act 737) to implement and comply to the requirement on FCA of medical devices imported and placed in market as stipulated in Section 41 of Act 737.

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 corrective action

Action to eliminate the cause of nonconformities to prevent a recurrence.

2.2 effectiveness check

Verification checks conducted, which can include surveys of those affected by the FCA (consignees) to verify they have received the FCA information and are aware of any appropriate action to be taken and may include verification of the action taken.

2.3 Establishment

As defined in Section 2 of Act 737.

2.4 field safety notice (FSN)

A communication sent out by an establishment to the medical device users in relation to a FCA.

2.5 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 as adverse event in ASEAN Medical Device Directive.

2.6 health hazard assessment

The scientific characterization of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process generally consists of the following steps:

a) hazard identification;

b) hazard characterization;

c) exposure assessment; and

d) risk characterization.

2.7 manufacturer

As defined in Section 2 of Act 737.

2.8 operator

Person handling a medical device.

2.9 preventive action

Action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

2.10 serious public health threat

Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action.
This would include:

a) Events that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the Authority or the manufacturer.

b) The possibility of multiple deaths occurring at short intervals.

2.11 user

The health care institution, professional, carrier or patient using or maintaining medical devices.

3 Requirements

Establishments shall undertake corrective or preventive action in relation to their medical devices that have been imported and placed in the market FCA is carried out to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include:

a) the return of a medical device to the manufacturer or its representative (recall);

b) device modification due to potential nonconformity, which may include:

   i. Retrofit in accordance with the manufacturer's modification or design change;

   ii. Permanent or temporary change to the labelling or instructions for use;

   iii. Software upgrades including those carries out by remote access; or

   iv. Modification to the clinical management of patients.

c) medical device exchange;

d) medical device destruction; and

e) specific advice given by establishment regarding the use of the medical device.

For FCA involving recall of a medical device, refer to guidance document MDA/GD/0015 on recall.

3.1 Determining the need for a FCA

Determining the need of a FCA is the responsibility of the manufacturer.

a) The manufacturer shall perform a risk assessment in accordance with ISO 14971. The Authority may instruct additional measures by the manufacturer or authorised representative to safeguard public health in case the Authority finds that the risk assessment performed by the manufacturer is deficient.

b) FCA could be triggered from the establishment's post market surveillance information (product complaint, adverse incidents, etc.) that indicate an unacceptable increase in risk.

Note. The Authority may advise establishment to implement FCA in relation to a medical device due to risk of serious injury or death to patients, users or others. Such risks are usually identified through incident reports or other means.

3.2 Submitting the FCA report

The manufacturer or Authorised Representative shall notify the Authority before initiating the field corrective or preventive action using the form in Annex B.

a) In the case of imported medical device, when the manufacturer decides to undertake a FCA he/she should immediately inform their authorised representative (AR) on the decision so that the AR can take necessary action and immediately notify the Authority.

b) If the medical device is exported to other countries, the establishment should notify the relevant authorities on the FCA.

c) The establishment shall submit a FCA report to the Authority within 30 days after completion of the FCA or such longer period as the Authority may allow.

3.2.1 Contents of the FCA report

The report shall include all necessary information as follows to assist the Authority to monitor the FCA:

a) identity of the manufacturer /authorised representative;

b) relevant parts from the risk analysis;

c) background information and reason for the FCA;

d) health hazard assessment;

e) description and justification of the action (corrective/preventive);

f) advice on actions to be taken by the distributor and the user (include as appropriate):

i. Identifying and quarantining the device;

ii. method of recovery, disposal or modification of device;

iii. recommended patient follow up, e.g. implants, IVD

iv. proposed timelines;

v. affected devices and serial/ lot/ batch number;

vi. in the case of an action concerning lots or parts of lots, an explanation why the other devices are not affected; and

vii. all other elements as listed in Annex B.

In the case of a recall, an establishment shall refer to Guidance Document MDA/GD/0015 on recall.

The Authority may close the FCA and notify the establishment in writing on its decision when all necessary actions have been undertaken and considered satisfactory.

3.3 Communicating the FCA via a Field Safety Notice (FSN)

a) FCA shall be effectively communicated to all parties involved in the supply chain including importers, exporters, distributors, consignees, retailers, healthcare facilities and users using Field Safety Notice (FSN) in a timely manner.

b) The establishment may also request the recipient of FSN to pass the FSN to all those who need to be aware of it within the organisation.

c) The establishment should use their distribution records in ensuring the appropriate parties or organisations have been informed, e.g. by confirmation of receipt. The establishment is responsible for conducting effectiveness checks, which may also be undertaken, or verified, by the Authority.

d) In certain cases, the Authority may require amendments to the FCA risk communication or FCA strategy. Where amendments to the FCA risk communication or FCA strategy are required, the Authority may require the establishment to issue a subsequent risk communication to further clarify with the affected parties on amendments to the FCA strategy.

e) It is recommended to copy the FSN to the conformity assessment body involved in the conformity assessment of that device.

f) Any comments and descriptions that attempt to serve to play down the level of risk in an inappropriate manner; and Advertise products or services shall be avoided.

3.3.1 Content of the field safety notice (FSN)

The FSN shall be on an establishment letterhead, and include the following:

a) A clear title to indicate and emphasize the urgency and importance of FSN, and followed by the commercial name of the affected product and the type of action.

b) Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.

c) A factual statement explaining the reasons for the FCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person and any possible risks to patients associated with previous use of affected devices.

d) Advice on actions to be taken by the user as appropriate, e.g. identifying and quarantining the device, method of recovery, disposal or modification of device, recommended review of patients' previous results or patient follow up.

e) If relevant, a request for the details of any affected devices that have been transferred to other organisations, to be given to the manufacturer and for a copy of the FSN to be passed on to the organisation to which the device has been transferred.

f) If relevant, a request that the recipient of the FSN alerts other organisations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.

g) Contact information of the establishment for all parties involved in the supply chain to provide feedback/acknowledgement of receipt of the FSN.

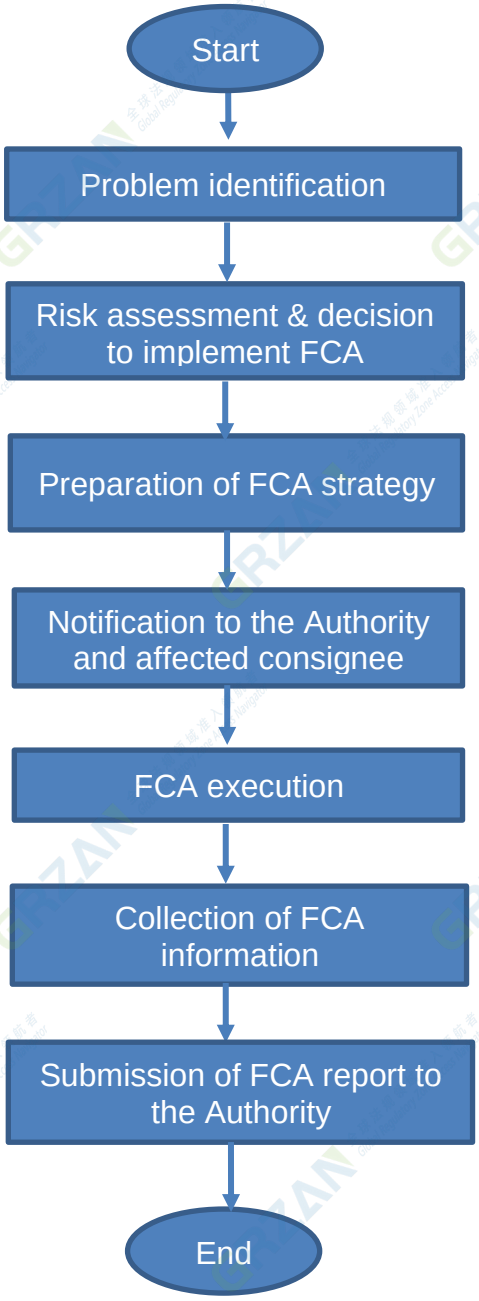
h) An acknowledgment form for the receiver should also be included (especially useful for establishment's control purposes).

i) The establishment may use the form in Annex C. A copy of the FSN shall be fowarded to the Authority via e-mail at Notice_FCA@mda.gov.my.

In the case that the FSN comes from a foreign manufacturer, the AR/distributor may send the FSN to the affected stakeholders with an accompanying official coverletter and adding in elements of the FSN that have not been covered by the manufacturer.

Annex A
(informative)

Process flow for Medical Device Field Corrective Action



Annex B
(informative)

Forms for submission to the Authority

1. Medical device field corrective action notification form.

MEDICAL DEVICE FIELD CORRECTIVE ACTION NOTIFICATION FORM

This form is to be used by establishment to notify the Authority any field corrective action of medical device. This form and other related attachments shall be completed and submitted to Medical Device Authority (MDA). It is recommended to submit the completed form via email.

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, Cyberjaya, Selangor, MALAYSIA.
Email : Notice_FCA@mda.gov.my
Tel: 03-8230 0300
Fax: 03-8230 0200

FIELD CORRECTIVE ACTION NOTIFICATION FORM			
Type of Field Corrective Action (FCA)	☐ Return ☐ Modification	☐ Exchange ☐ Destruction	☐ Specific Advice
Establishment Particulars			
Name of company			
Company address			
Contact person name			
Job title			
Tel No.		Fax No.	
Email Address			
Medical Device Details			
Medical device name			
Medical device intended use			
MDA Registration No. *(if device is registered)*			
Model No.			
Serial No.			
Lot/Batch No.			
Accessories/Associated medical devices affected *(if any)*			
Manufacturer name			
Manufacturer address			
AR/Distributor/Importer and contact details			
FCA Proposed Plan and Action			
FCA planned by establishent			

2. Medical device field corrective action report form

FCA Information	
Did the FCA arise due to an incident? *(Please select only one)*	☐ Yes ☐ No
If yes, what is the category of incident? *(Please select all if applicable)*	☐ Serious Public Health Threat ☐ Death ☐ Serious Injury ☐ Non-serious Injury
Did this incident occur in Malaysia?	☐ Yes ☐ No
Has the incident been reported to MDA? *(Please select only one)*	☐ Yes (incident ref. no.: .....) ☐ No
Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report)	
Background information, root cause and reason for the FCA	
FCA plan and action to be taken (corrective action)	
Advice on actions to be taken by the distributor and the user	
Has the FCA been communicated to all consignees?	☐ Yes (Date sent: .....(dd/mm/yyyy)) ☐ No (Expected date to be sent: .....(dd/mm/yyyy))
Number and name of affected units supplied to each consignee	
No. of affected units and the period that affected units are manufactured/imported/supplied in Malaysia	Manufactured in Malaysia: ..... Period: ..... (mm/yyyy) to ..... (mm/yyyy)
	Imported into Malaysia: ..... Period: ..... (mm/yyyy) to ..... (mm/yyyy)
	Supplied in Malaysia: ..... Period: ..... (mm/yyyy) to ..... (mm/yyyy)
	Expected shipments to Malaysia: ..... Expected date of arrival: ..... (mm/yyyy)
Date of commencement of FCA by manufacturer	

Date of commencement of FCA in Malaysia		
Proposed date of completion of FCA in Malaysia		
Follow Up / Final report		
FCA completed?	☐ Yes, Date: _____(dd/mm/yyyy)	☐ No
Progress of FCA, together with reconciliation status and/or effectiveness check and its method		
Proposed action to prevent recurrence of the problem (preventive action)		
Other Information		

I attest that the information submitted is true and correct.

Signature : .....
Name of Reporting Person : .....
Date of this report : .....
Company stamp :

Annex C
(informative)

Field Safety Notice Template

Establishment Letterhead

URGENT - Field Safety Notice

To all users of the <medical device name>

Re: <medical device name> with <short description of the malfunction>

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the *<part of the medical device that causes the malfunction>* of the *<medical device name with specific details to enable the affected medical device to be easily identified e.g. type of medical device, model name and number, batch/lot or serial numbers of affected medical devices and part or order number>.*

When does this malfunction occur and what are the potential risks?

<A factual statement explaining the reasons for the Field Safety Notice including description of the medical device deficiency or malfunction, clarification of the potential

hazard associated with the continued use of the medical device and the associated risk to the patient, user or other person and any possible risks to patients associated with previous use of affected medical devices>

What steps can the user take to avoid the potential risk of this issue?

<Include as appropriate:

o *Identifying and quarantining the medical device,*

o *method of recovery, disposal or modification of medical device,*

o *recommended review of patients previous results or patient follow up, if applicable,*

o *timelines>*

***<Only if applicable>* How will the issue finally be resolved?**

Xxxxx Sdn.Bhd. is preparing a modification of *<medical device name>* that will resolve this potential malfunction. The field modification will be available from <date>.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain

awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours

<signature of Manager / Regulatory Affairs >

<name>

<date>

Contact person of this notification:
……
Department ……
Telephone ……..
Fax ……..…….....
E-mail …….

Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the <*medical device name*> with the Serial number _____ (optional) that I received the following document:

Field Safety Notice

<medical device name> with <short description of the malfunction>

Place : _____

Date : _____

Name : _____

Signature: _____

Company stamp:

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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