

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-10: Guidance on Medical Device Field Safety
Corrective Action

Revision 3.5



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PREFACE

R3.1 ► This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. ◀

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**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide guidance on Field Safety Corrective Action (FSCA).

1.2. Background

The Health Products Act (*Act*) and Health Products (Medical Devices) Regulations 2010 (*Regulations*) requires FSCAs to be reported to the Authority.

A FSCA is required when it becomes necessary for the product owner of the medical device to take action (including recall of the device) to eliminate, or reduce the risk of, the hazards identified.

A FSCA may still be necessary even when the medical device is no longer on the market or has been withdrawn but could still possibly be in use (e.g. implants).

For further information on specific requirements that apply to recalls, please refer to the *GN-04: Guidance on Medical Device Recall*.

1.3. Scope

This document is applicable to all persons who register, manufacture, import and/or supply medical devices in Singapore.

1.4. Definitions

Definitions that do not indicate they are set out in the *Act* or *Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

AFFECTED DEVICE: R3.5 ► a medical device that is affected or likely to be affected by the problems, issues, or deficiencies identified by the product owner of the medical device that could impact the safety, quality and/ or efficacy of the medical device. The affected medical device information (e.g. model identifiers) is typically presented in the product owner's field safety notice. ◀

CONSIGNEE: anyone who received, purchased or used the device undergoing a Field Safety Corrective Action.

CONTROL NUMBER: a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the product owner and from which a history of the manufacture, packaging, labelling and distribution of a lot or batch of the device can be determined.

CORRECTION: an action to eliminate a detected nonconformity including the repair, modification, adjustment, relabeling, or inspection (including patient monitoring) of a device.

CORRECTIVE AND PREVENTIVE ACTION (CAPA): actions taken to address the identified root cause for the device problem or issue for which the FSCA was initiated. This can include amongst others, post-market surveillance, recalls, or corrective or preventive actions related to the design and manufacture of the device.

CORRECTED DEVICE: a medical device which is affected by the FSCA and has completed CAPA intended by the product owner to wholly correct for the FSCA.

CORRECTION-IN-PROGRESS DEVICE: a medical device which is affected by the FSCA and has not completed the CAPA intended by the product owner to wholly correct for the FSCA; i.e. devices having interim risk mitigation measures will be considered as a correction-in-progress device.

DEALER: any manufacturer, importer, supplier or registrant conducting the FSCA in Singapore.

NOTE: The dealer could either be (i) initiating the FSCA on their own accord as the product owner, (ii) initiating the FSCA on behalf of the product owner, or (iii) initiating the FSCA as mandated by the Authority.

EFFECTIVENESS CHECK: verification checks conducted, which can include surveys of those affected by the FSCA (consignees) to verify they have received the FSCA information and are aware of any appropriate action to be taken and may include verification of the action taken. The manufacturer, importer, supplier or registrant is responsible for conducting effectiveness checks, which may also be undertaken, or verified, by the Authority.

FIELD SAFETY CORRECTIVE ACTION (as set out in the Regulations): any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, including

- the return of the medical device to its product owner;
- replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;

- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;
- the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- any upgrade to any software used with the medical device, including any such upgrade carried out by remote access.

FSCA STRATEGY: a planned course of action taken by the dealer conducting a specific FSCA, including but not limited to the depth of FSCA, the need for public warnings, and the extent of effectiveness checks for the FSCA.

NOTE: The depth of the FSCA refers to whether the FSCA has to be conducted at the wholesale, retail or consumer level, etc.

FIELD SAFETY NOTICE (FSN): A communication sent out by a product owner or its representative to the device users in relation to a FSCA. This communication shall include the product identifier of affected units and a field for the consignee to acknowledge that he has understood the contents of the FSN.

HEALTH HAZARD ASSESSMENT (HHA): the scientific characterisation 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: (i) hazard identification (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.

MEDICAL DEVICE (as set out in the Act): means a medical device as described in the First Schedule of the Act.

PRODUCT OWNER (as set out in the Regulations): in relation to a health product, means a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

QUALIFIED PRACTITIONER (*as set out in the Regulations*): means —

- a registered medical practitioner under the Medical Registration Act (Cap. 174), when acting in the course of providing medical treatment to a patient under his care; or
- a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(a) of that Act, when acting in the course of providing dental treatment to a patient under his care.

QUARANTINE: effective restriction of the availability of material or device for use or distribution by the dealer or qualified practitioner, until released by a designated authority.

RECALL: any action taken to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device —

- may be hazardous to health; or
- may fail to conform to any claim relating to its quality, safety or efficacy.

ROOT CAUSE ANALYSIS: an analysis into the most likely reason(s) why a problem or issue had occurred with the medical device.

STOCK RECOVERY: a dealer's removal or correction of a medical device that has not been supplied or that has not left the direct control of the dealer.

2. DETERMINING THE NEED FOR A FSCA

The product owner of the medical device in question is responsible for determining the need for a FSCA.

FSCA may be triggered when information from the product owner's post market surveillance (including product complaints, adverse incidents, etc.) indicates an unacceptable increase in risk.

Where necessary, the Health Sciences Authority ("Authority") may instruct product owners or their representative to implement a FSCA 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 adverse events reports or other means.

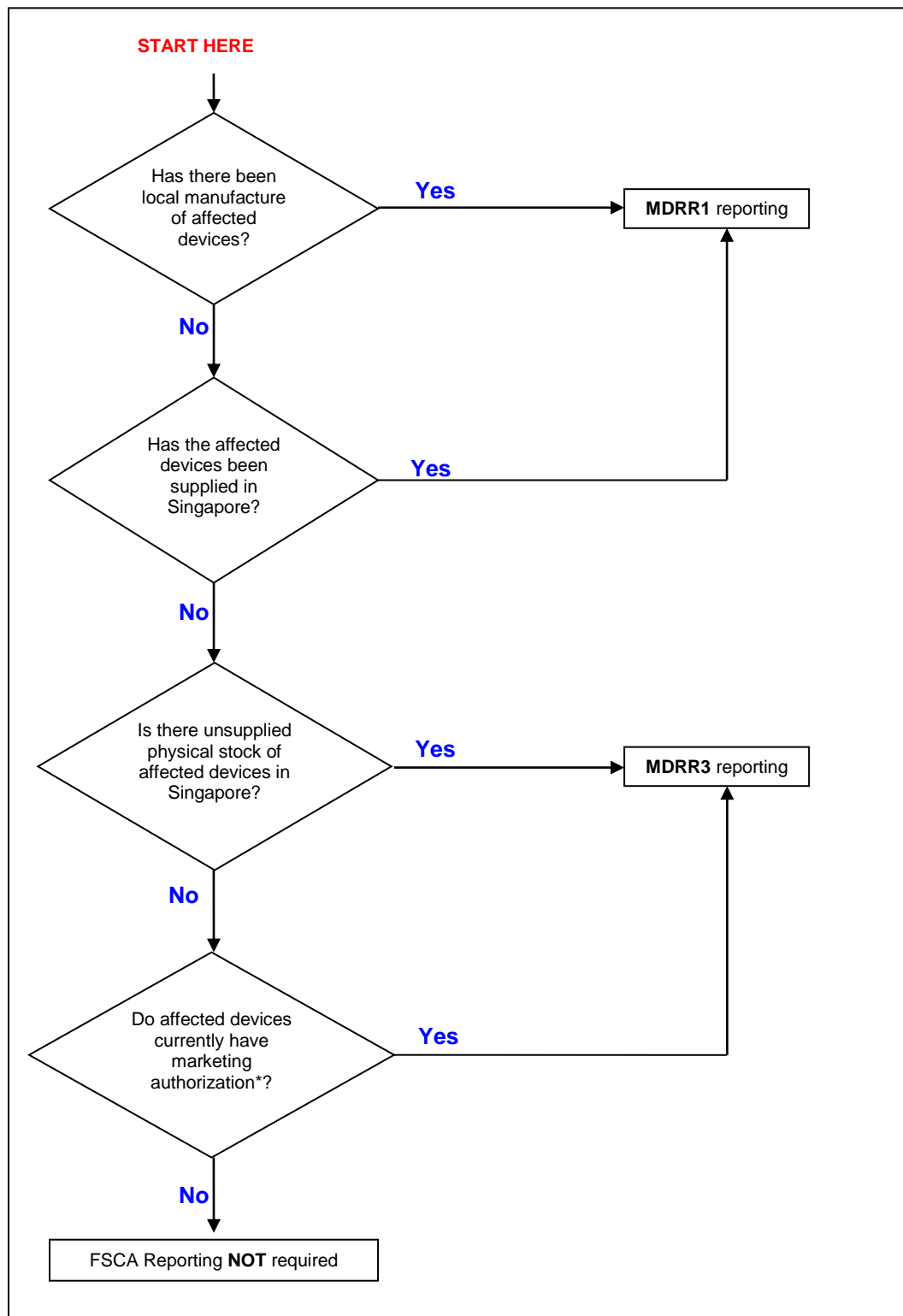
In certain cases, it may be necessary to use precautionary measures in the interest of public health and restrict or prohibit products subject to particular requirements. It may also be necessary to remove a medical device from the market. Risk communication to the general public may be necessary to ensure effective conduct of the FSCA.

3. NOTIFICATION OF FSCA

If medical devices affected by the FSCA have been manufactured, imported or supplied in Singapore, or have obtained a valid marketing authorization for local supply, the FSCA shall require notification to the Authority. The dealer that manufactured, imported or supplied the affected devices shall ensure that necessary measures (e.g. initiation of FSCA, stock recovery, etc.) in relation to the FSCA are undertaken without any undue delay.

Refer to Diagram 1 below for FSCA report submission decision flowchart.

Diagram 1 FSCA Report Submission Decision Flowchart



**NOTE: For the purposes of this guidance, marketing authorisation would refer to either (i) registration on the Singapore Medical Device Register (SMDR), (ii) placement on the Transition-List or (iii) Special Authorisation Routes for local supply (GN-26, GN-27, GN-29 or GN-30(CR)).*

NOTE: In cases where the medical devices affected by the FSCA have been imported but not supplied in Singapore or have obtained marketing authorisation from the Authority but have not been manufactured, imported or supplied in Singapore, a MDRR3 report form shall be submitted.

R3.5 ► NOTE: *Under circumstances where there is a subsequent clinical need for the devices affected by the FSCA reported under MDRR3, a review would be required prior to any supply. Hence, a subsequent MDRR1 report should be submitted to the Authority. ◀*

NOTE: In cases where the medical devices affected by the FSCA have been manufactured in Singapore, a MDRR1 report form shall be submitted, regardless of whether the affected medical devices have been supplied in Singapore.

4. WHO NEEDS TO NOTIFY FSCA TO THE AUTHORITY?

The party that performs the reporting obligations to the Authority is also referred to as the reporting person. The dealer that manufactured, imported or supplied or obtained marketing authorisation for the affected devices in Singapore shall be the reporting person. In cases, where more than one dealer has manufactured, imported or supplied the affected devices in Singapore, each dealer that manufactured, imported or supplied the affected devices may be required to report individually.

NOTE: However, in certain cases, if complete distribution and stock inventory details on affected devices can be obtained from one or more of the reporting persons, report submission from each of the dealers may not be requested by the Authority.

5. INITIATION OF FSCA IN SINGAPORE

Once the product owner initiates the FSCA, and affected devices have been supplied in Singapore, the implementation of the FSCA should not be delayed.

Prior to the initiation of the FSCA in Singapore, under the *Regulations*, it is a requirement that the FSCA is notified to the Authority. Once the FSCA is notified to the Authority, the dealer may proceed to initiate the FSCA or conduct stock recovery unless otherwise instructed by the Authority.

Dissemination of the product owner's FSN and implementation of the corrective actions listed in the FSN are some measures (but not limited to) that constitute initiation of the FSCA.

Once notified to the Authority, an approval from the Authority to proceed with dissemination of the FSN or conduct of the FSCA is not required. However, the Authority may instruct the dealer to perform additional measures (in relation to the FSCA) that are deemed necessary to safeguard public health.

In certain cases, the Authority may require amendments to the FSCA risk communication or FSCA strategy. Nevertheless, to ensure timely communication, the dealer should inform all affected consignees (e.g. through the dealer's initial FSN) of the FSCA. Where amendments to the FSCA risk communication or FSCA strategy are required, the Authority may require the dealer to issue a subsequent risk communication to further clarify with the affected consignees on amendments to the FSCA strategy.

6. REPORTING TIMELINES

FSCA that falls under MDRR3 reporting should be submitted within 30 days of the initiation in any country globally.

The FSCA MDRR1 Notification Report should be submitted before the initiation of FSCA or stock recovering in Singapore. There shall not be any undue delay in the initiation of the FSCA in Singapore once the product owner has initiated the FSCA globally.

Note: An acknowledgement notice for the FSCA Notification Report would be issued by the Authority after the submission of the FSCA Notification Report.

A Preliminary report, if requested by the Authority, shall be submitted within 24 hours after the commencement of the FSCA. A Follow-up or Final report is to be submitted to the Authority within 21 days from the date of commencement of the FSCA.

7. PRESCRIBED FORM AND MANNER FOR SUBMISSIONS

All reports shall be submitted in the following form and manner that the Authority prescribes:

- Form# MDRR1 for Notification/Preliminary reporting of FSCAs that require initiation in Singapore
- Form# MDRR2 for Follow-up/Final reporting of FSCAs that require initiation in Singapore
- Form# MDRR3 for reporting of medical device related post-market information

Refer to Diagram 1 for the decision flowchart on the FSCA report form to submit.

NOTE: For submission of FSCAs where the affected medical devices have been imported but not supplied in Singapore or have obtained marketing authorisation from the Authority but have not been manufactured, imported or supplied in Singapore, a MDRR3 report form shall be submitted.

Submission is via email as described in the forms. A scanned copy of the completed hardcopy FSCA Report is to be submitted, together with other accompanying documents/ information. Email size should be under 2MB.

NOTE: For email size above 2MB, please split the email accordingly to ensure that each email has a size of no more than 2MB.

Report forms are to be signed and dated. No unauthorised changes to the form shall be performed. The Authority reserves its right to reject reports that have not been received in the form or manner it prescribes.

8. INFORMATION FOR INCLUSION IN FSCA REPORT SUBMISSIONS

When the need for a FSCA has been established, the product owner or its representative should gather all relevant information on the medical device and its distribution, and the action proposed. Some information may not be available immediately (e.g. distribution chains, batch size etc.). Notification to the Authority should not be delayed pending collation of these data.

8.1. Information to be provided as part of the MDRR1 Notification or Preliminary Report

The dealer conducting the FSCA in Singapore shall ensure that the following information is provided as part of the FSCA Notification or Preliminary Report submission to the Authority (not limited to):

- Reason for the FSCA
- FSCA strategy (if affected stock have been supplied in Singapore)
- Product owner's Health Hazard Assessment (HHA)
- Product owner's Root Cause Analysis (RCA)
- Product owner's CAPA to reduce likelihood of recurrence of device issue
- Product owner's CAPA effectiveness/ validation
- Affected device status, including
 - List of affected consignees, including number of affected units per local consignee
 - Quantity manufactured, imported into, or supplied in Singapore.
 - For manufactured devices that have been exported, list of countries exported to and quantity of affected units exported shall be provided to the Authority
- Product owner's FSN or other risk communication documents
- A draft 'Dear Healthcare Professional' Letter (DHCPL) or print advertisement (if applicable)

NOTE: Refer to Section 10.1 for the necessary requirements of FSN submitted to the Authority during FSCA Report submission.

The RCA should contain important technical information detailing the root cause and the basis for determination and identification of devices affected by the FSCA. The CAPA and CAPA effectiveness constitutes important technical information detailing actions or measures undertaken to satisfactorily address the root cause behind the FSCA and to support that the likelihood of future supply being affected by a recurrence of the device defect/ problem/ issue has been satisfactorily reduced or eliminated. In the interest of public health, failure on the part of the dealer to promptly provide information on the RCA or CAPA may necessitate further regulatory actions being undertaken against the affected devices, including a stoppage to import, supply or use. Hence, the dealer should ensure that FSCA related information is submitted within deadlines stipulated in the Authority's Notices.

In cases where the medical devices affected by the FSCA have not been supplied in Singapore, this shall be indicated in the FSCA Notification Report submission.

NOTE: Submission of false or misleading information on FSCA is a serious offence under the Health Products Act. Dealers shall ensure that all submissions contain complete and accurate information.

R3.5 ► NOTE: All FSNs of FSCAs reported under MDRR1 must be copied to the Chairman Medical Board and/ or relevant Head-of-Departments of the affected healthcare facilities. ◀

Based on the Authority's risk assessment, the dealer conducting the FSCA may be instructed by the Authority to perform additional risk control measures. Such instructions shall be issued through written notice, which includes email. These measures could include (non-exhaustive list):

- Perform an inspection of affected devices supplied in Singapore and to revert with an inspection report;

- Modify/ amend risk communication on FSCA;
- Label existing supplied stock with information specified by the Authority; or
- Publish risk communication in specified media.

Failure on the part of the dealer to perform these measures when instructed by the Authority to do so, would constitute an offence under the Health Products Act.

8.2. Information to be provided as part of the Final or Follow-Up Report

A Final or a Follow-up report shall be submitted within 21 days of initiating the FSCA. If the FSCA has not been completed within 21 days, a Follow-up report shall be submitted to the Authority within 21 days. The Follow-up report should provide an update on progress of the reconciliation of stock affected by the FSCA, together with confirmation that the consignees have received the FSN. It should also provide a progress report on the investigation to date and any additional CAPA that is being considered by the product owner.

The dealer conducting the FSCA shall ensure that the following information is provided as part of the Follow-Up or Final Report submission to the Authority (non-exhaustive):

- Product owner's CAPA to reduce likelihood of recurrence of device issue
- Product owner's CAPA effectiveness/validation
- For recalls, destructions certificates or airway or shipment bill of return of recalled devices to the product owner
- Declaration letter from the dealer on dealer's letterhead stating the completion of field correction for affected consignees in Singapore (Refer to **ANNEX 1** for the template of this declaration letter) *Note: the declaration should include all affected devices in warehouse (unsupplied),*

those supplied at the point of FSCA notification and subsequent new supply of affected devices with FSN, or correction-in-progress devices.

- Consignee acknowledgement receipts confirming the receipt of the Field Safety Notice or DHCPL by the local affected consignees (*when requested*)
- For FSCAs that require a software upgrade or device modification, service reports for the completion of the corrective actions specified in the FSN or other risk communication documents (*when requested*).

NOTE: Both consignee acknowledgement receipts and service reports shall be signed-off by the affected consignee, prior to its submission to the Authority when requested. Unsigned documents shall not be accepted.

NOTE: For supply to overseas consignees, consignee acknowledgement receipts shall not be required for submission to the Authority. However, the dealer remains responsible for ensuring that information on the FSCA is disseminated to any overseas consignees.

All FSCA reports are to be submitted using the prescribed format. In some instances, the Authority may deem that further information is necessary to assess the adequacy and acceptability of the information provided and request for it accordingly.

8.3. Information to be provided as part of the MDRR3 Notification Report

The dealer conducting the FSCA in Singapore shall ensure that the following information is provided as part of the FSCA Notification Report submission to the Authority (not limited to):

- Product owner's FSN or other risk communication documents
- Quantity imported but not supplied and/or present as stock in warehouse (if applicable) *Note: prior to any supply of these devices, ensure that these are corrected of the FSCA, conforms to Essential Principles in the [R3.2](#) ►*

GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices ◀, and any other applicable regulatory requirements.

The purpose for requesting this information is to verify and confirm that there has been no manufacture or supply of the affected devices in Singapore. Furthermore, in the case of registered medical devices, the dealer shall ascertain whether there is a need for submission of a change notification for the medical devices corrected for the FSCA. The Authority reserves the right to request for the submission of information on the FSCA, if deemed necessary. Such information, when requested, shall be submitted within the deadline stated in the Authority's written Notice (e.g. email).

8.4. Identification of affected device information in FSN

For FSCA where the affected devices have been manufactured, imported and/or supplied in Singapore (i.e. MDRR1 report), the FSN can either:

- a) provide the complete global list of affected identifiers identified by product owner; *OR*
- b) only list local affected identifiers in Singapore. In such an instance, a statement (or any equivalent one) should be included to inform the recipient or reader of FSN that there may be other affected identifiers that are affected globally and that they should check with product owner in the event they obtained the device from an overseas dealer.

For FSCAs where the affected devices have not been supplied in Singapore (i.e. MDRR3 report), the affected identifiers listed in the FSN should be the global list.

9. FSCA INVOLVING CONSUMER-LEVEL MEDICAL DEVICES

In relation to FSCAs involving medical devices that have been supplied at consumer level (e.g. contact lenses, blood glucose test strips), a draft print advertisement shall be submitted to the Authority as part of the Notification Report submission. For consumer-level FSCA, a print advertisement in public media to the general public is deemed necessary for effective risk communication to all affected consumers of the FSCA. In general, the requirement would be to publish in each of the daily newspapers of the four official languages, unless otherwise allowed by the Authority. In certain cases, the Authority may also require a press release to be prepared. These instructions would be stated in the FSCA Acknowledgement Notices.

The contents of the press release and/or print advertisement shall include the following (non-exhaustive):

- Reason for FSCA
- Affected product identifier(s)
- Pictorial information on how affected products can be identified (in layman terms)
- Information on returns procedure (e.g. to exchange affected units with non-affected stock)
- Dealer contact hotline (including operating hours) and email address for enquiries

All consumer-level risk communications shall require prior clearance from the Authority. Consumer-level FSCAs are highly time-sensitive and require urgent actions to be undertaken. Dealers are expected to conduct such FSCAs expediently and effectively.

10. FSCA INVOLVING IMPLANTABLE MEDICAL DEVICES

For FSCAs involving implantable medical devices, dealers shall be required to prepare a 'Dear Healthcare Professional' Letter (DHCPL) for dissemination to qualified practitioners who have been supplied or performed implantations using the devices affected by the FSCA. The DHCPL shall contain information on the product owner's clinical management advice to qualified practitioners with regards to patients who have been implanted with medical devices affected by the FSCA.

The DHCPL shall only be disseminated upon receipt of written clearance from the Authority. Nevertheless, in the interim, the dealer should still inform all affected consignees of the FSCA through product owner's FSN, while changes to the DHCPL are being finalised.

NOTE: For guidance on drafting a DHCPL, please refer to GN-09: Guidance on the Component Elements of a DHCPL.

Dealers shall be required to report the number of implantations that had been performed in Singapore using the affected medical devices that had been supplied by them.

All qualified practitioners who have been supplied or performed the implantation using the devices affected by the FSCA shall receive a copy of the DHCPL from the dealer. The acknowledgement receipt of DHCPL is intended to be signed by the said qualified practitioner. In cases where the qualified practitioner has left his practice, the facility where the implantation occurred shall acknowledge receipt of the DHCPL on behalf of the qualified practitioner. Other recipients of the DHCPL should include the procurement department of the healthcare facility.

NOTE: Acknowledgement of the DHCPL constitutes a confirmation that the qualified practitioner involved has received a copy of the DHCPL or other risk communication associated with the FSCA. This is a form of effectiveness check that the Authority performs. FSN acknowledgement receipts will not be requested by The Authority for cases where DHCPL is required.

11. RISK MANAGEMENT PROCESS FOR SUPPLY OF MEDICAL DEVICES.

Medical devices that are affected by the FSCA are determined from the product owner's FSN. In general, supply of medical devices that are affected by a FSCA, and that have not been corrected, is not permitted. Medical devices that are not affected by the FSCA can continue to be supplied subject to standard regulatory requirements being continued to be satisfied.

Based on the corrective action intended by product owner, FSCAs can be divided into two categories: (1) recalls, and (2) other corrective actions.

For recalls, by default, new supply of medical devices affected by the recall is not permitted. Once affected devices have been recalled from the field, the dealer shall ensure that the recalled devices are quarantined / disposed and not permitted for further supply.

For other corrective actions, there are two main sub-categories: (1) corrections limited to labelling, and (2) corrections **not** limited to labelling.

For other corrective actions that are limited to labelling (e.g. advice given by product owner on device precaution or addition of user warning), new supply of affected device may be permitted with the condition that supply of affected device is accompanied by the product owner's FSN.

NOTE: For any FSCA, including those where correction is limited to labelling, Authority reserves its right to instruct additional measures where it deems necessary.

NOTE: For avoidance of doubt, when determining whether a FSCA is limited to labelling changes, changes in indication or shelf life would be deemed as corrections that are not solely limited to labelling.

For other corrective actions that are **not** limited to labelling, there are two further sub-categories: (1) correction-in-progress devices, and (2) corrected devices.

For corrected medical devices, supply may proceed, subject to standard applicable regulatory requirement such as change notification (CN). For further information on the types of changes to registered medical devices that require CN, please refer to *GN-21: Guidance on Change Notification*. Failure to notify and/or obtain approval from the Authority of changes made to registered medical devices is an offence under the Health Products Act.

For correction-in-progress medical devices, whether the product owner's interim risk mitigation measures are sufficient is the main consideration in relation to new supply. If the dealer and product owner substantiates to the Authority that the interim risk mitigation measures are sufficient, and the Authority concurs with the product owner's justification, new supply of correction-in-progress medical devices may be permitted, subject to conditions. Examples of conditions that may be issued include (but not limited to), ensuring correction-in-progress medical devices that were supplied undergo full correction upon availability of final CAPA, FSN to be provided with each supply, and a declaration to confirm that full correction for all correction-in-progress medical devices has been completed.

Refer to Annex 2 for illustration on the risk management process for new supply of medical devices.

NOTE: The Authority's Notice would include instructions regarding supply of correction-in-progress medical devices. Non-compliance to this Notice would constitute a serious offence under the Health Products Act.

12. COMPLIANCE TO NOTICES

Pursuant to Regulations 46(4) of the Health Products (Medical Devices) Regulations 2010, non-compliance to notices issued by the Authority would constitute a serious offence. Penalties that apply for failure to perform the measures required under notices issued by the Authority are a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 6 months, or to both.

13. PUBLICATION OF FIELD SAFETY NOTICES ON HSA WEBSITE

Safety communications of FSCAs reported to the Authority are publicly accessible as field safety notices (FSN) on the HSA website. Accessibility to safety information regarding medical devices will facilitate timely identification and management of risks posed by medical devices affected by FSCAs.

Please note that FSNs are issued by the product owner or dealer of medical devices pursuant to the requirements under the Health Products Act (Cap. 122D). These persons take full responsibility for all information contained in the FSN.

Consignees who receive a FSN from a product owner or dealer must always act on it. The Authority makes FSNs publicly available for information only.

For any specific questions on a FSN, consignees have been advised to contact the product owner or dealer (as the case may be).

13.1. FSN Requirements for Publication

The FSN for publication should:

- be submitted as a single Adobe PDF document instead of a Microsoft Word document;
- not be tagged as “Draft”;
- not include or add information that has not been authorised by the product owner or the Authority;
- not have information regarding the FSCA deleted, altered or concealed from;
- not be password-protected;
- not contain any third party marks (e.g. contact details of consignees); and
- be accessible to any person who may have potentially been supplied with affected devices. Therefore, the presence of “Privileged and Confidential” or “Restricted” tags in the FSN is inappropriate and strongly discouraged.

NOTE: The publication of FSN is to ensure FSCA related safety information is accessible to any party who may have received affected medical devices so as to safeguard public health.

14. COMPLETION OF REPORTING OBLIGATIONS FOR FSCA

The FSCA reporting obligation will be considered completed when all appropriate corrective actions have been undertaken by the dealer, subject to the concurrence of the Authority. The FSCA reporting obligation is only considered completed upon receipt of written confirmation from the Authority.

The dealer should maintain records related to the FSCA for a minimum period of either 2 years or the projected useful life of the medical devices, whichever is longer. Such records should include, *inter alia*, the FSN, list of affected consignees, acknowledgement receipts for dissemination of FSN or DHCPL, or service reports documenting device corrections performed.

Although the FSCA is deemed completed, the Authority reserves its right to request for additional information in related to the FSCA when necessary.

ANNEX 1

Declaration Template

[To be printed on dealer Letterhead of dealer]

Medical Devices Branch
 Medical Devices Cluster
 Health Products Regulation Group
 Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Declaration on completion of correction for Field Safety Corrective Action Ref No. *<HSA FSCA Ref No. HSA 600:41:01-xxx/yy/xx>*

1. We, *[name of dealer]*, hereby declare that the list of consignees in Singapore supplied with medical device affected by FSCA, *<HSA FSCA Ref No.>*, are limited to:

Consignee Name	Quantity	Status of correction of affected device
<i><Consignee 1, provide full name of e.g. clinic or hospital></i>		<i><completed></i>
<i><Consignee 2, provide full name of e.g. clinic or hospital></i>		

2. We confirm that we have provided to all affected consignees in Singapore, listed in paragraph 1, a copy of the Field Safety Notice (FSN), and have completed all corrections required to complete the aforementioned FSCA.

3. Written acknowledgements confirming full and effective completion of the field corrections required as per product owner's FSN have been collected from consignees listed in paragraph 1. Records of acknowledgement receipts will be provided to HSA when requested.

4. We attest the information submitted as part of this declaration has been verified to be true and accurate, and are aware of the penalties that apply under the Health Products Act and its subsidiary legislation for false or misleading submissions.

Yours Sincerely,

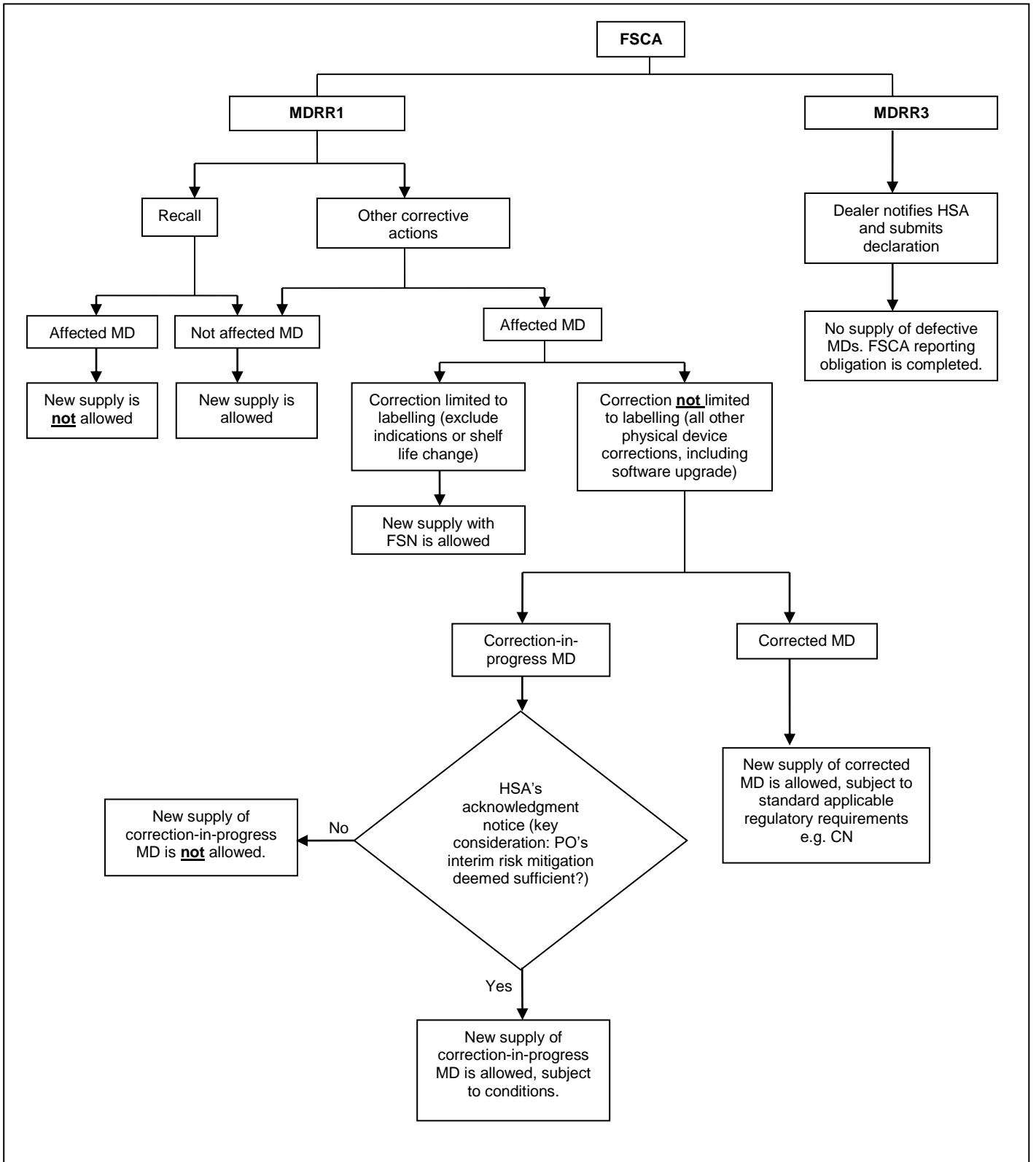
[Signature]

[Full Name and Title]

[Name and address of company]

ANNEX 2

Risk Management Process for New Supply of Medical Devices (MD)



HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg

<https://crm.hsa.gov.sg/event/feedback>

