HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

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

Revision 4

HSA
Health Sciences Authority

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PREFACE

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.

REVISION HISTORY

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A FSCA may still be necessary even when the medical device is no longer on the market or has been withdrawn but could still possibly be in use (e.g. implants).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

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.

R4 ►

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

- a registered medical practitioner under the Medical Registration Act 1997, when acting in the course of providing medical treatment to a patient under his care; or
- a registered dentist ◄

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 (RCA): 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.

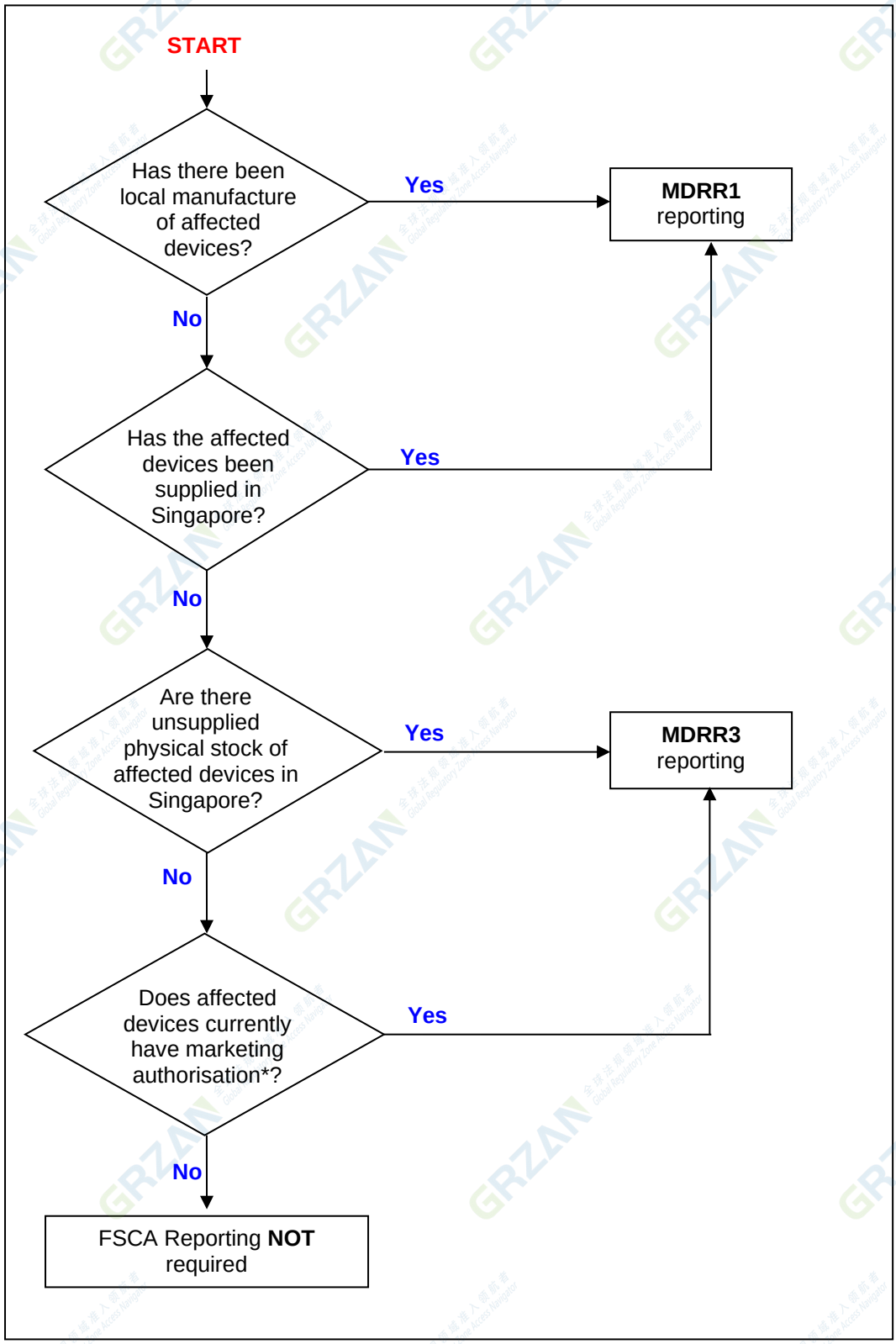
Where necessary, the Health Sciences Authority ("Authority") may instruct product owners or their representative to implement a FSCA in relation to a medical device due to risk of serious injury or death to patients, users or others. Such risks are usually identified through adverse events reports or 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.

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), R4 ► (ii) devices*

listed on the Class A database (ii) Special Access Routes (SAR) granted 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.

R4 ► -- ◄

7. HOW TO REPORT THE FSCA?

Dealers should report their FSCA via the online platform which can be accessed via the following link: https://oscar.hsa.gov.sg/oscar/

R4 ► -- ◄

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 Report

R4 ►

Following information shall be provided as part of the Notification Report (non-exhaustive):

- Reason for the FSCA
- FSCA strategy (if affected stock have been supplied in Singapore)
- Product owner's HHA
- Product owner's 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
- Product owner's FSN or other risk communication documents
- A draft of print advertisement (if applicable)

NOTE: Refer to Section 13 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.

R4 ► For FSCAs involving implantable medical devices, dealers are required to:

- Disseminate the FSN to qualified practitioners who have been supplied with or performed implantations using the FSCA affected devices
- Report the number of implantations performed in Singapore using their supplied affected devices

The FSN shall contain product owner's clinical management advice to qualified practitioners for implanted patients.

The FSN acknowledgement receipt is intended to be signed by the said qualified practitioner. In cases where the qualified practitioner has left their practice, the facility where the implantation occurred shall acknowledge receipt of the FSN on their behalf. Other recipients of the FSN should include the procurement department of the healthcare facility. ◄

In cases where the medical devices affected by the FSCA have not been supplied in Singapore, this shall be R3.6 ► indicated correctly as part of 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 notice.

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 *Act*.

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

R4 ► 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.

Following information shall be provided as part of the Follow-Up or Final Report (non-exhaustive):

- Product owner's CAPA to reduce likelihood of recurrence of device issue

- Product owner's CAPA effectiveness/validation
- Declaration letter on dealer's letterhead stating the completion of field correction and dissemination of FSN/DHCPL to affected healthcare professionals where applicable, for affected consignees in Singapore (Refer to **ANNEX 1**)

  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 FSN or "Dear Healthcare Professional" Letter (DHCPL) by the local affected consignees (*when requested*)
- For recalls, destructions certificates or airway or shipment bill of return of recalled devices to the product owner (*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.

R3.6 ► In certain 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

Following information shall be provided as part of the Notification Report (non-exhaustive):

- 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 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 deem necessary. R3.6 ► Such information, when requested, shall be submitted within the deadline stated in the Authority's Notice. ◄

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. R4 ►--◄ These instructions would be stated in the FSCA Acknowledgement Notices.

The contents of the R4 ►--◄ 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 "DEAR HEALTHCARE PROFESSIONAL" LETTER (DHCPL)

For situations where a DHCPL is deemed necessary by HSA for dissemination to qualified practitioners who have been supplied with FSCA affected devices, dealer shall submit a draft DHCPL upon request. These instructions will be stated in the FSCA Acknowledgement Notices.

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.

All qualified practitioners who have been supplied or performed treatment using the devices affected by the FSCA shall receive a copy of the DHCPL. 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 procedure 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.

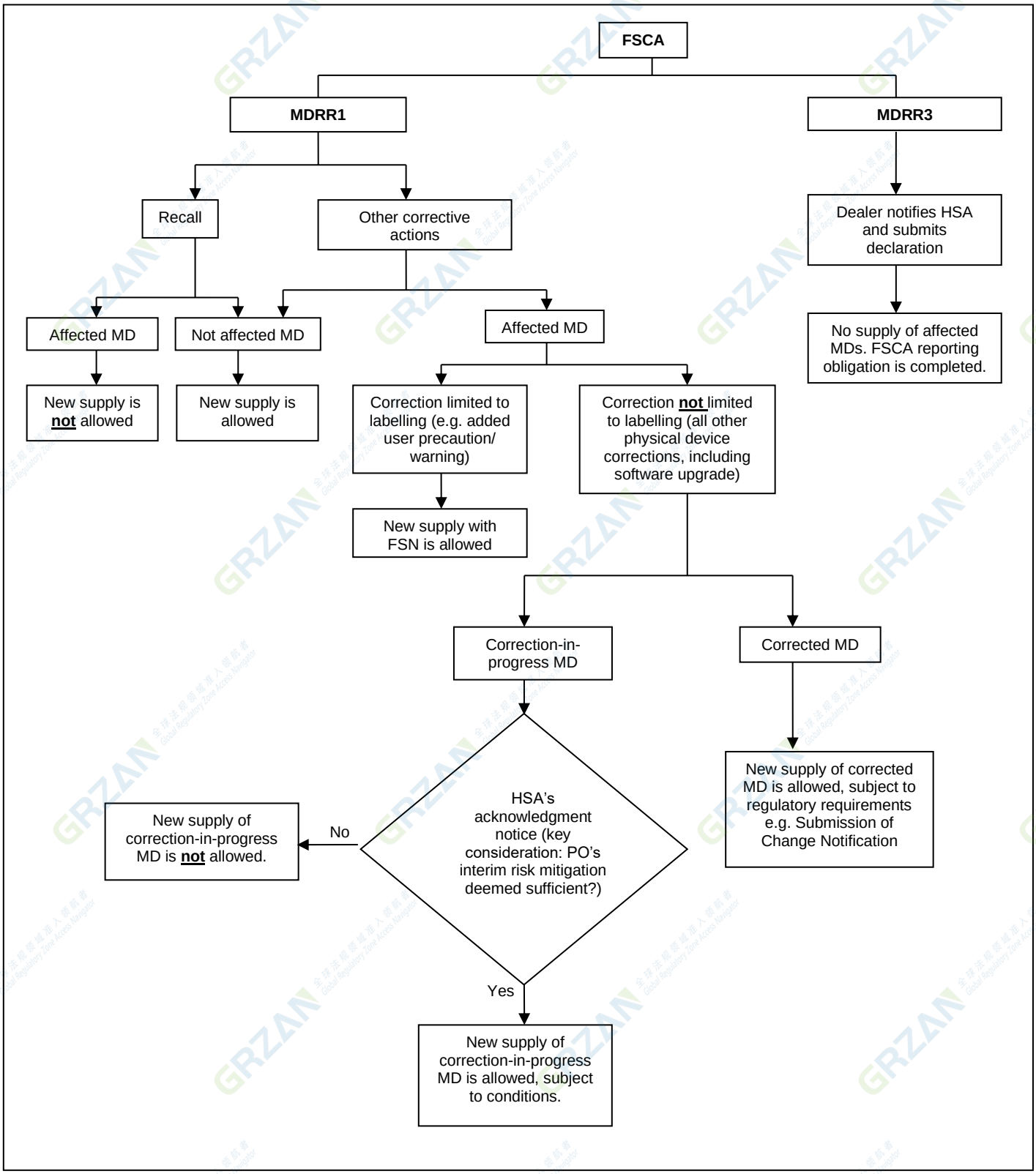
NOTE: Acknowledgement of the DHCPL constitutes a confirmation that the qualified practitioner involved has received a copy of the DHCPL or other risk communication associated with the FSCA. This is a form of effectiveness check that the Authority performs. FSN acknowledgement receipts will not be requested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

11. RISK MANAGEMENT PROCESS FOR SUPPLY OF MEDICAL DEVICES

R4 ►--◄

Based on the corrective action intended by product owner, medical devices affected by MDRR1 FSCAs can be divided into two categories: (1) recalls, and (2) other corrective actions.

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



R4 ► For recalls, the dealer shall ensure that the affected devices recalled from the field are quarantined / disposed. New supply of devices affected by recall is not permitted. ◄
R4 ►--◄

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 Authority concurs that the product owner's interim risk mitigation measures are sufficient, new supply of correction-in-progress medical devices may be permitted, subject to conditions. Conditions that may be issued as part of the Authority's Notice include ensuring correction-in-progress medical devices 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.

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 *Act*.

R4 ► For any FSCA, including those where correction is limited to labelling, Authority reserves its right to instruct additional measures where it deems necessary. ◄

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 FSN ON HSA WEBSITE

Safety communications of FSCAs reported to the Authority are publicly accessible as 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 *Act*. 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.

R3.6 ►

NOTE: The dealers conducting the FSCA shall take responsibility for the information contained in their FSN submitted to the authority and verify that any sensitive or confidential information has been removed from the copy of the notice for dissemination. The FSN will be published on the authority's website as-is based on the copy submitted by the dealer. The Authority will not be responsible for the contents of the FSN. ◄

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

[To be printed on dealer letterhead]

Declaration on FSCA Completion

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 *(For FSCA involving implantable devices, provide qualified practitioner name and relevant healthcare institution in each row)*	**Quantity**	**Status of FSCA for affected device** *(Provide reason if incomplete)*
[Provide consignee full name e.g. clinic or hospital]		*[e.g. completed]*

R4 ► For all affected consignees whose status of FSCA is listed as completed in paragraph 1:

1. We confirm that we have provided a copy of the Field Safety Notice (FSN)/ 'Dear Healthcare Professional' Letter (DHCPL) and have completed all correction activities for the aforementioned FSCA.

2. We confirm that:
☐ FSN/ DHCPLs have been disseminated to affected Healthcare Professionals (HCPs). Completed FSN/DHCPL acknowledgements have been obtained from all impacted HCPs.
(Select only if FSN/ DHCPL is required to be disseminated to HCPs.)

3. Following evidence confirming completion of field corrections for the affected devices has been collected (if applicable).

☐ Service reports for all corrected devices.
(Applicable for devices which require repair/ correction)

☐ Completed FSN acknowledgements confirming affected devices will be disposed of as per product owner's instruction.
(Applicable for recalls where consignees are instructed to dispose of affected device)

☐ Destruction certificates or airway/shipment bill for all recalled devices.
(Applicable for recalls where affected devices are to be retrieved from consignees)

4. All records will be provided to HSA upon request. ◄

5. 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 and Date]
[Full Name and Title]
[Name and address of company]

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
Health Products Regulation Group
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HSA
Health Sciences Authority