

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-04: Guidance on Medical Device Recall

Revision 2.2



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PREFACE

R2.2 ► 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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REVISION HISTORY

<u>Guidance Version (Publish Date) [3 latest revisions]</u>	<u>Revision</u>
GN-04: Revision 1 (October 2008)	R1
R2 ► GN-04: Revision 2 (September 2013)	R2
R2.1 ► GN-04: Revision 2.1 (July 2015)	R2.1
R2.2 ► GN-04: Revision 2.2 (01 November 2017)	R2.2

**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 provides guidance for handling recalls related to medical devices.

1.2. Background

Manufacturers, importers, wholesalers and registrants of medical devices are to establish and implement documented procedures:-

- to conduct effective and timely recalls;
- to ensure that defective or potentially defective medical devices are removed from the market or that measures are taken to correct the defect in an effective and timely manner;
- to ensure that any medical devices to be recalled are notified to the Authority on or before initiation of any action;
- to ensure that the Authority is made aware of their results and of the action taken to prevent recurrence of the problem.

1.3. Scope

This document is applicable to all persons who register, manufacture, import and supply by wholesale medical devices in Singapore. Persons who register, manufacture, import and supply medical devices in Singapore shall also be referred to as dealers of medical devices in this document.

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act (*Act*) and Health Products (Medical Devices) Regulations (*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.

CONSIGNEE: the person that something is delivered to.

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.

IMPORTER: for the purposes of this guidance document, an importer is a person who causes the medical device to be brought into Singapore.

MANUFACTURER: for the purposes of this guidance document, a manufacturer is a person who manufactures medical devices in Singapore.

MEDICAL DEVICE: 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.

RECALL (*as set out in the Act*): in relation to a health product, means any action taken by its manufacturer, importer, supplier or registrant to remove the health product from the market or to retrieve the health product from any person to whom it has been supplied, because the health product:

- (a) may be hazardous to health;
- (b) may fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or efficacy; or
- (c) may not meet the requirements of this Act.

REGISTRANT (*as set out in the Act*): in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the Act.

REMOVAL: means the physical removal of a medical device from the location where it was supplied to, to some other location for repair, modification, adjustment, relabelling, destruction or inspection.

WHOLESALE: for the purposes of this guidance document, a wholesaler is a person who supplies the medical device by wholesale in Singapore.

2. KEY RESPONSIBILITIES OF REGISTRANT AND DEALERS OF MEDICAL DEVICE WITH RESPECT TO PRODUCT RECALL

2.1. Notifying the Authority of the Recall

The time frame for notification of a recall is described as “before carrying out the recall”. This is satisfied by submitting as much of the recall detail as is known within 24 hours of having made the decision to recall. A preliminary report containing full information on the recall must be submitted within 24 hours from the commencement of the recall. A final report is to be submitted to the Authority within 21 days from the date of commencement of the recall.

All notification and reports are to be submitted in the manner that the Authority prescribes.

2.2. Establishing and Implementing Standard Operating Procedures (SOP) for Medical Device Recall

The registrants and dealers of medical devices are required to establish and implement documented procedures that will enable them to carry out effective and timely recalls. The recall SOP identifies all internal and external personnel involved, along with their functions and responsibilities, and sets out the channels and means of communications for executing the recall. The procedure also determines the level of priority and assigns a time frame for completion of the recall. The written recall procedure guides the development of the recall strategy. All staff involved in a medical device recall should be trained in the procedures and have access to a copy of the company’s SOP. The possible elements that could be included in a recall SOP is outlined in Annex 1.

3. RECALL STRATEGY

The recall strategy is a detailed plan for implementing a company's recall procedure in a specific case. The recall strategy will address the following elements below, regarding the conduct of the recall.

3.1. Depth of Recall

Depending on the medical device's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:-

- consumer or user level;
- retail level;
- wholesale level.

3.2. Recall Communications

Recall communications refers to the communications sent to each of its consignees notifying them of the recall and the actions required of them. The registrant and dealers of medical devices are responsible for promptly notifying each of its consignees about the recall. A guideline on the elements that should be present in a recall communication is in Annex 2.

NOTE:

Any comments and descriptions that attempt to:-

- misrepresent the level of risk in relation to the hazards associated with the medical device;
 - advertise medical devices or services;
- should be omitted.

3.3. Effectiveness checks

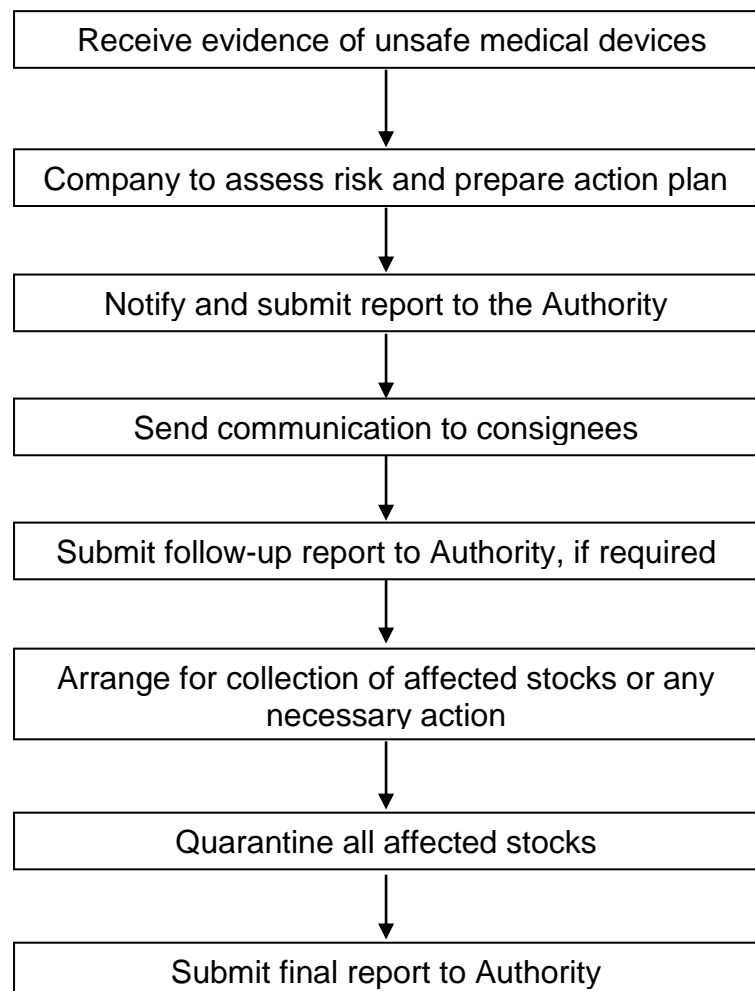
The firm initiating the recall should verify that consignees have received notification about the recall and have taken appropriate action and perform effectiveness checks. The firm initiating the recall may conduct effectiveness checks through personal visits, telephone calls, facsimiles, letters or a combination of various means.

3.4. Stock Control

The firm initiating the recall is responsible for ensuring that the medical device returned to it is properly identified and isolated until a decision has been made with approval from Authority on its eventual fate. Such a decision may include disposal of medical devices, return of medical devices to the product owner or correction of medical devices. The recalled medical device must not be put back on the market unless the Authority gives authorisation.

ANNEX 1**ELEMENTS OF A RECALL SOP**

The manufacturer, importer, wholesaler and registrant will have roles in each of the elements to a varying degree.



ANNEX 2**ELEMENTS OF RECALL COMMUNICATION TO CONSIGNEES**

The recall notice sent to all consignees notifying them of the recall should include the following:-

A. Company Particulars

- name of company
- name of contact person(s)
- contact number(s) / hotline(s) for enquiry
- fax number
- contact email address
- address

B. Product Description

- medical device name
- model name / number
- lot / Batch numbers or serial numbers
- name of product owner
- country of manufacture
- other details to enable immediate and accurate identification of the medical device that is subject to recall

C. Hazards Associated with the Medical device

- reasons for the recall
- nature and cause of the medical device defect
- 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

- any possible risks to patients associated with previous use of affected medical devices

NOTE Any comments and descriptions that attempt to play down the level of risk in an inappropriate manner should be omitted.

D. Actions to be Taken

Examples of actions that may be taken:-

- identify and quarantine the medical device
- cease the use of the medical device immediately
- cease the sale /distribution of the medical device immediately
- method of recovery, disposal or modification of the medical device
- recommended patient follow up
- return confirmation form to the product owner if an action is required. (e.g. return of medical devices)

E. Other Details

- a request to pass the recall notice to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period
- date of recall letter

NOTE Any comments and descriptions that attempt to advertise medical devices or services should be omitted.

HEALTH SCIENCES AUTHORITY

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