HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

September 2023

MEDICAL DEVICE GUIDANCE

GN-07: Guidance on Complaint Handling of Medical Devices

Revision 3

HSA Health Sciences Authority

CONTENTS

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

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
GN-07: Revision 1 (October 2008)	R1
R2 ►GN-07: Revision 2 (September 2013)	R2
R2.1 ►GN-07: Revision 2.1 (July 2015)	R2.1
R2.2 ►GN-07: Revision 2.2 (01 November 2017)	R2.2
GN-07: Revision 2.2 (01 November 2022) – Reviewed: Remains valid	R2.2
R3 ► GN-07: Revision 3 (08 September 2023)	R3

**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 of complaints related to medical devices.

1.2. Background

An effective complaint handling system is an important part of any quality system. Any complaint received on a medical device should be evaluated and if necessary, thoroughly investigated and analysed, and corrective actions should be taken. The results of the evaluation should lead to a conclusion regarding whether the complaint was valid, the causes of the complaint, and what actions were necessary to prevent further occurrences.

Manufacturers, importers, wholesalers and registrants of medical devices are to:-

- maintain records of complaint reports and of actions taken in response to these reports, and produce such records for inspection by the Authority or an enforcement officer as and when required; and
- establish and implement documented procedures to conduct effective and timely investigations of reported problems.

1.3. Scope

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

Complaints concerning death or serious injuries should be reported to the Authority in accordance to mandatory reporting timelines stipulated in the Health Products (Medical Devices) Regulations 2010 (*Regulations*). Please refer to GN-05 Guidance on Reporting of Adverse Events for Medical Devices.

R3 ► Note: Medical device dealers should encourage feedback from all users, including healthcare professionals, patients and consumers, to establish a comprehensive and effective post-market surveillance system. The analysis and trending of feedback could lead to invaluable insights and improve medical device safety. ◄

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act (*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.

CUSTOMER COMPLAINT[1]: any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

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.

[1] ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes (Terms and definitions 3.4)

2. MAINTENANCE OF RECORDS

Under the *Regulations*, manufacturers, importers, wholesalers and registrant of medical devices must maintain records of complaints related to the medical devices.

The records on complaints related to a medical device may include the following information:-

- the device brand name, licence number, model/catalogue number or bar code, control/serial/lot number and any other means of identification of the device;
- the name(s) and address(es) of the manufacturer, importer, wholesaler and/or registrant;
- records pertaining to the problem investigation.

All actions taken by the manufacturer, importer, wholesaler and registrant in response to the problems and complaints must be kept on record. These actions include any communications with the reporter/complainant, the evaluation of the problem/complaint, and any steps taken to correct the problem or prevent the recurrence of the problem. Such steps might include increased post-market surveillance of the medical device, corrective and preventive action with respect to the design and manufacture of the medical device, or product recall.

Attention should also be given to identifying the development of patterns or trends in problems with medical devices. The report of an isolated incident would assume much greater significance if other similar occurrences were reported.

3. COMPLAINT HANDLING PROCEDURE

Manufacturers, importers, wholesalers and registrants should have in place a written procedure for complaint handling that outlines the steps to be taken once a complaint report is received. The procedure should identify the personnel involved, and describe their functions and responsibilities.

In addition, the procedure should explain how to maintain records of the complaint reports, and where appropriate, how to assess these records and a reasonable time frame for completion of the investigation.

The procedure may contain the following:-

- determination of whether there is a health hazard associated with the medical device;
- determination of whether the medical device fails to conform to any claim made by the manufacturer, importer, wholesaler or registrant relating to its effectiveness, benefits, performance characteristics or safety;
- determination of whether the medical device fails to meet any legislative requirements;
- determination of the most appropriate preventive/corrective action; and
- justification when no action is taken, for example, in the case of receiving an unfounded or invalid complaint.

4. RETENTION OF COMPLAINT RECORDS

Complaint records maintained with respect to a medical device should be retained for a period of five years on top of the projected useful life of the medical device as determined by the product owner. For example, if the projected useful life of the medical device is one year, the complaint records should be kept for six years.

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