HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

May 2022

MEDICAL DEVICE GUIDANCE

GN-09: Guidance on the Component Elements of a Dear Healthcare Professional Letter

Revision 3.6

HSA Health Sciences Authority

CONTENTS

PREFACE

R3.2 ►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. ◄

REVISION HISTORY

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
GN-09: Revision 1 (October 2008)	R1
R2 ►GN-09: Revision 2 (September 2013)	R2
R2.1►GN-09: Revision 2.1 (July 2015)	R2.1
R3 ►GN-09: Revision 3 (April 2016)	R3
R3.1►GN-09: Revision 3.1 (March 2017)	R3.1
R3.2►GN-09: Revision 3.2 (01 November 2017)	R3.2
R3.3►GN-09: Revision 3.3 (21 August 2018)	R3.3
R3.4►GN-09: Revision 3.4 (03 October 2018)	R3.4
R3.5►GN-09: Revision 3.5 (01 August 2019)	R3.5
R3.6►GN-09: Revision 3.6 (09 May 2022)	R3.6

**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 drafting of “Dear Healthcare Professional” letters or its equivalent.

1.2. Background

In the interest of public health and safety, there will be occasions whereby persons who register, manufacture, import and supply by wholesale medical devices (hereinafter referred to as dealers of medical devices) may need to provide new or additional information about medical devices to healthcare practitioners.

A “Dear Healthcare Professional” letter is an integral tool of any effective post market vigilance system. Dealers of medical devices are expected to disseminate and describe important information about the use of medical devices they have marketed in Singapore.

The risks associated with deficiencies in “Dear Healthcare Professional” letters, which include delays in dissemination, inaccurate information, vague information and omitted (intentional or otherwise) material information, can range from little or no risk to patients and users to significant potential risks inherent in continued incorrect medical device use.

1.3. Scope

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

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act (*Act*) or Health Products (Medical Devices) Regulations 2010 (*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.

"DEAR HEALTHCARE PROFESSIONAL" LETTER: A letter drafted by dealers of medical devices addressed to doctors, pharmacists, and healthcare professionals regarding important new medical device issues, e.g., new warnings, other safety information, or other important changes to the prescribing information (labelling). In essence, it is commonly issued to communicate risk to medical device users, typically in response to an adverse event or to provide additional information to enable safer and/or effective use of medical device. Such letters may also be known as "Dear Doctor" letters.

2. COMPONENT ELEMENTS OF A "DEAR HEALTHCARE PROFESSIONAL" LETTER

Refer to **ANNEX 1** for the format of a "Dear Healthcare Professional" letter.

The following components are required to be included in a "Dear Healthcare Professional" letter:

2.1. Name of product owner

The product owner is the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

2.2. Name & Contact Details of the Dealer

A dealer is any natural or legal person established in Singapore who, explicitly designated by the product owner, acts on behalf of the product owner to fulfill regulatory obligations.

In cases where the product owner is based outside of Singapore, the Authority has to be able to contact an entity or person who is based within Singapore, and who has been appointed by the product owner to act on his behalf.

Contact information of the product owner or dealer should be provided to allow recipients to obtain any additional information.

2.3. Affected Medical Device Proprietary Name

Medical Device Proprietary Name is the name of the medical device as it appears on the medical device label.

2.4. Affected Device Intended Use and Indications

This paragraph should contain the statement of intended use and any indications relevant to the adverse event or device malfunction or failure. In addition, it should contain relevant information on the device affected by the issue (e.g. device family or models affected, batch number).

2.5. Subject Matter of the Letter

Association of [Medical Device Proprietary Name] with [specific adverse event].

2.6. Problem Identified & Description of Health Risk

This paragraph should contain a description of the health risk and any problems identified thus far. For example, it can contain:-

- any adverse events reported;
- their seriousness (e.g., hospitalisation, transplantation, fatality, etc);
- the rationale for suspecting a causal relationship or causative factor (e.g. features that are compromised by the device failure, how device failure would manifest clinically);
- whether the event is linked to an “unapproved” indication or “unapproved” condition of use;
- specify what is known about the adverse event and how likely sensitive populations within the general public (e.g., children or the elderly) are affected;

- indicate how reliable the knowledge is on which the communication is based;
- indicate whether the quality of this knowledge is expected to improve (e.g. through further research) and who is responsible for improving it;
- provide a qualitative description of the uncertainties that may exist in the base of knowledge from which the content of the communication is drawn. Indicate what further steps may reduce these uncertainties;
- provide a qualitative and quantitative description of the estimates of probability; and
- the number of events of interest reported domestically and internationally with estimations of patient exposure.

NOTE *This is not an exhaustive list.*

2.7. Suggested Actions, Advisory & Recommendations

This paragraph recommends actions to be taken, and should provide justifications (if any) for these recommendations:-

- highlight contraindications relevant to the adverse event(s);
- reinforce warnings relevant to the adverse event(s), (e.g., comprehensive list of signs, symptoms, laboratory findings, clinical outcome, laboratory monitoring, risk factors);
- provide an extended list of possible known adverse reactions to be expected or likely to occur;
- provide information for the consumer (e.g., description of risk and possible consequences, warnings regarding prodromal[1] symptoms);
- indicate what is thought to be an acceptable level of risk for the issue described in the communication. Provide a justification for this acceptable level; and
- provide a clear description of the actions taken to mitigate the risk. Provide a compelling justification for the action that was taken;

[1] An early symptom indicating the onset of an attack or a disease

- provide details on any ongoing or pending field safety corrective action(s) (if any), as well as issues (if any) related to modification, replacement, medical device update, warranty, etc.

Generally, this paragraph should include additional detailed instructions on how to use the current disseminated safety or therapeutic effectiveness information.

2.8. Signatory for the Letter

The letter should be dated and should contain the name and designation of the signatory.

ANNEX 1

"Dear Healthcare Professional" Letter Format

[To be printed on dealer's letterhead]

[Date]

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

[Subject Matter of the Letter]

[Dealer's name] is issuing the letter to inform…

Include:

- *Introduction of safety update or device problem (e.g. device malfunction or failure)*
- *Concise description of affected device name, model/lot/batch/serial number identified*

Background/Description of Problem

Include:

- *Brief product description or device intended use*
- *Factual statement explaining the reason of FSCA, including description of safety update or device problem*
- *Description of hazard and health risk associated to the device problem, where appropriate include, the severity and likelihood of the problem*

Advisory to Healthcare Professionals

Healthcare professionals are advised to do the following:

Include patient management advice and/or recommended actions to be taken to manage patients previously implanted or to be implanted with the affected device

Reporting of Adverse Event

The Health Sciences Authority has been notified of this issue. Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to *[dealer contact person's name* R3.6 ► *and contact information* ◄*].* Alternatively, healthcare professionals may report the adverse events to the Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online at R3.6 ► www.hsa.gov.sg/adverse-events ◄. Events that are reported to *[dealer's name]* will be investigated and subsequently reported to HSA.

Yours Sincerely,
[Signature]
[Full name & Title]
[Name and address of company]

Possible Attachments:

a) Photography image of affected device or device defect
b) FAQs
c) Acknowledgement receipts of DHCPL
d) Recall forms

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
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