HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

OCTOBER 2008

MEDICAL DEVICE GUIDANCE

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

Revision 1

HSA
Health Sciences Authority

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. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

CONTACT INFORMATION

For further information, please contact:

Medical Device Branch
Therapeutic Products Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667

Fax: (65) 6478 9028
Email: hsa_md_info@hsa.gov.sg
Website: www.hsa.gov.sg

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 updated 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 supply by wholesale medical devices in Singapore.

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act 2007 (*Act*) or 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.

"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 an update on safer use of medical device. Such letters may also be known as "Dear Doctor" letters.

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

It is proposed that the following components 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 Registrant

A registrant 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 registrant 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. In addition, it should contain relevant information on the device family or models affected, batch number, etc.

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., pharmacodynamic mechanism, temporal relationship, etc);
- 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 & 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;
- 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.

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

2.8. Signatory for the Letter

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

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Officers:

Mr Cai Yiting
Regulatory Specialist

Mr Sanjay S Kumar
Regulatory Specialist

Medical Device Branch
Therapeutic Products Division
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
T: 6866 3560
F: 6478 9028

HSA
Health Sciences Authority