Description of Current Risk Communication Documents for Marketed Health Products for Human Use

GUIDANCE DOCUMENT

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. *We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.*

Published by authority of the Minister of Health.

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Lignes directrices – Description des documents actuels de communication des risques concernant les produits de santé commercialisés destinés aux humains.

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FOREWORD

Guidance documents are meant to provide assistance to industry and stakeholders on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

ACKNOWLEDGEMENT

The contents of sections 1 and 3 of this guidance document are based in large part on the European Commission (EC) publication "*Rules Governing Medicinal Products in the European Union*" (final January 2007), Volume 9A, PART IV, Section 2 (*"Direct Healthcare Professional Communications*"). Health Canada gratefully acknowledges the EC for this background information.

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Caveat: This document serves as a guide to stakeholders. In the interest of public health, Health Canada reserves the right to communicate safety-related information with the risk communication document of its choice. A non-exhaustive list of possible considerations for the issuance of risk communication documents for health products is provided in this document. Not all factors considered need to be met for the issuance of a risk communication document.

1. Introduction

Risk communication is an important element of any risk management program, which involves identifying, assessing, understanding, acting on, and communicating risk issues to support better decision making. Within the public health field, risk communication may be defined as the development and dissemination of information concerning potential or existing health risks to enable patients and their healthcare professionals to make better-informed decisions about their health.

Building on the principles established in Health Canada's *Strategic Risk Communications Framework*[1]*,* which emphasizes a strategic, systematic approach to formulating and implementing effective risk communications, this guidance document serves to describe the current risk communication documents used as well as situations where Health Canada and/or Market Authorization Holders (MAH) consider the development and dissemination of risk communication documents regarding health products marketed in Canada. This document is intended to be used as a complement to the *Guidance Document for Industry: Issuance of Health Professional Communications (HPCs) and Public Communications (PCs) by Market Authorization Holders*[2] to operationalize the guiding principles and the general process of risk communication identified in the *Framework*.

It should be noted that Health Canada will continue to evaluate and enhance the effectiveness of the various methods used to communicate health risks, including the mechanisms described in this guidance. It is Health Canada's intention to update this guidance as appropriate, to reflect any substantial modifications to risk communications processes as they arise. This constitutes an important step forward and will serve as a basis to continue further discussions.

In this guidance document, the terms "MAH" and "industry" are used interchangeably.

This guidance document is primarily intended for MAH and health professionals. Consumers, patients, and other interested stakeholders (e.g., associations, professional licensing bodies, and academia) may also benefit because of its public availability on Health Canada's MedEffect™ Canada Web site.

Section 1 outlines the scope, application and key principles. Section 2 presents key stakeholders, including those issuing and receiving the risk communication documents. Section 3 outlines general considerations for issuing risk communication documents. Section 4 presents

an overview of how to use this guidance document and how the risk communication tools are classified based on the urgency of communication[3]. Finally, section 5 provides information on the considerations for issuance of each risk communication document.

A list of acronyms and useful definitions are available at the end of the document.

1.1 Scope and Application

This guidance document provides information on the considerations for issuing one or several of the current thirteen (13) risk communication documents (section 5) regarding health products available on the Canadian market and that fall under the regulatory oversight of the Health Products and Food Branch.

This document is meant to reflect current practices. It is not intended to describe the regulatory decision making process for the issuance of risk communication documents.

Providing information about an emerging health product safety issue does not necessarily mean that Health Canada has concluded there is a causal relationship between the health product and the adverse reactions described. Risk communications are not intended as medical advice, but rather to provide healthcare professionals and consumers with the most current information to enable them to make informed decisions on the health product at issue. In order to understand the implications of this information to their health and before making modifications to the way the health product is used, it is important that consumers consult with their doctor or healthcare professional.

Some of the risk communication documents discussed herein could also be issued for products other than marketed health products for human use (e.g., consumer products, foods and veterinary drugs), but this document will only address the application to marketed health products for human use.

1.2 Key Principles

The following key principles should be considered for risk communications on marketed health products for human use destined for the public and for health professionals, including hospitals.

- The overriding principle should be to ensure that the right message is delivered to the right persons at the right time.
- Provision of objective information about the safe and effective use of marketed health products supports their appropriate use and must be considered as a public health responsibility shared by industry, Health Canada, healthcare professionals, patients, consumers, and provincial licensing authorities.
- Communication of such information needs to be considered throughout the risk management process.

- It is essential that such information is communicated to health professionals and relevant partners, including patient and health professional associations and licensing bodies, and Market Authorization Holders (MAH).
- In principle, new or emerging health product safety information should be brought to the attention of health professionals before the general public, in order to enable health professionals to take action and respond to patients adequately and promptly. The important function of health professionals in disseminating such information to patients and the general public is recognized and should be supported.
- Communications on safe and effective use of marketed health products authorized in Canada require:
    - co-operation of all partners;
    - co-ordination between relevant partners, within and, if possible, outside of Canada;
    - a strategy, which meets the requirements resulting from the urgency to communicate and the expected public health impact of the information.

2. Key Stakeholders

2.1 Lead for Issuance

Depending on the risk communication document, the lead for issuance will be:

- Health Canada; and/or
- Market Authorization Holders (MAH)

Nine (9) of the thirteen (13) current risk communication documents are issued by Health Canada. Four (4) are issued by MAH.

The MAH has a responsibility to communicate new safety information in an effective and timely manner. MAH should engage in discussions with Health Canada early in the process of developing risk communication documents as this facilitates a consistent approach to risk communication strategies and ensures that information communicated to health professionals and the public is as accurate and complete as possible. For the full description of industry issued Health Professional Communications and Public Communications, their development and use, please, refer to the *Guidance for Industry - Issuance of Health Professional Communications and Public Communications by Market Authorization Holders* [2] .

Lead for Issuance	
Health Canada	**MAH (i.e., Industry)**
• Health Canada Public Warning *(PW - document 1)* • Health Canada Public Advisory *(PA - document 2*) • Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 3)* • Health Canada Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 4)* • Health Canada Foreign Product Alert (*FPA - document 9*) • Health Canada Information Update (*IU - document 10*) • Canadian Adverse Reaction Newsletter (*CARN - document 11*) - publication • It's Your Health (*IYH - document 12*) - publication • Fact Sheets and Backgrounders (*document 13*)	• Industry Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 5*) • Industry Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 6)* • Industry Issued Public Communication (*MAH-PC - document 7*) • Health Product Recall Notice (*with Type I or Type II Health Hazard - document 8*)

2.2 Target Audiences

Risk communication documents can be targeted to two audiences:

- The public
- Health professionals and hospitals

2.2.1 Communications Intended for the Public

Eight (8) of the thirteen (13) current risk communication documents are primarily intended for the public.

Risk Communication Documents Intended for the Public
• Health Canada Public Warning (*PW - document 1*) • Health Canada Public Advisory (*PA - document 2*) • Industry Issued Public Communication (*MAH-PC - document 7*) • Health Product Recall Notice (*with Type I or Type II Health Hazard - document 8*) • Health Canada Foreign Product Alert (*FPA - document 9*) • Health Canada Information Update (*IU - document 10*) • It's Your Health (*IYH - document 12*) - publication • Fact Sheets and Backgrounders (*document 13)*

An Industry Issued Public Communication *(MAH-PC - document 7)* should accompany the issuance of a corresponding Industry Issued *HPC-DHCPL - document 5*. The same should apply to an Industry Issued *HPC-NtoH - document 6*, unless a Health Canada Public Advisory *(PA - document 2)* or a Health Canada Public Warning *(PW - document 1)* has been or is planned to be issued. A Public Communication is the plain language version of a Health Professional Communication on the same issue. Because all *DHCPL* and *NtoH* are posted on the MedEffect™ Canada Web site and available to the public, there should always be a plain language version of the document available to the public even if the product is only used in hospitals or other limited settings. A plain language version of the safety information can assist patients and their caregivers in understanding their treatment options and discussing these issues with their health professionals.

2.2.2 Communications Intended for Health Professionals and Hospitals

Five (5) of the thirteen (13) current risk communication documents are primarily intended for health professionals and hospitals. Four (4) of the documents are named Health Professional Communications *(HPC)*. There are two (2) types of *HPC*. Those targeted to health professionals *(HPC-DHCPL)* and those targeted to hospitals *(HPC-NtoH)*.

Risk Communication Documents Intended for Health Professionals and Hospitals
• Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 3*) • Health Canada Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 4)* • Industry Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 5*) • Industry Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 6*) • Canadian Adverse Reaction Newsletter (*CARN - document 11*) - publication

Issuance of a Health Canada Issued *HPC-DHCPL - document 3* or a *HPC-NtoH - document 4* should be accompanied by the issuance of a corresponding communication intended for the public, a Health Canada Public Advisory *(PA - document 2)*, or a Health Canada Public Warning - *(PW - document 1)*.

Issuance of an Industry Issued *HPC-DHCPL - document 5* or a *HPC-NtoH - document 6* should be accompanied by the issuance of a corresponding Industry Issued Public Communication *(MAH-PC - document 7)*. Because all *DHCPL* and *NtoH* are posted on the MedEffect™ Canada Web site and available to the public, there should always be a plain language version of the document available to the public even if the product is only used in hospitals or other limited settings. A plain language version of the safety information can assist patients and their caregivers in understanding their treatment options and discussing these issues with their health professionals.

An *HPC* should be used to provide safety information such as (but not limited to) changes to the product monograph or label, which impacts on the conditions of appropriate use of the health product or informs of newly identified adverse reactions. For more information regarding the considerations for the issuance of risk communications, please refer to section 3 and section 5.1.

3. General Considerations for Issuing Risk Communications

Section 5 provides a detailed description of all thirteen (13) current risk communication document types. In general, the issuance of a risk communication document should be considered when there is:

- suspension, withdrawal or recall of the marketed health product from the market for safety reasons; or
- important changes to the label or product monograph, for instance those introduced by means of an urgent safety restriction (e.g., introduction of new contraindications, warnings, reduction in the recommended dose, restriction in the indications, restriction in the availability of the health product); or
- any other situation relevant to the safe and effective use of the health product upon request of Health Canada; or
- a change in the outcome of the evaluation of the risk-benefit balance due to:
    - data, in particular from spontaneous reporting or from studies (e.g., clinical trials or epidemiological studies), indicative of a previously unknown risk or of a change in the frequency or severity of a known risk; or
    - new data on risk factors on how adverse reactions may be prevented; or
    - new data on the efficacy of a health product; or
    - evidence that the risks of a particular product are greater than those of alternatives with similar efficacy;
- availability of new recommendations for treating adverse reactions; or
- ongoing assessment of a possible significant risk, but data are insufficient at this stage to take any regulatory action (in this case, the communication will encourage close monitoring of this safety concern in clinical practice and encourage reporting, or provide information about means to minimize the potential risk); or
- need for communication of other important information, in particular where this has been or is expected to be covered by the media.

The considerations for issuance of all thirteen (13) risk communication documents are separated into primary considerations and other considerations (section 5). The consideration of these different factors requires the application of sound scientific judgement and related guidances.[2,4]

4. How to Use the Guidance Document

This section presents all risk communication documents and classifies them according to the urgency of the communication.

4.1 Urgency of Communication

In the table below, the risk communication documents are classified according to the urgency with which the risk must be communicated.

Urgency of Communication	Risk Communication Documents
High	• Health Canada Public Warning *(PW - document 1)* • Health Product Recall Notice (*with Type I Health Hazard - document 8*)
Medium	• Health Canada Public Advisory (*PA - document 2*) • Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 3*) • Health Canada Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 4*) • Industry Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 5)* • Industry Issued Health Professional Communication - Notice to Hospitals (HPC-*NtoH - document 6*) • Industry Issued Public Communication (*MAH-PC - document 7*) • Health Product Recall Notice (*with Type II Health Hazard - document 8*) • Health Canada Foreign Product Alert (*FPA - document 9*) • Health Canada Information Update (*IU - document 10*)
Low	• Canadian Adverse Reaction Newsletter (*CARN - document 11*) • It's Your Health (*IYH - document 12*) • Fact Sheets and Backgrounders (*document 13*)

4.2 Risk Communication Documents Mapping

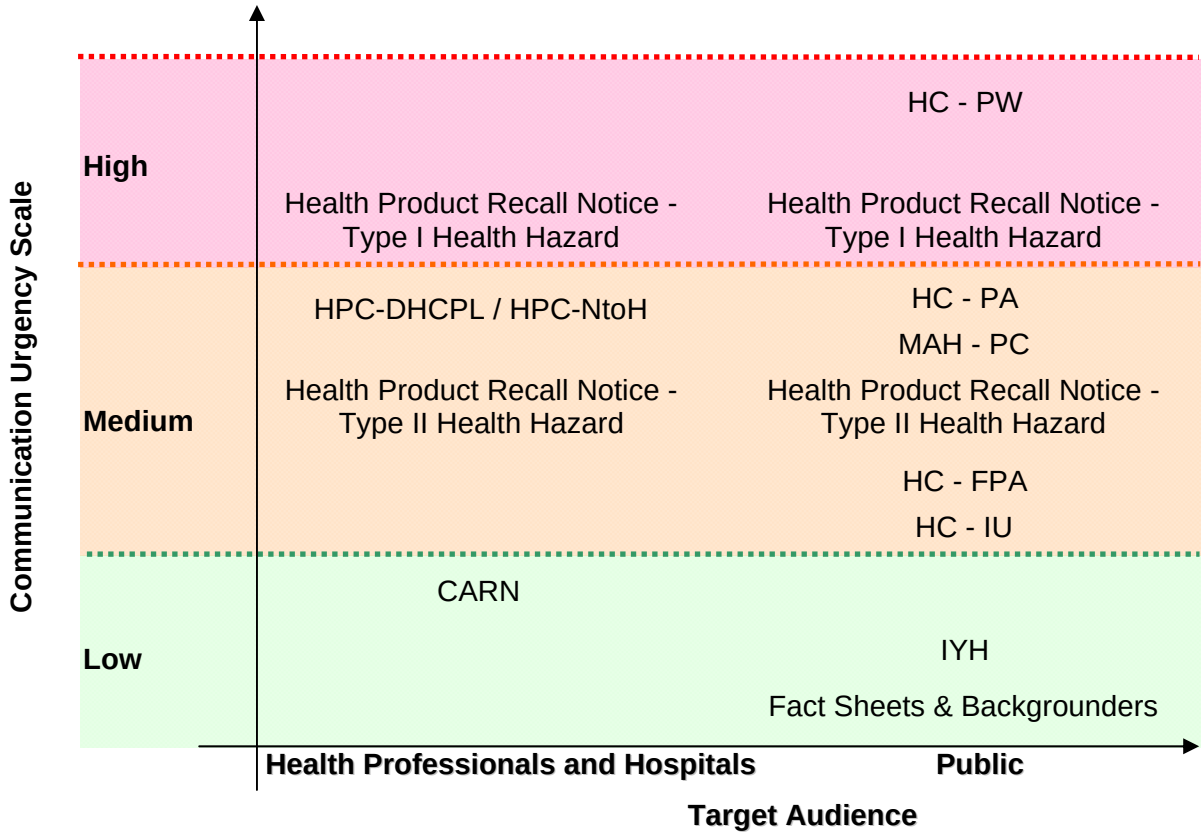
This scale is provided for ease of visual ranking and provides general guidance. Section 5 includes more detailed considerations for the issuance of various risk communication documents. The determination of urgency of risk communication is based on sound scientific judgement and application of related guidance.[3] Health Canada considers many factors in the course of evaluating an emerging health product safety concern and deciding on the urgency with which the risk must be communicated. The factors that are considered include, but are not limited to, the following:

- Availability and reliability of the data
- Magnitude of the risk
- Seriousness of the event relative to the disease being treated
- Extent of patient exposure
- Potential to prevent or mitigate the risk in the patient population

- Relevance to clinical practice
- Disproportionate impact on vulnerable populations (e.g., children or the elderly)

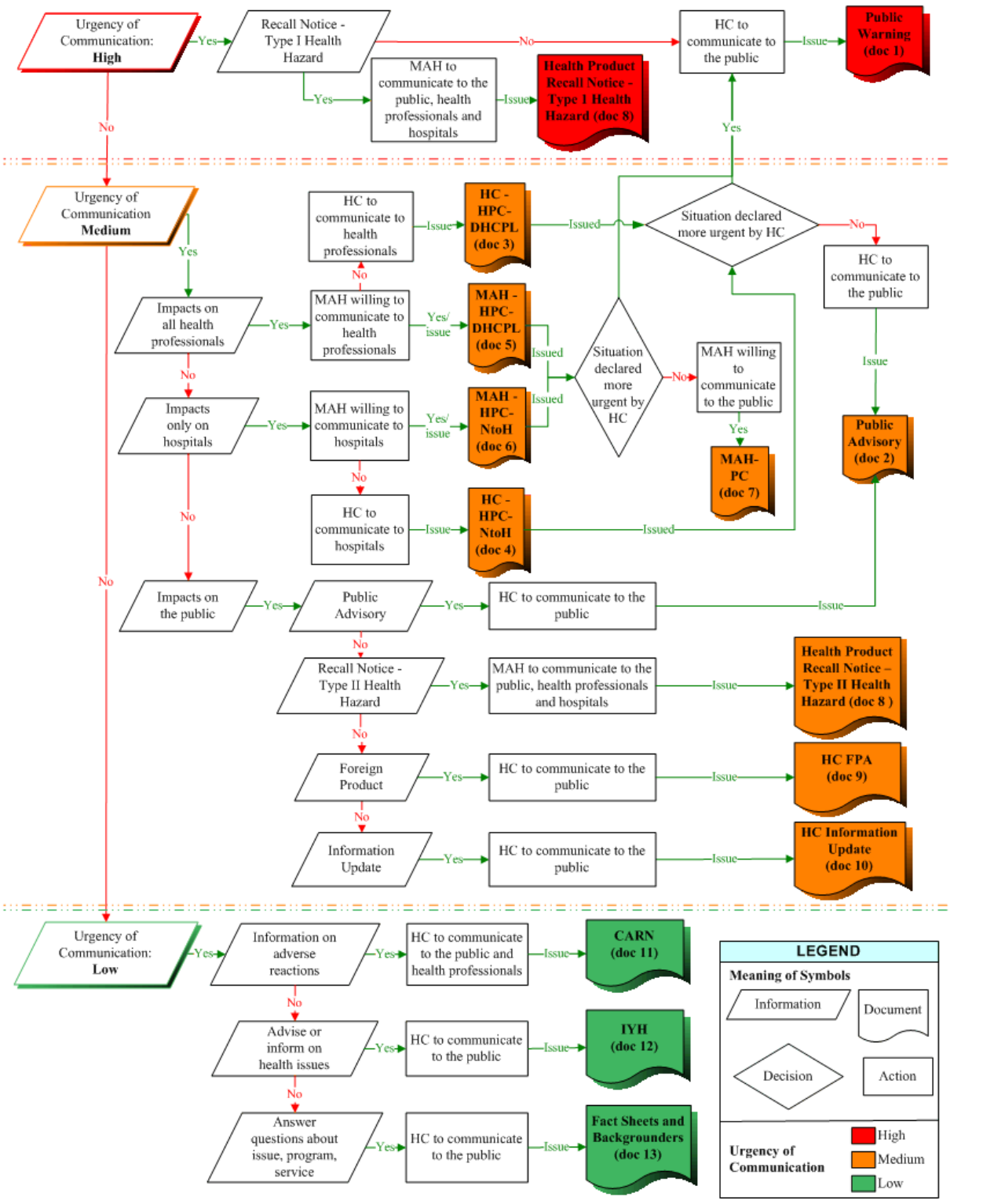
In the interest of public health, Health Canada reserves the right to communicate safety related information with the risk communication document of its choice, either individually or together as complementary tools.

Urgency of Communication



4.3 Decision Tree to Select Document Type

As previously stated, all risk communication documents have different purposes, different target audiences and may be issued by different stakeholders. This decision tree serves as general guidance. Risk communication documents apply to specific situations as outlined in section 5. In the interest of public health, Health Canada reserves the right to communicate safety related information with the risk communication document of its choice, either individually or together as complementary tools.


Urgency of Communication: High
Yes
Recall Notice - Type I Health Hazard
No
HC to communicate to the public
Issue
Public Warning (doc 1)
Yes
MAH to communicate to the public, health professionals and hospitals
Issue
Health Product Recall Notice - Type I Health Hazard (doc 8)
No
Yes
Urgency of Communication Medium
Yes
HC to communicate to health professionals
Issue
HC - HPC-DHCPL (doc 3)
Issued
Situation declared more urgent by HC
No
HC to communicate to the public
No
Impacts on all health professionals
Yes
MAH willing to communicate to health professionals
Yes/ issue
MAH - HPC-DHCPL (doc 5)
Issued
Situation declared more urgent by HC
No
MAH willing to communicate to the public
Yes
MAH-PC (doc 7)
Issue
Public Advisory (doc 2)
No
Impacts only on hospitals
Yes
MAH willing to communicate to hospitals
Yes/ issue
MAH - HPC-NtoH (doc 6)
Issued
No
HC to communicate to hospitals
Issue
HC - HPC-NtoH (doc 4)
Issued
No
Impacts on the public
Yes
Public Advisory
Yes
HC to communicate to the public
Issue
No
Recall Notice - Type II Health Hazard
Yes
MAH to communicate to the public, health professionals and hospitals
Issue
Health Product Recall Notice – Type II Health Hazard (doc 8)
No
Foreign Product
Yes
HC to communicate to the public
Issue
HC FPA (doc 9)
No
Information Update
Yes
HC to communicate to the public
Issue
HC Information Update (doc 10)
Urgency of Communication: Low
Yes
Information on adverse reactions
Yes
HC to communicate to the public and health professionals
Issue
CARN (doc 11)
No
Advise or inform on health issues
Yes
HC to communicate to the public
Issue
IYH (doc 12)
No
Answer questions about issue, program, service
Yes
HC to communicate to the public
Issue
Fact Sheets and Backgrounders (doc 13)
LEGEND
Meaning of Symbols
Information
Document
Decision
Action
Urgency of Communication
High
Medium
Low

5. Considerations for Issuance of Risk Communication Documents

Health Canada and/or Market Authorization Holders (MAH) can issue the following current thirteen (13) risk communication documents:

- Health Canada Public Warning (*PW - document 1*)
- Health Canada Public Advisory (*PA - document 2*)
- Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 3)*
- Health Canada Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 4)*
- Industry Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 5)*
- Industry Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 6)*
- Industry Issued Public Communication (*MAH-PC - document 7*)
- Health Product Recall Notice (*with Type I or Type II Health Hazard - document 8*)
- Health Canada Foreign Product Alert (*FPA - document 9*)
- Health Canada Information Update (*IU - document 10*)
- Canadian Adverse Reaction Newsletter (*CARN - document 11*)
- It's Your Health (*IYH - document 12*)
- Fact Sheets and Backgrounders (*document 13*)

The following summary table provides an overview of the risk communication documents including the urgency of risk communication, target audience, lead for issuance and the considerations for use for each risk communication document which are classified as primary and other considerations.

Risk Communication Document Number

Document Name	Name of the risk communication document.
Urgency of Risk Communication	On a High / Medium / Low scale, urgency of issuance of the risk communication document.
Target Audience	Audience to which the risk communication document is targeted.

Lead for issuance	Entity leading the issuance of the risk communication document (Health Canada or MAH).
Related requirements	Guidances as to the requirement for issuing other risk communication documents.
Scope	Marketed health products for human use.
Description	Purpose of the risk communication document.
Distribution	Means of distribution of the risk communication document.
Considerations for the Issuance of Risk Communication	Primary considerations and other considerations for issuing the risk communication document.
Other applications	Other products to which the document may apply (e.g., foods) beyond this guidance document.

5.1 Summary Tables of Considerations for Issuance of Risk Communication Documents

The tables are intended to capture a brief description of each document and to outline the primary considerations and other considerations for issuing the risk communication documents. For the full description of industry issued Health Professional Communications and Public Communications, their development and use, please, refer to the *Guidance for Industry - Issuance of Health Professional Communications and Public Communications by Market Authorization Holders.*[2]

Document 1

Document Name	Health Canada Public Warning *(PW - document 1)*
Urgency of Risk Communication	High (the most urgent risk communication document).
Target Audience	Public (consumers, patients, patient associations, the media and the general public).
Lead for issuance	Health Canada
Related requirements	A Health Canada Public Warning *(PW - document 1)* may accompany the issuance of a corresponding Health Canada issued *HPC-DHCPL* or *HPC-NtoH - documents 3 & 4* or a MAH issued *HPC- DHCPL* or *HPC-NtoH - documents 5 & 6*. It can also be issued as the only form of communication.

Scope	Marketed health products for human use.
Description	Inform about a situation in which the use of, or exposure to, a product will cause death or other serious adverse health effects.
Distribution	• Posting on the Health Canada and MedEffect™ Canada Web sites. • Distribution of the message to the media and the public through Marketwire, Health Canada's media listserv and the MedEffect™ e-Notice mailing list. • Distribution to various parties including regional offices, health professional associations, licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Urgent safety information requiring rapid communication. • The outcome, or potential risk, is very serious (e.g., Health Hazard Type I) with a reasonable probability that the use of, or exposure to, a product will cause death or other serious adverse health effects, such that the public should stop using the product or consult their physician immediately. **Other considerations (list includes but is not restricted to):** • New safety information on recurring safety issue (update) which impacts on prescriber/user utilization, or monitoring/follow-up. • Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product. • A problem with use of a medical device by a health professional or patients, or where the recommendations relate to actions by health professionals or others. • Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business). • Evidence that a product originating from another jurisdiction and not authorized for sale in Canada has entered the Canadian market (by shipments intercepted, prominent Internet advertising, report of Canadian cases of adverse reactions (ARs)).
Other applications	Consumer products, Veterinary drugs.

Document 2

Document Name	Health Canada Public Advisory *(PA - document 2)*
Urgency of Risk Communication	Medium
Target Audience	Public (consumers, patients, patient associations, the media and the general public).
Lead for issuance	Health Canada
Related requirements	A Health Canada Public Advisory *(PA - document 2)* may accompany the issuance of a corresponding Health Canada issued *HPC-DHCPL* or *HPC-NtoH - documents 3 & 4* or a MAH issued *HPC- DHCPL* or *HPC-NtoH - documents 5 & 6*. It can also be issued as the only form of communication.
Scope	Marketed health products for human use.
Description	Inform about a situation in which the use of, or exposure to, a product may cause adverse health consequences or where the probability of serious adverse health consequences is remote.
Distribution	• Posting on the Health Canada and MedEffect™ Canada Web sites. • Distribution of the message to the media and the public through Marketwire, Health Canada's media listserv and the MedEffect™ e-Notice mailing list. • Distribution to various parties including regional offices, health professional associations, licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Important safety information requiring rapid communication; • AND outcome, or potential risk, is serious but probability of severe, permanent adverse health consequences is remote (e.g., Health Hazard Type II or Type I in some circumstances); • AND/OR any of the following three conditions: o Industry refuses to issue or refuses to issue in a timely manner. o Company disagrees with or will not discuss with Health Canada content of industry-issued communication. o Multiple companies or multiple products involved (where attempts to have the companies issue shared public communication have failed or cannot be achieved in a timely manner). **Other considerations (list includes but is not restricted to):** • New safety information on recurring safety issue (update) which impacts on prescriber/user utilization, or monitoring/follow-up. • Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product. • A problem with use of a medical device by a health professional or patients, or where the recommendations relate to actions by health professionals or others. • Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business). • Evidence that a product originating from another jurisdiction and not authorized for sale in Canada has entered the Canadian market (by shipments intercepted, prominent Internet advertising, report of Canadian cases of adverse reactions (ARs)).
Other applications	Consumer products, Foods, Veterinary drugs.

Document 3

Document Name	Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 3)*[5]
Urgency of Risk Communication	Medium

Target Audience	Health professionals (e.g., physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians, and other medical and support personnel involved in the delivery of healthcare).
Lead for issuance	Health Canada
Related requirements	A Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 3)* should be accompanied by the issuance of a corresponding communication intended for the public, a Health Canada Public Advisory *(PA - document 2)* or a Health Canada Public Warning *(PW - document 1)*.
Scope	Marketed health products for human use.
Description	Inform about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product.
Distribution	• Distribution by mail-out of printed copies (fax-out under exceptional circumstances e.g., urgency to communicate the safety information). • Posting on MedEffect™ Canada and possible association Web sites following distribution. • Dissemination to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters. • Distribution to licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Distribution through MedEffect™ e-Notice mailing list • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Product withdrawals / recalls for safety reasons. • New safety (toxicity) information/analysis that indicates an increased risk of serious adverse event(s): o Especially serious unlabelled event(s). o Impacts on prescriber / user utilization or monitoring/follow-up.

	○ Involves a vulnerable user population. ○ Involves a product that is widely used, or a new safety issue that impacts on the decisions/actions of a significant number of health professionals in multiple fields. • Product fails to conform to MAH/importer claims regarding effectiveness, benefits or performance characteristics. • Serious medication incidents or near misses have occurred due to sound-alike names or look-alike packaging or labelling. • New safety (toxicity) information/analysis that introduces a shift in the benefit/risk profile of the product. • Unique properties of a new product, which could lead to inappropriate use, including use in non-authorized indications (off-label use). • Industry refuses to issue or refuses to issue in a timely manner. • Multiple companies or multiple products (where attempts to have the companies issue shared notice have failed or cannot be achieved in a timely manner). **Other considerations (list includes but is not restricted to):** • New safety information on recurring safety issue (update) which impacts on prescriber/user utilization, or monitoring/follow-up. • Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product. • A problem with use of a medical device by a health professional or where the recommendations relate to actions by health professionals or others. • Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business).
Other applications	Veterinary drugs.

Document 4

Document Name	Health Canada Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 4*)[6]
Urgency of Risk Communication	Medium

Target Audience	Canadian hospitals to the attention of Chiefs of Medical Staff, hospital pharmacies or blood banks for distribution to relevant departments (e.g., Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, Intensive Care), Long Term Care Facilities and other involved professional staff and for posting in the institution.
Lead for issuance	Health Canada
Related requirements	A Health Canada Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 4)* should be accompanied by the issuance of a corresponding communication intended for the public, a Health Canada Public Advisory *(PA - document 2)* or a Health Canada Public Warning *(PW - document 1)* when the information helps the public to make informed decisions concerning the continued use of the marketed health product in question.
Scope	Marketed health products for human use which are used in limited areas such as hospitals, nursing homes, institutions.
Description	Inform health professionals about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product which is primarily used in hospital or is limited to a select group of practitioners who exclusively practise in hospital or selected clinics.
Distribution	• Distribution by fax-out or mail-out of printed copies, with request to be posted in the institution. • Posting on MedEffect™ Canada and association Web sites following distribution. • Dissemination to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters. • Distribution to licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Distribution through MedEffect™ e-Notice mailing list. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	The following considerations apply to products used in or dispensed in hospitals, nursing homes, institutions or inpatient clinic settings. **Primary considerations (list includes but is not restricted to):**

	• Product withdrawals/recalls for safety reasons.
	• New safety (toxicity) information/analysis that indicates an increased risk of serious adverse event(s):
	  o Especially serious unlabelled event(s).
	  o Impacts on prescriber/user utilization or monitoring/follow-up.
	  o Involves a vulnerable user population.
	  o Involves a product that is widely used, or a new safety issue that impacts on the decisions/actions of a significant number of health professionals in multiple fields.
	• Product fails to conform to MAH/importer claims regarding effectiveness, benefits or performance characteristics.
	• Serious medication incidents or near misses have occurred due to sound-alike names or look-alike packaging or labelling.
	• New safety (toxicity) information/analysis that introduces a shift in the benefit/risk profile of the product.
	• Unique properties of a new product, which could lead to inappropriate use, including use in non-authorized indications (off-label use).
	• Industry refuses to issue or refuses to issue in a timely manner.
	• Multiple companies or multiple products (where attempts to have the companies issue a shared notice have failed or cannot be achieved in a timely manner).
	Other considerations (list includes but is not restricted to):
	• New safety information on recurring safety issue (update) which impacts on prescriber / user utilization, or monitoring/follow-up.
	• Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product.
	• A problem with use of a medical device by a health professional or where the recommendations relate to actions by health professionals or others.
	• Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business).

Other applications	Foods

Document 5

Document Name	Industry Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 5)*
Urgency of Risk Communication	Medium
Target Audience	Health professionals (e.g., physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians, and other medical and support personnel involved in the delivery of healthcare).
Lead for issuance	MAH
Related requirements	Industry Issued Health Professional Communication - Dear Health Care Professional Letter *(HPC-DHCPL - document 5)* should be accompanied by the issuance of a corresponding Industry Issued Public Communication *(MAH-PC - document 7)*.
Scope	Marketed health products for human use.
Description	Inform health professionals about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product.
Distribution	• Distribution by mail-out of printed copies (fax-out under exceptional circumstances e.g., urgency to communicate the safety information). • Posting on MAH, MedEffect™ Canada, and association Web sites following distribution. • May be disseminated to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters. • Distribution to licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Distribution through MedEffect™ e-Notice mailing list. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.

Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):**
	• Product withdrawals / recalls for safety reasons.
	• New safety (toxicity) information/analysis that indicates an increased risk of serious adverse event(s):
	  o Especially serious unlabelled event(s).
	  o Impacts on prescriber / user utilization or monitoring/follow-up.
	  o Involves a vulnerable user population.
	  o Involves a product that is widely used, or a new safety issue that impacts on the decisions/actions of a significant number of health professionals in multiple fields.
	• Product fails to conform to MAH/importer claims regarding effectiveness, benefits or performance characteristics.
	• Serious medication incidents or near misses have occurred due to sound-alike names or look-alike packaging or labelling.
	• New safety (toxicity) information/analysis that introduces a shift in the benefit/risk profile of the product.
	• Unique properties of a new product, which could lead to inappropriate use, including use in non-authorized indications (off-label use).
	Other considerations (list includes but is not restricted to):
	• New safety information on recurring safety issue (update) which impacts on prescriber / user utilization, or monitoring/follow-up.
	• Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product.
	• A problem with use of a medical device by a health professional or where the recommendations relate to actions by health professionals or others.
	• Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business).

Other applications	Foods, Veterinary drugs.

Document 6

Document Name	Industry Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 6)*
Urgency of Risk Communication	Medium
Target Audience	Canadian hospitals to the attention of Chiefs of Medical Staff, hospital pharmacies or blood banks for distribution to relevant departments (e.g., Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, and Intensive Care), Long Term Care Facilities and other involved professional staff and posting in the institution.
Lead for issuance	MAH
Related requirements	Industry Issued Health Professional Communication - Notice to Hospitals *(HPC-NtoH - document 6)* should be accompanied by the issuance of a corresponding Public Communication *(MAH-PC - document 7)* when the information helps the public to make informed decisions concerning the continued use of the marketed health product in question.
Scope	Marketed health products for human use which are used in limited areas such as hospitals, nursing homes, institutions.
Description	Inform health professionals about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product which is primarily used in hospital or is limited to a select group of practitioners who exclusively practise in hospital or selected clinics.

Distribution	• Distribution by fax-out or mail-out of printed copies, with request to be posted in the institution. • Posting on MAH, MedEffect™ Canada, and association Web sites following distribution. • May be disseminated to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters. • Distribution to licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies. • Distribution through MedEffect™ e-Notice mailing list. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	The following considerations apply to products used in or dispensed in hospitals, nursing homes, institutions or inpatient clinic settings. **Primary considerations (list includes but is not restricted to):** • Product withdrawals / recalls for safety reasons. • New safety (toxicity) information/analysis that indicates an increased risk of serious adverse event(s): o Especially serious unlabelled event(s). o Impacts on prescriber / user utilization or monitoring/follow-up. o Involves a vulnerable user population. o Involves a product that is widely used, or a new safety issue that impacts on the decisions/actions of a significant number of health professionals in multiple fields. • Product fails to conform to MAH/importer claims regarding effectiveness, benefits or performance characteristics. • Serious medication incidents or near misses have occurred due to sound-alike names or look-alike packaging or labelling. • New safety (toxicity) information/analysis that introduces a shift in the benefit/risk profile of the product. • Unique properties of a new product, which could lead to inappropriate use, including use in non-authorized indications (off-

	label use). **Other considerations (list includes but is not restricted to):** • New safety information on recurring safety issue (update) which impacts on prescriber / user utilization, or monitoring/follow-up. • Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product. • A problem with use of a medical device by a health professional or where the recommendations relate to actions by health professionals or others. • Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business).
Other applications	Foods

Document 7

Document Name	Industry Issued Public Communication *(MAH-PC - document 7)*
Urgency of Risk Communication	Medium
Target Audience	Public (consumers, patients, patient associations, the media and the general public).
Lead for issuance	MAH
Related requirements	Industry Issued Public Communication *(MAH-PC - document 7)* should accompany the issuance of a corresponding Industry Issued *HPC-DHCPL - document 5* and Industry Issued *HPC-NtoH - document 6*.
Scope	Marketed health products for human use.
Description	Communicate new health safety information to the public regarding marketed health products. A *MAH-PC - document 7* is the plain-language version of an issue covered in an Industry issued *HPC-DHCPL* or *HPC-NtoH - document 5 & 6*.

Distribution	• Posting on MedEffect™ Canada Web site. • Posting on MAH Web site. • Distribution of the message to the media and the public through any agreed upon channel, including MedEffect™ e-Notice mailing list and Marketwire. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	The following considerations apply to information that needs to be communicated to the public. **Primary considerations (list includes but is not restricted to):** • Product withdrawals / recalls for safety reasons. • New safety (toxicity) information/analysis that indicates an increased risk of serious adverse event(s): o Especially serious unlabelled event(s). o Impacts on prescriber / user utilization or monitoring/follow-up. o Involves a vulnerable user population. o Involves a product that is widely used, or a new safety issue that impacts on the decisions/actions of a significant number of health professionals in multiple fields. • Product fails to conform to MAH/importer claims regarding effectiveness, benefits or performance characteristics. • Serious medication incidents or near misses have occurred due to sound-alike names or look-alike packaging or labelling. • New safety (toxicity) information/analysis that introduces a shift in the benefit/risk profile of the product. • Unique properties of a new product, which could lead to inappropriate use, including use in non-authorized indications (off-label use). • Issuance of any Industry Issued *HPC-DHCPL* or *HPC-NtoH - document 5 & 6*. • Stand alone *(MAH-PC - document 7)* important safety information requiring rapid communication to the public. • For medical devices used mostly at home (for example blood

	glucose monitors). **Other considerations (list includes but is not restricted to):** • New safety information on recurring safety issue (update) which impacts on prescriber / user utilization, or monitoring/follow-up. • Emerging safety information does not present a new safety issue but introduces a shift in the benefit-risk profile of the product. • A problem with use of a medical device by a health professional or where the recommendations relate to actions by health professionals or others. • Uncertainty whether all end-users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business).
Other applications	Veterinary drugs, foods.

Document 8

Document Name	Health Product Recall Notice (with Type I or Type II Health Hazard - *document 8*)
Urgency of Risk Communication	With Type I Health Hazard: High. With Type II Health Hazard: Medium. (refer to Health Hazard Classification in the Definitions section)
Target Audience	Health professionals (e.g., physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians, and other medical and support personnel involved in the delivery of healthcare), distributors, and the public (consumers, patients, patient associations, the media and the general public), possibly hospitals to the attention of Chiefs of Medical Staff, hospital pharmacies or blood banks for distribution to relevant departments (e.g., Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, and Intensive Care), Long Term Care Facilities and other involved professional staff and posting in the institution.
Responsibility for issuance	MAH
Related requirements	For medical devices: requirements as per sections 64 and 65 of the *Medical Devices Regulations*.[7]
Scope	Marketed health products for human use, mainly medical devices.

Description	Before or upon initiating a recall, the recalling manufacturer should notify the HPFB. Basic information required includes the name of the recalled product and, where applicable, any other means of identification, the total quantity of the recalled product, area of the distribution of the recalled product (by province and, if exported, by country) and the reason for initiating the recall (for medical devices: as per sections 64 and 65 of the *Medical Devices Regulation*).[7]
Distribution	• The HPFB Inspectorate (HPFBI) posts recalls on drugs for human use and medical devices on its Web site[8] (date of recall, MAH, health product identification, reason for recall). • Notices/advisories from companies may be posted on MedEffect™ Canada when Health Canada deems that it is important to have the detailed safety information available for everybody who may need to know it. The criteria for posting industry-issued advisories related to recalls are: o the device defect/malfunction may cause serious health problems or death; o users belong to a vulnerable group; o devices may be used in non-hospital settings (at home, in nursing homes); o high likelihood that not all users can be reached by the company (moved, lost to follow-up, lost list of clients, out of business); o public health implications. • Not all recall notices on the HPFBI Web site are posted on the MedEffect™ Canada Web site. • Not all recalls trigger an advisory. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary of advisories when an advisory is warranted.

Considerations for the Issuance of Risk Communication	Recalls are defined differently for Marketed Health Products and Medical Devices. Marketed Health Product other than a Medical Device: • Removal from further sale or use or correction of a marketed health product that: o Presents a risk to the health of consumers; or o Violates legislation administered by the HPFB. Medical Device: • Recall or correction of a medical device, or notification to its owners and users of its defectiveness or potential defectiveness, if the device: o May be hazardous to health; o May fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or o May not meet the requirements of the Act or *Medical Device Regulations*.
Other applications	Includes any product under the mandate of the Health Products and Food Branch (HPFB), with the exception of food products.

Document 9

Document Name	Health Canada Foreign Product Alert *(FPA - document 9)*
Urgency of Risk Communication	Medium
Target Audience	Public (consumers, patients, patient associations, the media and the general public).
Lead for issuance	Health Canada
Related requirements	None
Scope	Health products

Description	Web-based tool that provides general warnings about the use of products not authorized for sale in Canada and details on identified foreign products in a table format.
Distribution	• Posting within the "Advisories, Warnings and Recalls" section of the Health Canada Web site and on the MedEffect™ Canada Web site. • Distribution of a notice of Web updates to media and the public via the Health Canada media listserv and the MedEffect™ e-Notice mailing list. • Canadian Adverse Reaction Newsletter *(CARN - document 11)* summary table of health professional and consumer advisories.
Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Safety information received by Health Canada about foreign products that are not authorized for sale in Canada, which have not been found on the Canadian market, but which may have entered the country through personal importation or by purchase over the Internet. **Other considerations:** • Advisories from foreign agencies. • If evidence exists that these products are available in Canada, then a Warning or Advisory could be used as appropriate.
Other applications	None

Document 10

Document Name	Health Canada Information Update *(IU - document 10)*
Urgency of Risk Communication	Medium
Target Audience	Health professionals (e.g., physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians, and other medical and support personnel involved in the delivery of healthcare) and public (consumers, patients, patient associations, the media and the general public).
Responsibility for issuance	Health Canada

Related requirements	None
Scope	Marketed health products for human use.
Description	Web-based tool used when the nature of a communication is less urgent than for an advisory or warning.
Distribution	• When warranted, can be distributed through Marketwire, Health Canada's media listserv and the MedEffect™ e-Notice mailing list. • Posting on Health Canada and MedEffect™ Canada Web sites. • May also be distributed to various parties including regional offices, health professional associations, licensing bodies, provincial ministries of health, and foreign regulatory agencies. • Advance notification to foreign regulatory agencies on an ad hoc basis.
Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Need to inform of a risk situation where a *PW or a PA - document 1 & 2* was previously issued. • Need to state Health Canada's position on an issue. • Need to counter industry / media / public misconception. • Need to convey Health Canada's awareness of an issue and indicate that work is underway. **Other considerations:** • Small groups of people affected. • Need to expand on risk information already available through previous communication or to reinforce safety recommendations previously issued.
Other applications	Foods, consumer products, potential use outside of risk communication, Veterinary drugs.

Document 11

Document Name	Canadian Adverse Reaction Newsletter *(CARN - document 11)*
Urgency of Risk Communication	Low

Target Audience	Health professionals (e.g., physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians, and other medical and support personnel involved in the delivery of healthcare).
Responsibility for issuance	Health Canada
Related requirements	None
Scope	Marketed health products for human use.
Description	A source of adverse reaction information published quarterly, in January, April, July and October of each year. This publication informs health professionals and the public about potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk-benefit evaluations and regulatory decisions are undertaken.
Distribution	• Posting on the MedEffect™ Canada Web site. • Published within the Canadian Medical Association Journal (targets 67,000 physicians). • Distribution through a hard copy mailing list to pharmacists, naturopaths and other stakeholders (e.g., Drug Information Centres, health professional associations, MAH, other international regulatory agencies) across Canada and internationally (26,000 copies quarterly). • Advance notification to foreign regulatory agencies. • Dissemination through MedEffect™ e-Notice mailing list where the public and media are amongst the subscribers. • A summary of topics is provided to the Canadian Family Physician (CFP) and the Canadian Pharmacists Journal (CPJ), which they publish in their journals depending on availability of space. • Courtesy copy sent by fax to relevant MAH prior to publication. • Indexed in CINAHL (Cumulative Index to Nursing and Allied Health Literature) electronic database.
Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Canadian cases. • Serious adverse reactions.

	• Adverse reactions that are unexpected, unlabelled, not yet described. • Safety issue with recently marketed health product. • Public health impact and clinical relevance of safety issue. • Public risk perception of a safety issue. • Safety issues concerning specific populations (e.g., children, elderly, pregnant or nursing women, HIV/AIDS, etc.). • Emerging significant safety information. **Other considerations:** • Increased frequency of an AR (dependent on seriousness of reaction). • Clinically relevant Product Monograph changes to sensitize health professionals if not adequately addressed by another communication vehicle. • Safety concerns identified in pharmacovigilance plans or risk management plans to share findings, stimulate reporting. • Safety issues in other countries for products authorized for market in Canada. • Other safety concerns, e.g., reminder of ongoing safety issues with inappropriate use of a health product (e.g., drug abuse, misuse, off-label use, medication incidents), new health product interactions, health product defects, lack of effect (need several reports). • Suitable timing of topic publication (consideration of environmental context, sensitivities). **Additional considerations for case presentations:** • Serious unexpected adverse reaction. • Clinical relevance of safety issue, strong case report with a plausible causality. • Recent report (preferably within last 2 years of date of proposed publication). • Not a case presentation recently published for this health product (within last year of date of proposed publication - unless different reaction).
Other applications	None

Document 12

Document Name	It's Your Health (*IYH - document 12*)
Urgency of Risk Communication	Low
Target Audience	Public (consumers, patients, patient associations, the media and the general public) and special interest groups.
Responsibility for issuance	Joint publication produced by Health Canada and the Public Health Agency of Canada.
Related requirements	None
Scope	Covers a wide range of health and safety issues that affect Canadians or are of interest to them.
Description	Series of article-style fact sheets -- written in plain language, and generally 2-3 pages in length -- that cover a wide range of health and safety issues. Articles aim to advise Canadians about the benefits and risks of products, procedures and substances, as well as informing them on how to minimize their risk in relation to diseases and conditions. In addition, *IYH - document 12* contains a section describing the role(s) of Health Canada, the Public Health Agency of Canada (PHAC) and/or other Government of Canada departments/agencies in addressing the *IYH* topic covered, and includes Internet links and references to more information.
Distribution	• Published by Health Canada for the Web and for print publication. • Notice of new and recently updated articles is issued via e-mail to over 5,100 IYH subscribers. • Hard copies of the articles are also distributed as requested by organizations and through targeted conferences and fairs. • If a marketed health product is involved, a MedEffect™ e-Notice is issued. • If a marketed health product is involved, will be added to the Canadian Adverse Reaction Newsletter summary of advisories.

Considerations for the Issuance of Risk Communication	**Primary considerations (list includes but is not restricted to):** • Topic covered has long shelf life, i.e. not a rapidly evolving issue. **Other considerations:** • Timeliness / relevance of the subject matter, i.e. issue in the public spotlight or tied to a health-related awareness day / week / month. • Targeted message to Canadians at higher risk for health effects. • Reinforce to Canadians that they have a role to play in maintaining and improving their health. • Reinforce public health messages. • Clarify information or correct misinformation/myths about health and safety issues. • Inform Canadians of new regulations, policies, consultations or directions undertaken by Health Canada/PHAC.
Other applications	*IYH – document 12* does NOT provide diagnosis or treatment recommendations and should NOT be used in place of medical advice, instruction and/or treatment. Content currently includes: • Disease (prevention, information). • Environment (air, water, work). • Food (storage, safety, tips). • Lifestyle (personal products). • Medical (treatments, devices, health products). • Products (consumer, hobbies).

Document 13

Document Name	Fact Sheets and Backgrounders *(document 13)*
Urgency of Risk Communication	Low
Target Audience	Public (consumers, patients, patient associations, the media and the general public).
Responsibility for issuance	Health Canada

Related requirements	Used on a case-by-case basis, never as a stand-alone document.
Scope	Marketed health products for human use.
Description	Communication tool to provide information in a clear and concise manner. Provides information about an issue, program or service. A fact sheet is structured to answer commonly asked questions about an issue, program or service.
Distribution	• Posted on the Health Canada Web site. • Can be distributed widely to a specific audience or serve as a resource document. • May also be used as handouts at events to consistently convey program messages.
Considerations for the Issuance of Risk Communication	• General information on a significant public health issue that impacts a large number of stakeholders (insulin, influenza pandemic preparedness, blood products etc.) • Communicate risks that may exist for a class of products, or for multiple treatments that are used for one indication (e.g., Status of Terfenadine-Containing Drugs in Canada). • Could involve general issues (e.g., How Adverse Reaction Information on Health Products is Used). • Fact sheets are often prepared for products under the Notice of Compliances with Conditions (NOC/c) policy, so patients can be made aware of the lack of efficacy information and safety issues associated with these products. Often provided for medications such as HIV treatments, oncology products. • Vehicle for communicating accurate information for which there are misconceptions, misinformation, or conflicting information in the public domain.
Other applications	Consumer products, Foods, Veterinary drugs.

ACRONYMS

AE:	Adverse Event
AIDS:	Acquired Immune Deficiency Syndrome
AR:	Adverse Reaction
CARN:	Canadian Adverse Reaction Newsletter
CFP:	Canadian Family Physician
CINAHL:	Cumulative Index to Nursing and Allied Health Literature
CPJ:	Canadian Pharmacists Journal
DIN:	Drug Identification Number
DIN-HM:	Homeopathic Medicine Number
EC:	European Commission
FPA:	Health Canada Foreign Product Alert
HC:	Health Canada
HHE:	Health Hazard Evaluation
HPC:	Health Professional Communication
HPC-DHCPL:	Health Professional Communication - Dear Health Care Professional Letter
HPC-NtoH:	Health Professional Communication - Notice to Hospitals
HPFB:	Health Products and Food Branch
HPFBI:	Health Products and Food Branch Inspectorate
IYH:	It's Your Health
MAH:	Market Authorization Holders
MAH-PC:	Industry Issued Public Communication
MHPD:	Marketed Health Products Directorate
NOC/c:	Notice of Compliance with conditions
NPN:	Natural Product Number
PA:	Health Canada Public Advisory
PHAC:	Public Health Agency of Canada

DEFINITIONS

Adverse Event (AE)

An adverse event is any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product. [International Conference on Harmonisation, Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting (ICH E2D) (2003) (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/consultation/e2d_step2_etape2-eng.php)].

Adverse Reaction (AR)

An adverse reaction is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.

Canadian Adverse Reaction Newsletter *(CARN - document 11)*

The Canadian Adverse Reaction Newsletter *(CARN - document 11)* is a source of information regarding adverse reactions suspected to be associated with marketed health products. It is published quarterly, in January, April, July and October of each year. The Newsletter was launched in January 1991 and is produced by the Marketed Health Products Directorate.

Canadian Adverse Reaction Newsletter - Case presentation

The CARN case presentation outlines details of specific serious unexpected AR cases. It is intended to raise awareness and prompt additional reporting.

Fact Sheets and Backgrounders *(document 13)*

Fact Sheets and Backgrounders are communication tools that provide information about an issue, program or service in a clear and concise manner.

Health Canada Foreign Product Alert *(FPA – document 9)*

Web-based tool used to advise consumers of health risks related to foreign products not authorized for sale in Canada and not found on the Canadian marketplace.

Health Canada Information Update *(IU - document 10)*

Web-based tool used when the nature of a communication is less urgent than for an advisory or

warning.

Health Canada Public Advisory *(PA – document 2)*

This risk communication document is used to inform the public of possible serious health hazards and enable Canadians to make informed decisions concerning the continued use of marketed health products.

Health Canada Public Warning *(PW - document 1)*

This risk communication document is used in the most urgent situations when there is a high probability that the use of, or exposure to, a product will cause death or other serious adverse health effects, and the public should stop using the product or consult their physician immediately.

Health Hazard Classification

The numerical designation, i.e. Type I, II or III, assigned by Health Products and Food Branch (HPFB) to a particular product to indicate the relative degree of health hazard presented by the product. The following definitions are taken from the Health Products and Food Branch Inspectorate - Recall Policy (POL-0016) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php):

> **Type I:** a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death
>
> **Type II:** a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote, or
>
> **Type III:** a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences.

Health Products

Health products include pharmaceutical drugs (which include prescription and non-prescription pharmaceutical drugs); biologics (which include biotechnology products, therapeutic and diagnostic vaccines and fractionated blood products); radiopharmaceutical drugs; natural health products; and medical devices.

Health Products and Food Branch (HPFB)

The HPFB is mandated to take an integrated approach to the management of the risks and benefits to health related to health products and food by minimizing health risk factors to Canadians, while maximizing the safety provided by the regulatory system for health products and food; promoting conditions that enable Canadians to make healthy choices; and providing information so that they can make informed decisions about their health.

Health Product Recall Notice

With respect to a health product other than a medical device, it means a firm's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates legislation administered by the Health Products and Food Branch.

In the *Medical Devices Regulations* a recall is defined as: any action taken by the manufacturer, importer or distributor of the device that has been sold, to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device:

- may be hazardous to health;
- may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
- may not meet the requirements set in the Act or the Regulations.

Health Professional

Includes, but is not limited to, physicians, dentists, naturopaths, pharmacists, nurses, registered dieticians and other medical and support personnel involved in the delivery of health care.

Health Professional Communication (HPC)

Inform about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product to health care professionals. *HPCs* include Dear Doctor Letter or a Dear Health Professional Letter *(DHCPLs*) and Notice to Hospitals *NtoHs*.

Health Professional Communication-Dear Health Care Professional Letter *(HPC-DHCPL)*

Also known as a Dear Doctor Letter or a Dear Health Professional Letter, a *HPC-DHCPL* is used to inform health professionals about time-sensitive issues regarding the safety or effectiveness (or both) of marketed health products. It is a letter issued by the MAH containing content approved by Health Canada *(HPC-DHCPL – document 5)*, or issued by Health Canada *(HPC-DHCPL – document 3)*. For the purposes of this document, a *HPC-DHCPL* is a vehicle to disseminate safety information. This document does not apply to *HPC-DHCPL*s used for promotional purposes, which are pre-cleared by the Pharmaceutical Advertising Advisory Board and issued by MAH.

Health Professional Communication-Notice to Hospitals *(HPC-NtoH)*

A *HPC-NtoH* is a vehicle to communicate health professionals about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product which is primarily used in hospital or is limited to a select group of practitioners who exclusively practise in hospital or selected clinics. The *HPC-NtoH* can be issued either by MAH *(HPC-NtoH - document 6)* or by Health Canada *(HPC-NtoH - document 4)*.

It's Your Health (*IYH - document 12*)

It's Your Health *(IYH - document 12)* is a joint publication produced by Health Canada (HC) and the Public Health Agency of Canada (PHAC) that provides reliable information to consumers on a wide range of health and safety issues.

Market Authorization Holders (MAH)

Also referred to as Sponsor or Manufacturer, the MAH is the legal entity that holds the Notice of Compliance, the Drug Identification Number (DIN), the medical device licence number, the Natural Product Number (NPN), the Homeopathic Medicine Number (DIN-HM), the product licence number, or that has received approval to initiate clinical trials in Canada.

In this guidance document, the terms "manufacturer", "industry", "firm" and "MAH" are used interchangeably.

Marketed health products

Marketed health products include pharmaceutical drugs (which include prescription and non-prescription pharmaceutical drugs); biologics (which include biotechnology products, therapeutic and diagnostic vaccines and fractionated blood products); radiopharmaceutical drugs; natural health products; and medical devices.

Marketwire

Subscription service used to disseminate some Health Canada communication products to the major newspapers, television stations and radio stations across the country.

MedEffect™ Canada

MedEffect™ Canada is the Health Product and Food Branch's single window access to collect and disseminate new safety information about health products.

MedEffect™ e-Notice

Electronic mailing list, which distributes Health Canada's most recent publication of the Canadian Adverse Reaction Newsletter and marketed health product advisories for health professionals and the public. All members of the public can sign up to the list via the MedEffect™ Canada Web site.

Media listserv

Health Canada-maintained e-mail distribution list that provides Departmental news releases, some health advisories and warnings, and notices to the media shortly after they have been issued. All members of the public and the media can sign up for the list via the Health Canada Web site.

Medication Incident (MI)

Any preventable event that may cause or lead to an inappropriate use of the medication or patient harm while the medication is in the control of the health care professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, or procedures and systems. Such incidents include prescribing product labelling, packaging, or nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Natural Health Product

A substance set out in Schedule 1 of the *Natural Health Product Regulations* or a combination of substances in which all the health product ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 of the *Natural Health Product Regulations* or any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Natural Product Number (NPN)

An eight digit numerical code following the acronym NPN assigned to each natural health product approved to be marketed under the *Natural Health Products Regulations*.

Public

Includes Canadian consumers, patients, patient associations, the media and the general public.

Public Communication *(MAH-PC – document 7)*

A *MAH-PC - document 7* is a risk communication tool used to communicate new health safety information to consumers, patients and the general public regarding marketed health products. It is the plain language version of a health professional communication on the same issue.

Serious adverse drug reaction (Food and Drug Regulations - C.R.C., c. 870)
(http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/)

A noxious and unintended response to a drug, which occurs at any dose and requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

Serious deterioration in the state of health (Medical Devices Regulations - SOR/98-282)
(http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/)

A life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.

Footnotes:

1. A Framework for Strategic Risk Communications Within the Context of Health Canada and the PHAC's Integrated Risk Management (http://www.hc-sc.gc.ca/ahc-asc/pubs/ris-comm/index-eng.php)

2. Guidance Document for Industry: Issuance of Health Professional Communications and Public Communications by Market Authorization Holders (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2005-guid-dir_indust_hppc-cpsp/index-eng.php)

3. The determination of the urgency of risk communications is based on sound scientific judgment and application of related guidances [i.e., Guidance Document for Industry: Issuance of Health Professional Communications and Public Communications by Market Authorization Holders (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2005-guid-dir_indust_hppc-cpsp/index-eng.php) and *Recall Policy (POL-0016)* (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)].

4. Health Products and Food Branch Inspectorate - Recall Policy (POL-0016) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)

5. The Health Canada Issued *HPC-DHCPL – document 3* is not normally developed with the MAH.

6. The Health Canada Issued *HPC-NtoH – document 4* is not normally developed with the MAH.

7. Canada Gazette, Vol. 132, No 11 - May, 1998, Medical Devices Regulations, SOR/98-282, 07/05/98, sections 64 and 65 (http://canadagazette.gc.ca/partII/1998/19980527/html/sor282-e.html).

8. Drug and Medical Device Recall Listings (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/_list/index-eng.php)