Health Canada Santé Canada

July 11, 2007

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NOTICE

Draft Guidance Document - Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use

Health Canada is pleased to announce the release of the draft guidance document: *Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use.*

In Canada, when a health risk occurs with a marketed health product for human use, Health Canada or the Market Authorization Holders (MAHs) have to consider the issuance of one or more of 13 risk communication documents.

Currently, a *Guidance Document for Industry: Issuance of Health Professional Communications (HPCs) and Public Communications (PCs) by Market Authorization Holders* is available on the Health Canada Web site. This document assists MAHs in developing and disseminating HPCs and their accompanying PCs once a decision to issue these documents has been made. To complement the *Guidance Document for Industry*, Health Canada has developed a guidance document on the triggers for issuance of the 13 risk communication documents.

The draft guidance document *Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use* describes situations where Health Canada and/or the MAHs consider the development and dissemination of risk communication documents regarding health products marketed in Canada.

Should you wish to provide comments on the draft guidance document, you are requested to do so by September 30, 2007. The Marketed Health Products Directorate will consider any comments received by this date, in the finalization of the document. Your comments should be sent to:

Health Canada
Marketed Health Products Directorate
Therapeutic Effectiveness and Policy Bureau
200 Tunney's Pasture Driveway, A.L. #0701C
Ottawa, Ontario K1A 0K9
E-mail: mhpd_dpsc@hc-sc.gc.ca

Canada

Health Canada Santé Canada

DRAFT for External Consultation, June 2007

DRAFT GUIDANCE DOCUMENT

Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use

This guidance document is being distributed for comment purposes only.

Published by authority of the
Minister of Health

Draft Date	2007/06

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of 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; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre :

ÉBAUCHE DU DOCUMENT D'ORIENTATION - Éléments déclencheurs de la diffusion de documents de communication des risques concernant les produits de santé commercialisés destinés aux humains

Catalogue No.: H164-48/2007E-PDF
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The Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use can be obtained via the internet from the Website listed below:

Health Canada
Marketed Health Products Directorate
Therapeutic Effectiveness and Policy Bureau
200 Tunney's Pasture Driveway, A.L. #0701C
Ottawa, Ontario K1A 0K9
Web site: www.healthcanada.gc.ca/medeffect
E-mail: mhpd_dpsc@hc-sc.gc.ca

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 mandates and how 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 Medicines Agency (EMEA) "*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 EMEA for this background information.

European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

This Guidance Document has been prepared in collaboration with the Health Products and Food Branch Risk Communications Working Group.

Table of Contents

1 Introduction

The aim of this guidance document is to describe situations where Health Canada and/or the Market Authorization Holders (MAH) consider the development and dissemination of risk communication documents regarding health products marketed in Canada.

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 the Health 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 seriousness of risk (probability of health hazard and probability of occurrence)[1] and urgency of communication. Finally, section 5 provides information on the triggers for issuance of each risk communication document.

A list of acronyms and useful definitions are available on pages 39 to 45.

1.1 Scope and Application

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

Some of the risk communication documents discussed herein could also be issued by other organizations 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] The determination of the seriousness of risk (probability of health hazard and probability of occurrence) and 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://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html and *Recall Policy (POL-0016):* http://hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/docs/pol_0016_recall_policy-politique_retrait_ltr-doc_e.html#4

1.2 Key Principles

The following key principles should be considered for risk communications on marketed health products for human use destined to the public and to 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 information about the safe and effective use of marketed health products supports their appropriate use and must be considered as a public health responsibility.
- 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.

Lead for Issuance	
Health Canada	**MAH**
• 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 Available to the Public

Nine (9) of the thirteen (13) current risk communication documents are available to the public.

Risk Communication Documents Available to 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*) • Canadian Adverse Reaction Newsletter (*CARN - document 11*) - publication • 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.

2.2.2 Communications Intended for Health Professionals and Hospitals

Five (5) of the thirteen (13) current risk communication documents are 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
• Canadian Adverse Reaction Newsletter (*CARN - document 11*) - publication
Health Professional Communications Intended for Health Professionals
• Health Canada Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 3*) • Industry Issued Health Professional Communication - Dear Health Care Professional Letter (*HPC-DHCPL - document 5*)
Health Professional Communications Intended for Hospitals
• Health Canada Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 4*) • Industry Issued Health Professional Communication - Notice to Hospitals (*HPC-NtoH - document 6*)

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).*

An *HPC* should only be used to provide safety information, which requires an urgent communication such as 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.

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 triggers for issuance of all risk communication documents are separated into primary triggers and other considerations (see section 5). The application of these different triggers requires the application of sound scientific judgement and related guidances.[2,3]

4 How to Use the Guidance Document

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

[2] Guidance Document for Industry: Issuance of Health Professional Communications and Public Communications by Market Authorization Holders: http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html
[3] Recall Policy (POL-0016): http://hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/docs/pol_0016_recall_policy-politique_retrait_ltr-doc_e.html#4)

seriousness of the risk (probability of health hazard and probability of occurrence) and the urgency of the communication. It also outlines the decision-making process for choosing the right risk communication document based on these criteria.

4.1 Seriousness of Risk and Urgency of Communication

Risk communication documents may be classified according to various degrees of seriousness of risk (probability of health hazard and probability of occurrence) and urgency with which the risk must be communicated (urgency of communication).

In the table below, the risk communication documents are classified according to their level of urgency.

Seriousness of Risk (probability of health hazard and probability of occurrence) **and Urgency of Communication**	**Risk Communication Documents**
High	• Health Canada Public Warning (*PW - document 1*) • Health Canada Public Advisory (*PA - document 2*)* • 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*)

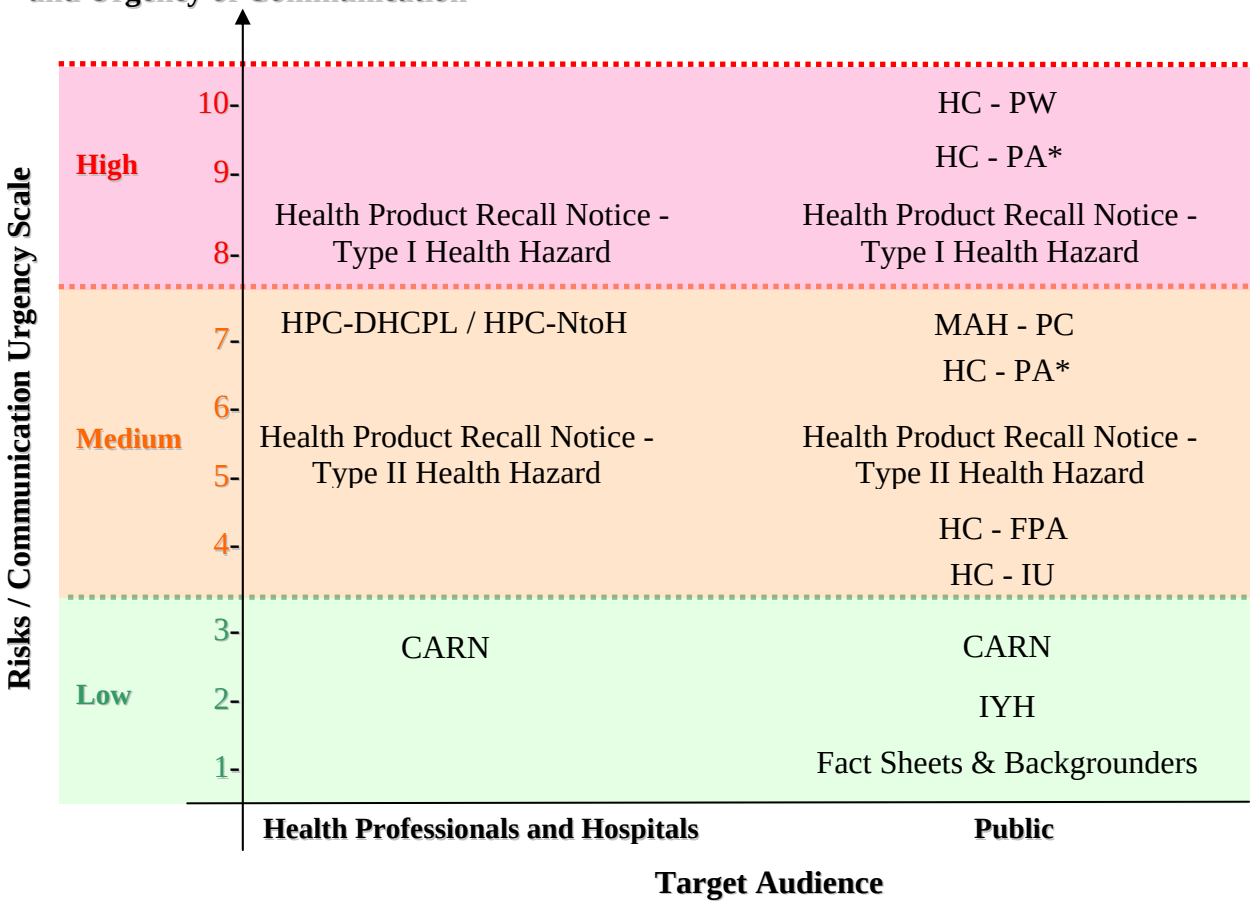
**A Health Canada Public Advisory (PA - document 2) may be issued in high or medium risk situations, depending on circumstances.*

4.2 Risk Communication Documents Mapping

This scale is provided for ease of visual ranking and provides general guidance. Section 5 includes more detailed triggers for the issuance of various risk communication documents. The determination of the seriousness of risk (probability of health hazard and probability of occurrence) and urgency of risk communication is based on sound scientific judgement and application of related guidance.[4,5] 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.

[4] The Guidance Document for Industry can be found at: http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html
[5] Recall Policy (POL-0016): http://hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/docs/pol_0016_recall_policy-politique_retrait_ltr-doc_e.html#4)

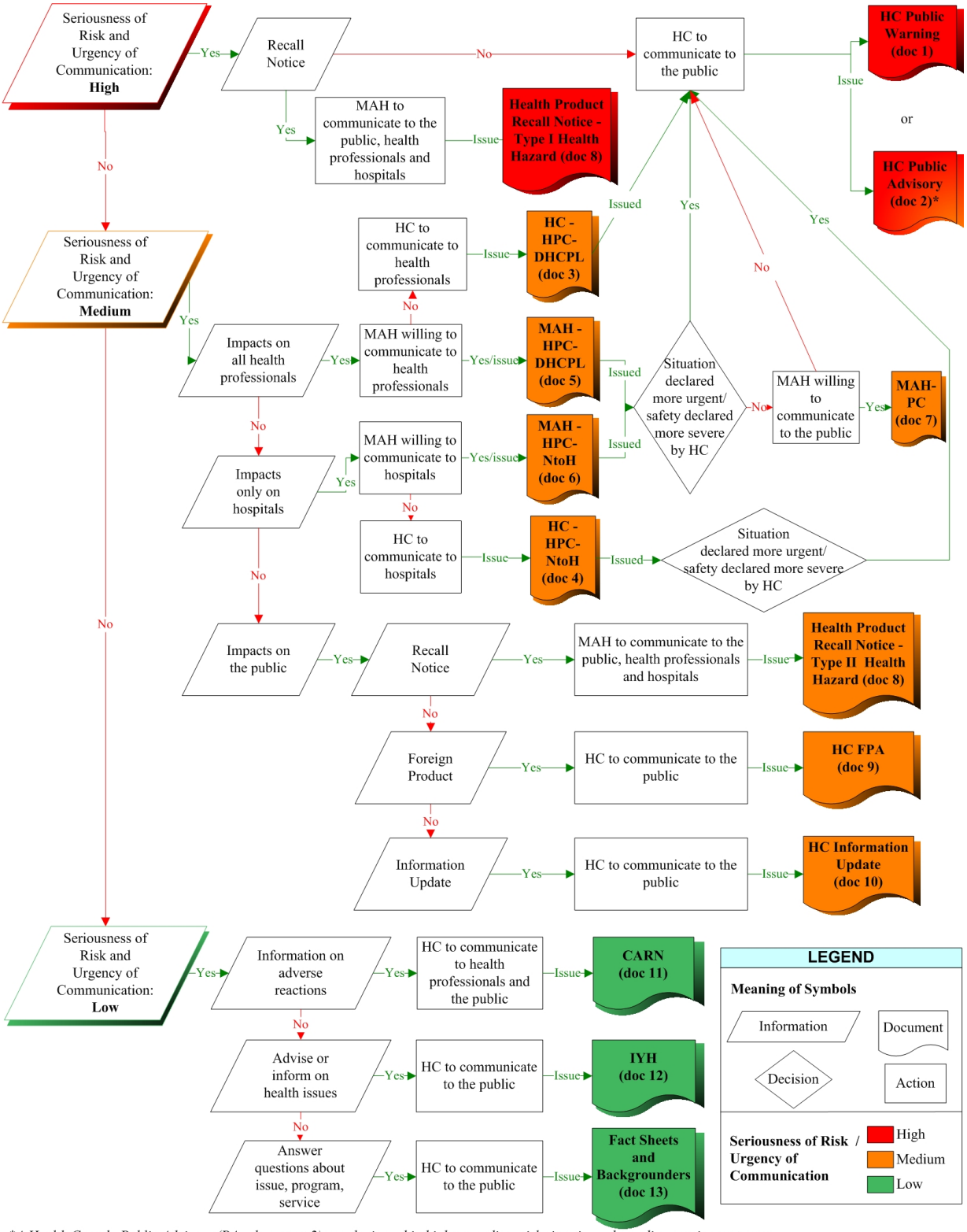
Seriousness of Risk (Probability of Health Hazard and Probability of Occurrence) and Urgency of Communication



** A Health Canada Public Advisory (PA - document 2) may be issued in high or medium risk situations, depending on circumstances.*

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.



**A Health Canada Public Advisory (PA - document 2) may be issued in high or medium risk situations, depending on circumstances.*

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 triggers for the issuance of risk communication documents for health products is provided in this document. Not all triggers need to be met for the issuance of a risk communication document.*

5 Triggers 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 seriousness of risk, target audience, lead for issuance and the triggers 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.
Seriousness of Risk	On a High / Medium / Low scale, urgency of issuance of the risk communication document and seriousness of the risk (probability of health hazard and probability of occurrence).
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.
Risk Communication Triggers	Primary triggers 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 Triggers for Issuance of Risk Communication Documents

The tables are intended to capture a brief description of each document and to outline the primary triggers 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."*[6]

[6] Guidance Document for Industry: Issuance of Health Professional Communications and Public Communications by Market Authorization Holders : http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html

Document 1

Document Name	Health Canada Public Warning (*PW - document 1*)
Seriousness of Risk	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 that there is a reasonable probability that the use of, or exposure to, a product will cause death or other serious adverse health effects, such that affected members of the public should stop using the product or consult their physician immediately.
Distribution	- Posting on the Health Canada Website - Distribution of the message to the media and the public through CCN Matthews, 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. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

Risk Communication Triggers	**Primary triggers (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*)
Seriousness of Risk	High or Medium (depending on circumstances)
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	Alert to 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 Website. - Distribution of the message to the media and the public through CCN Matthews, Health Canada's media listserv and the MedEffect e-Notice mailing list. - May also be distributed to various parties including regional offices, health professional associations, licensing bodies, provincial ministries of health, and foreign regulatory agencies. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

Risk Communication Triggers	**Primary triggers (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:
	  - Industry refuses to issue or refuses to issue in a timely manner.
	  - Company disagrees with or will not discuss with Health Canada content of industry-issued communication.
	  - 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*)[7]
Seriousness of Risk	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*). It can also be issued as the only form of communication.
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 Health Canada and possible association Websites following distribution. - Dissemination to relevant professional associations to encourage posting on their Websites and publication in their journals and newsletters. - Distribution to licensing bodies, provincial ministries of health, and foreign regulatory agencies. - Distribution through MedEffect e-Notice mailing list and CCN Matthews. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

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

Risk Communication Triggers	**Primary triggers (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):
	  - Especially serious unlabelled event(s).
	  - 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*) [8]
Seriousness of Risk	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)* 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; involves products used in hospitals, nursing homes, institutions.
Description	Vehicle to communicate risk where products are primarily, if not exclusively, used in hospital, rather than outpatient settings. The *HPC-NtoH - document 4* is also used in select circumstances where the use of a product is limited to a select group of practitioners who exclusively practise in hospital or selected clinics.
Distribution	- Distribution by mail-out of printed copies, with request to be posted in the institution, Health Canada, and association Websites, or by fax-out. - Posting on Health Canada Website following distribution. - Dissemination to relevant professional associations to encourage posting on their Websites and publication in their journals and newsletters. - May be distributed to licensing bodies, provincial ministries of health, and foreign regulatory agencies. - Distribution through MedEffect e-Notice mailing list and CCN Matthews. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

[8] The Health Canada Issued HPC-NtoH is not normally developed with the MAH.

Risk Communication Triggers	The following triggers apply to products used in or dispensed in hospitals, nursing homes, institutions or inpatient clinic settings.
	Primary triggers (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):
	  - Especially serious unlabelled event(s).
	  - 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 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*)
Seriousness of Risk	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)* 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.
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, Health Canada, and association Websites following distribution. - May be disseminated to relevant professional associations to encourage posting on their Websites and publication in their journals and newsletters. - May be distributed to licensing bodies, provincial ministries of health, and 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.

Risk Communication Triggers	**Primary triggers (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):
	  - Especially serious unlabelled event(s).
	  - 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).
	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*)
Seriousness of Risk	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; involves products used in limited areas such as hospitals, nursing homes, institutions.
Description	Vehicle to communicate risk where products are primarily, if not exclusively, used in hospital, rather than outpatient settings. Used in select circumstances where the use of a product is limited to a select group of practitioners who exclusively practice in hospitals or selected clinics.
Distribution	- Distribution by mail-out of printed copies, with request to be posted in the institution, Health Canada, and association Websites, or by fax-out. - Posting on MAH, Health Canada, and association Websites following distribution. - May be disseminated to licensing bodies, provincial ministries of health, and foreign regulatory agencies. - May be disseminated to relevant professional associations to encourage posting on their Websites and publication in their journals and newsletters. - Distribution through MedEffect e-Notice mailing list. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

Risk Communication Triggers	The following triggers apply to products used in or dispensed in hospitals, nursing homes, institutions or inpatient clinic settings.
	Primary triggers (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):
	  - Especially serious unlabelled event(s).
	  - 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).
	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*)
Seriousness of Risk	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 should also apply to an 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*. Because all *DHCPL* and *NtoH* are posted 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.
Distribution	- Posting on Health Canada Website. - Posting on MAH Website. - Distribution through MedEffect e-Notice mailing list and CCN Matthews. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary table of health professional and consumer advisories.

Risk Communication Triggers	The following triggers apply to information that needs to be communicated to the public.
	Primary triggers (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):
	  - Especially serious unlabelled event(s).
	  - 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).
	- 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*)
Seriousness of Risk	With Type I Health Hazard: High. With Type II Health Hazard: 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), 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[9].
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)[8].

Distribution	- The HPFB Inspectorate (HPFBI) posts recalls on drugs for human use and medical devices on its Website (date of recall, MAH, health product identification, reason for recall).
	- Notices/advisories from companies may be posted on MedEffect 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:
	  - the device defect/malfunction may cause serious health problems or death;
	  - users belong to a vulnerable group;
	  - devices may be used in non-hospital settings (at home, in nursing homes);
	  - high likelihood that not all users can be reached by the company (moved,

[9] *Reference:* 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)

	lost to follow-up, lost list of clients, out of business); - public health implications. - Not all recall notices on the HPFBI Website are posted on MedEffect. - Not all recalls trigger an advisory. - Canadian Adverse Reaction Newsletter (*CARN - document 11*) summary of advisories when an advisory is warranted.
Risk Communication Triggers	Recalls are defined differently for Marketed Health Products and Medical Devices. - Removal from further sale or use or correction of a marketed health product that: - Presents a risk to the health of consumers. - Violates legislation administered by the HPFB. - Recall or correction of a medical device, or notification to its owners and users of its defectiveness or potential defectiveness, if 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. - May not meet the requirements of the Act or Medical Devices Regulations.
Other applications	Include 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*)
Seriousness of Risk	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 information vehicle that provides general warnings about the use of unauthorized products and reporting of adverse reaction information, and provides details on identified foreign products in a table format.
Distribution	- Posting within the "Advisories, Warnings and Recalls" section of the Health Canada Website. - 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.
Risk Communication Triggers	**Primary triggers (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, and for which no Canadian adverse reactions reports have been received. **Other considerations:** - Advisories from foreign agencies. - If evidence exists that these products are being used in Canada or are easily available to Canadians over the Internet, then a Warning or Advisory would be used as appropriate.
Other applications	None.

Document 10

Document Name	Health Canada Information Update *(IU - document 10*)
Seriousness of Risk	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 product used when the nature of a communication is less urgent than for an advisory or warning, where the risk of a product is lower, or where the product involved does not generally affect a large number of people. Can also be used to indicate the progress of Health Canada's review of a risk situation (involving previously communicated serious risk) or to reinforce safety recommendations previously issued.
Distribution	- Information updates can, when warranted, be distributed as well through the CCN Matthews, Health Canada's media listserv and the MedEffect e-Notice mailing list. - Posting on Health Canada Website. - May also be distributed to various parties including regional offices, health professional associations, licensing bodies, provincial ministries of health, and foreign regulatory agencies.
Risk Communication Triggers	- Need to inform of medium level risk situation or high risk situation where a *PW* or a *PA - document 1 & 2* was previously issued. - Small groups of people affected. - 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. - Need to expand on risk information already available through previous communication which could involve a high level risk situation.
Other applications	Foods, consumer products, potential use outside of risk communication, Veterinary drugs.

Document 11

Document Name	Canadian Adverse Reaction Newsletter (*CARN - document 11*)
Seriousness of Risk	Low (urgency of risk communication).
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	A source of adverse reaction information published quarterly, in January, April, July and October of each year. This publication alerts health professionals and the public to 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 Health Canada Website. - 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, MAHs, other international regulatory agencies) across Canada and internationally (26,000 copies quarterly). - 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 by fax to relevant MAH one week prior to publication. - Indexed in CINAHL (Cumulative Index to Nursing and Allied Health Literature) electronic database.

Risk Communication Triggers	**Primary triggers (list includes but is not restricted to):** - Canadian cases. - Serious reactions. - Adverse reactions so as to 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 errors), new health product interactions, health product defects, lack of effect (need several reports). - Suitable timing of topic publication (consideration of environmental context, sensitivities). **Additional triggers for case presentations[10]:** - Serious unexpected 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.

[10] See definitions and acronyms at the end of this document.

Document 12

Document Name	It's Your Health (*IYH - document 12*)
Seriousness of Risk	Low (urgency of risk communication).
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 2,600 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.

Risk Communication Triggers	**Primary triggers (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: - Diseases (prevention, information). - Environment (air, water, work). - Foods (storage, safety, tips). - Lifestyles (personal products). - Medical (treatments, devices, health products). - Products (consumer, hobbies).

Document 13

Document Name	Fact Sheets and Backgrounders (*document 13*)
Seriousness of Risk	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 Website. - 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.
Risk Communication Triggers	- 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 Physicians
CINAHL:	Cumulative Index to Nursing and Allied Health Literature
CPJ:	Canadian Pharmacists Journal
DIN:	Drug Identification Number
DIN-HM:	Homeopathic Medicine Number
EMEA:	European Medicine Agency
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 Holder
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_e.html)].

Adverse Reaction (AR)
A noxious and unintended response to a health product that occurs at doses or applications normally used or tested for the diagnosis, treatment, or prevention of disease, or the modification of an organic function.

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.

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

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*)
This web-based risk communication document advises 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)*
This risk communication document is used when there is information to be conveyed about a product that carries a lower level of risk or that affects a very small group of people. The Information Update may also be used to indicate the progress of Health Canada's review of a risk situation or to reinforce safety recommendations previously issued.

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://hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/docs/pol_0016_recall_policy-politique_retrait_ltr-doc_e.html#4

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*)
An *HPC* is a risk communication tool used to communicate new information about safety and therapeutic effectiveness of marketed health products to health care professionals in a timely manner. *HPC*s include, for example, *DHCPL*s and *NtoH*s.

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 care 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)*. *HPC-DHCPL*s may be distributed to physicians, dentists, naturopaths, pharmacists, nurses, hospitals, and others. The distribution list is tailored to the safety issue being addressed. 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 MAHs.

Health Professional Communication-Notice to Hospitals (*HPC-NtoH*)
A *HPC-NtoH* is a vehicle to communicate risk where products are primarily, if not exclusively, used in hospital, rather than out-patient settings. The *HPC-NtoH* is also used in select circumstances where the use of a product is limited to a select group of practitioners who exclusively practice in hospital or selected clinics. It can be issued either by MAH (*HPC-NtoH - document 6*) or solely by Health Canada (*HPC-NtoH - document 4).*

Homeopathic Medicine Number (DIN-HM)
An eight (8) digit numerical code following the acronym DIN-HM assigned to each homeopathic medicine approved to be marketed under the Natural Health Products Regulations.

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 Holder (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.

MedEffect e-Notice
Electronic mailing list, which distributes e-mail updates from Health Canada for the most recent publication of the Canadian Adverse Reaction Newsletter and marketed health product advisories for health professionals and the public.

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

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.870/233448.html)
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/SOR-98-282/228535.html)
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.

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