Guidance Document for Industry -
Issuance of Health Professional
Communications and Public
Communications by Market
Authorization Holders

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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.

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Foreword

Guidance documents are meant to provide assistance to industry and interested stakeholders on how to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring mandates are implemented in a fair and effective manner.

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 guidance document may be acceptable provided they are supported by adequate scientific 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 guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of marketed health products. 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 relevant sections of other applicable guidance documents.
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1.0 Introduction

1.1 Purpose

The purpose of this document is to assist Market Authorization Holders (MAHs) in developing and disseminating Health Professional Communications (HPCs) and their accompanying Public Communications (PCs) to address health and safety concerns associated with health products.

1.2 Scope

It provides guidance on the following topics:
- Roles and responsibilities;
- Correspondence with and submissions to Health Canada;
- The recommended process for developing and disseminating HPCs and PCs in a timely manner;
- Standard format and content; and
- Communication of scientific information to the general public.

This document does not include a description of the criteria used by Health Canada to determine whether a HPC is required. All of the recommended steps in this document take place once a decision to issue a HPC and accompanying PC has been made.

1.3 Background

Health Professional Communications (HPCs) are one of the principal means used by industry to communicate new information about safety and therapeutic effectiveness of marketed therapeutic products to health care professionals in a timely manner. HPCs include, for example, Dear Health Care Professional Letters (DHCPLs) and Notices to Hospitals (NtoHs).

The signal that a HPC may be needed could be generated from a variety of sources, including:
- data provided by the MAH in a new or subsequent entry submission or application;
- adverse reaction (AR) reports from active clinical trials;
- AR reports, mandatory problem reports (MPRs), or medication incidents (MIs) resulting from marketed health products;
- Periodic Safety Update Reports (PSURs);
- international or foreign regulatory actions;
- medical literature references;
- coroner reports or queries; or
- media reports.

MAHs are expected to prepare a public communication with every HPC in order to inform the public of health product safety issues and to enable them to make informed decisions concerning continued use of the product. All HPCs are posted on the MedEffect™ Canada Web site, therefore, the messages in the PC must be crafted in a manner that is appropriate to the intended audience to ensure that both the technical content and the intent behind the communication effort is understood.

HPCs and the accompanying PC are risk management communication instruments aimed at informing health care professionals and the public of newly recognized and clinically significant safety concerns, recalls, or withdrawals affecting a health product — they are not marketing tools. It is important that messages intended to inform health care professionals of health safety issues not be mistaken for advertising or any other type of information. The effectiveness of risk communications, in particular through HPCs, has been shown to depend in part on the attention of health care professionals to the vehicle, which may be adversely affected if the recipient perceives it as advertising.
1.4 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.

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.

Chief Executive Officer (CEO)
For the purposes of this document, the CEO is the most senior executive of a company who is responsible for a company’s operations and is usually the most important spokesperson of the company. This person is often but not always the president of a company, but could also be a director. The CEO reports to the Chairman of the Board and Board members.

Dear Health Care Professional Letter (DHCPL)
Also known as a Dear Doctor Letter or a Dear Health Professional Letter, a DHCPL is used to inform health care professionals about time-sensitive issues regarding the safety or effectiveness or both of a marketed health product. It is a letter issued by the MAH containing content approved by Health Canada. DHCPLs may be distributed to physicians, dentists, naturopaths, pharmacists, hospitals, and others. The distribution list is tailored to the safety issue being addressed. For the purposes of this document, a DHCPL is a vehicle to disseminate safety information. This document does not apply to DHCPLs used for promotional purposes, which are pre-cleared by the Pharmaceutical Advertising Advisory Board.

Drug Identification Number (DIN)
A DIN is an eight-digit numerical code assigned to each drug product approved under the Food and Drugs Act and Regulations (except for Schedule C drugs).

Health Care Professional
Health care professionals include, but are not limited to, physicians, dentists, naturopaths, pharmacists, registered dieticians, and other medical and support personnel involved in the delivery of health care.

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 Professional Communication (HPC)
A 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. HPCs include, for example, DHCPLs and NtoHs.

Lead Directorate
The Lead Directorate is the directorate within the HPFB of Health Canada that is responsible for working with the MAH to ensure the timely drafting, approval, and dissemination of the HPC and accompanying PC.

Lead Risk Manager
This person is the principal coordinator within the Lead Directorate. This person will act as the liaison with the MAH and will coordinate the input of HPFB staff.
Mandatory Problem Report (MPR)
This report documents serious incidents involving medical devices and is required when the incident relates to the failure of a device, a deterioration in its effectiveness, or any inadequacy in its labelling or use that has led or could lead to the death or serious deterioration in the health of a person.

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 product licence number, or that has received approval to initiate clinical trials in Canada.

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, and 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 medicinal 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.

NPN/DIN-HM
Natural Product Number is an eight (8) digit numerical code following the acronym NPN, assigned to each natural health product approved to be marketed under the Natural Health Products Regulations. DIN-HM is an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the Natural Health Products Regulations.

Notice to Hospitals (NtoH)
A NtoH is a vehicle to communicate risk where products are primarily, if not exclusively, used in hospital, rather than out-patient settings. The NtoH 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.

Periodic Safety Update Report (PSUR)
A PSUR is a standard report used internationally by the regulatory authorities to systematically monitor the safety of marketed drug products and is a primary source of clinical safety information concerning a given drug. The submission of PSURs are not required in Canada, but in certain cases, Health Canada may request the MAH to submit the most recently available PSUR to present the worldwide safety experience of a product (typically every six months or annually) and is a primary source of clinical safety information concerning a given drug.

In the case of natural health products, annual summary and interim summary reports are used.

Post-Market Surveillance
The continued monitoring for, and the study of, effects and other safety and effectiveness related aspects of marketed health products.
**Public Communication (PC)**
A PC is a risk communication tool used to communicate new health safety information to consumers, patients and the general public regarding marketed health products. A PC is the plain language version of a health professional communication on the same issue.

**Request Letter**
A Request Letter is correspondence initiated by Health Canada formally asking a MAH to draft and disseminate, subject to Health Canada approval, a HPC and accompanying PC.

**Signal**
A signal is reported information on a possible causal relationship between an adverse event and a health product, where the relationship was previously unknown or where data was incomplete. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information\(^1\).
2.0 Guidance

2.1 Roles and Responsibilities

2.1.1 Shared Responsibility
Many different organizations and individuals contribute to health care in Canada including Health Canada, health care providers, manufacturers, consumers and others. All parties have a role to play in the effective and timely communication of new health safety information to health care professionals and the general public in a timely fashion, that is easy to understand, and that is relevant to those who it is intended to inform. To ensure effective communication of safety information, the use of HPCs and PCs for other purposes (e.g., attempt to show product superiority) is discouraged as it may result in miscommunication and misrepresentation of the information.

2.1.2 Market Authorization Holder
If the MAH becomes aware of the need to issue a HPC in Canada, either through new safety information in Canada or through foreign regulatory action, the MAH has a responsibility to inform Health Canada. The MAH should engage in discussions with Health Canada early in the process of developing a HPC, as this facilitates a consistent approach to risk communication strategies and ensures that information communicated to health care professionals and the public is as accurate and complete as possible.

When the need for a HPC has been identified, either by the MAH or by Health Canada in a Request Letter, the MAH is expected to undertake the following activities:

- Submit for Health Canada review and approval of the documents outlined in Section 2.4;
- Issue both the HPC and accompanying PC as requested using the recommended format (see the templates for the Dear Health Care Professional Letter, Notice to Hospitals and Public Communication) to clearly communicate the intended message to the target audiences, and within the requested time frame (see Section 2.2.5 and Appendix C);
- Submit the Supplemental New Drug Submission (SNDS), Notifiable Change (NC), or licence amendment as described in Section 2.6; and
- Post the HPC and PC on the MAH Web site, if available.

If the MAH has received a Request Letter but does not believe that a HPC is necessary in Canada, the MAH is requested to provide justification in writing. However, this can not be allowed to impede the timely issuance of the HPC and accompanying PC.

If the MAH is aware that a HPC or PC was issued in a foreign jurisdiction for a similar product, the MAH is expected to notify Health Canada, Marketed Health Products Directorate (MHPD).

If the MAH has issued a HPC or PC without the knowledge of Health Canada, the MAH is expected to advise Health Canada, MHPD, that this has occurred, including to whom the HPC was distributed and by what method.

2.1.3 Health Canada
Health Canada is responsible for:

- reviewing the draft HPC and accompanying PC in a timely manner (see Section 2.2.4 and Appendix C, “HPC Timeline”);
- approving the final HPC and accompanying PC;
- notifying foreign regulators; and
- posting the final HPC and PC on the MedEffect Canada Web site.

Both Health Canada and the MAH have a responsibility to determine whether any labelling changes or changes in status pertaining to the Special Access Program or Clinical Trial Unit are required.

Action to resolve impasses will be taken on a case by case basis, taking into consideration the significance of the timely issuance of the HPC and accompanying PC. Resolution will be sought on the premise that actions are transparent, fair, and appropriate to the risk. Ultimately, the responsibility and authority for resolving impasses rests with Health Canada and if required Health Canada will issue the HPC and PC.
Health Canada will notify foreign regulatory authorities when the HPC is approved. A copy of the draft HPC or PC will not be provided as part of the notice. At a minimum, countries and organizations with which HPFB maintains formal and regular communication will be notified such as the International Conference on Harmonisation (ICH) countries (United State of America (USA), European Union (EU), and Japan), and the Forum on Harmonization of Herbal Medicines countries (Hong Kong, China, Singapore, Vietnam, South Korea, Australia and New Zealand).

2.2 Issuance Process

2.2.1 Initiating the Process
The Request Letter will outline the nature of the issue and will request the MAH to draft a HPC and accompanying PC. When a Request Letter is received it is expected that the MAH will designate an individual as the company contact for the issue.

Where appropriate, the Request Letter will also indicate whether the issue requires any changes in status or labelling changes and, if applicable, the type of submission or application required (i.e., SNDS, NC, or licence amendment).

2.2.2 Issuance by more than one Market Authorization Holder
In the simplest case, the safety issue will be linked to a single product sold by one MAH in Canada. There may be situations, however, in which more than one MAH may be involved in issuing the HPC, including the following:

- The safety issue with one product is due to an interaction with another type of product that may be sold by many MAHs (e.g., interaction between health product x and health product y).
- The safety issue is linked to a component found in many products (e.g., plasticizers in tubing, phenylpropanolamine (PPA) in cold remedies).
- There is a safety concern with a class of products.
- The safety concern is linked to more than one class of drugs (e.g., QT prolongation).
- A product for which patent protection has expired could have both an innovator and generic companies who market the product in Canada.

The objective is to have the necessary information reach and be read by health care professionals and consumers. Multiple HPCs from different MAHs could lead to confusion or could result in health care professionals disregarding HPCs.

Where the number of MAHs involved is relatively limited (i.e., 2 or 3) MAHs should work together to issue a single HPC and accompanying PC. For a larger number of MAHs or where MAHs refuse to issue a single letter, the HPC and accompanying PC may be issued by Health Canada.

2.2.3 Correspondence and Submissions
The name of the contact person at Health Canada, from here on referred to as the Lead Risk Manager, will be provided in the Request Letter along with his or her contact information. Health Canada will address initial correspondence to the Director of Regulatory Affairs with a copy to the Chief Executive Officer (CEO) (or equivalent). As noted above, the MAH will be requested to designate an individual to serve as the company contact for the issue and supply Health Canada with the preferred contact information for further correspondence. The MAH can respond to the Request Letter in either official language. With the exception of regulatory letters, which are sent in hard copy, all communications will take place via fax, or electronically in Portable Document Format (PDF). Documents that may require further editing, such as drafts of the HPC and accompanying PC, may also be sent in WordPerfect or Microsoft Word format.

The Lead Risk Manager may call the designated contact to clarify typographical errors or non-substantive inconsistencies or to request minor additional information.

Meetings are not normally required before the issuance of a HPC and accompanying PC. If, however, meetings are required to resolve disagreements on content, they must not interfere with the timely issuance of the HPC and PC.
2.2.4 Process Overview
The following diagram illustrates the flow of work in developing a HPC and the accompanying PC.

- first draft HPC and PC
- dissemination strategy
- final draft
- translation

- submission to Health Canada

- distribution of HPC to health care professionals and PC to the Public
- submission to Health Canada of list of recipient and method of dissemination

- NC/SNDS/Licence Amendment

- Periodic Safety Update Reports (PSURs)
- Annual/Interim Summary Reports

2.2.5 Timeline
HPCs should be developed and disseminated within 12 working days after the date on which the Request Letter is received, or the date on which the MAH informed Health Canada of the need for a HPC. The accompanying PC should be issued 3 working days after the issuance of the HPC, to allow health care professionals sufficient time for preparation to answer questions from the public. If the MAH believes that the accompanying PC should be issued at the same time as the HPC, a written confirmation should be provided to Health Canada for approval prior to dissemination.

Given the importance of issuing the HPC and PC in a timely manner, repeated revisions are to be avoided.

A graphical timeline illustrating the phases of HPC development and dissemination is provided in Appendix C.
2.3 Content Development

2.3.1 Envelope Format
To reduce the possibility of HPCs being discarded unopened, envelopes and letter subject lines should bear a prominent red box warning, inscribed with the following text in bold white lettering: “Health Canada Endorsed Important Safety Information on [HEALTH PRODUCT]” (see the templates for the Dear Health Care Professional Letter² and Notice to Hospitals³). In cases where the issuance of the HPC is based on a potential drug interaction or where multiple products are involved, all health products or a class designation should be included on the envelope red box warning.

In addition, for disseminations by fax or e-mail, facsimile cover pages and e-mail subject lines should bear the above text.

It is recommended that the printing of the envelopes for the HPC begin as early as possible. It can take approximately 7–10 days to print envelopes with the product(s) name in the red box warning. If, due to urgency, it is not possible to include the health product name in the red box warning on the envelope, justification in writing to Health Canada is expected.

The envelopes should be printed with the MAH’s return address, not Health Canada’s.

Refer to the Canada Post Web site for envelope guidelines and standards at: http://www.canadapost.ca/business/tools/pg/default-e.asp.

2.3.2 Format for Health Professional Communications
Health Canada will specify in the Request Letter whether a DHCPL² or a NtoH³ is needed.

All HPCs and PCs are to be provided in both official languages⁶ and should reflect the following formatting guidelines:
• Every effort should be made that the HPC and PC should not exceed two pages in either official language.
• The MAH logo should be inserted at the beginning of the HPC.
• True Type (TT) Arial (11 pt) font should be used.
• The text should be left justified and the document should be paginated on the bottom right of the page.
• Underlining, indenting, and graphics should not be used (with the exception of the MAH logo).
• For NtoHs only, the following text should be included before the subject line: “Please distribute to relevant Departments [Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, Intensive Care and/or other Departments as required], and other involved professional staff and post this notice in your institution.”

2.3.3 Standard Content for Health Professional Communications

First Paragraph - Description of Health Risk
This paragraph should describe:
• the adverse events reported;
• their seriousness² (e.g., hospitalization, transplantation, fatality, etc.);
• the rationale for suspecting a causal relationship (e.g., pharmacodynamic mechanism, temporal relationship, positive rechallenge or dechallenge, etc.);
• whether the event is linked to an unapproved indication or unapproved condition of use; and
• the number of events of interest reported domestically and internationally with estimations of patient exposure.

Include key messages in a bulleted list in a box of text after the opening paragraph. Underlining should not be used in key messages. Additional detailed instruction(s) on how to use the new safety or therapeutic effectiveness information should follow the boxed and bulleted key messages.

Subsequent paragraphs - Risk management measures
These paragraphs can be tailored to the type of AR and should describe:
• contraindications;
• warnings (e.g., comprehensive list of signs, symptoms, laboratory findings, time course, clinical outcome, laboratory monitoring, risk factors, recommended actions in the event of prodromal symptoms, reinforced warnings concerning metabolic drug interactions);
• adverse reactions (e.g., extended list of post-market adverse events); and
• information for the consumer (e.g., description of risk and possible consequences, warnings regarding prodromal symptoms).


Final paragraphs - AR reporting instructions
A statement such as the following should be included in both DHCPLs and NtoHs:

Managing marketed health product-related adverse reactions depends on health care professionals reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious [SPECIFIC ADVERSE REACTION] or other serious or unexpected adverse reactions in patients receiving [BRAND NAME] should be reported to [NAME OF SPONSOR] or Health Canada at the following addresses:

A list of addresses by product type is included in the templates provided for DHCPLs², NtoHs³, and PCs⁴.

2.3.4 Accompanying Public Communication
As the target audience for PCs includes consumers, patients, and the general public, the accompanying PC should contain easy-to-understand safety information, and should contain the same information on how to report adverse drug reactions and medication incidents as the HPC. See Appendix D, “Tips for Public Communications” for guidance on content development principles, the minimum level of content, and how to write for a general audience.

2.3.5 Translating the Health Professional Communications and the Public Communications
The MAH is responsible for the translation of the HPC and accompanying PC in both official languages², using the bilingual templates provided for DHCPLs², NtoHs³, and PCs⁴. Translated versions should be provided with the final draft to allow Health Canada to review the translation to ensure consistency between the different language versions. Given the importance of issuing the HPC and PC in a timely manner, repeated revisions to translated copies should be avoided.

2.4 Approval Process

2.4.1 Submitting the First Draft and Dissemination Strategy
The following items should be included with the first draft submission for Health Canada review:
• First draft of the HPC (DHCPL or NtoH, etc.) including a “draft” watermark, the date (Month dd, yyyy), and version number;
• Mock-up of the envelope with the product(s) name in the red box (or justification in writing if the MAH is unable to include the product name in the red box);
• Dissemination strategy (including the distribution list of targeted groups and method of dissemination);
• Up-to-date list of medical literature references dealing with relevant AEs associated with this health product;
• List of any references to be issued with the final HPC and accompanying PC; and
• Copies of HPCs issued to date by other regulatory jurisdictions associated with this health product.

To ensure that the HPC is finalized in a timely manner, Health Canada will review the drafts and provide the MAH with any revisions required within four working days. The MAH should begin drafting the PC once the HPC nears finalization.
2.4.2 Submitting the Final Draft
Upon receipt of revisions from Health Canada, the MAH should provide the Lead Risk Manager with the final draft HPC and PC and translated versions within two working days. Health Canada requests that a statement of awareness indicating that the HPC and PC will be posted on the MedEffect™ Canada Web site and released to parties that may request it be submitted with the final draft.

In the final draft, the MAH is requested to include the date of issuance as well as the MedEffect™ Canada Web site address, http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php, specifying where the HPC and PC can be found.

The following items should be included with the final draft submission for Health Canada approval:

- Translated, signed, dated, printed copy of the final draft of the HPC (DHCPL, NtoH, etc.) and PC;
- Final draft of the HPC (DHCPL or NtoH, etc.) and PC in both official languages, in PDF;
- Final draft of the HPC (DHCPL or NtoH, etc.) and PC in both official languages in WordPerfect or Microsoft Word format;
- List of references to be issued with the approved HPC and accompanying PC.

The MAH will be notified in writing when the HPC and PC have been approved by Health Canada.

2.5 Dissemination and Notification

2.5.1 Developing the Dissemination Strategy
The MAH is requested to provide, along with the draft HPC and PC, a draft dissemination strategy including a distribution list of targeted groups and method of dissemination for review and approval by Health Canada.

The dissemination strategy should reflect, but is not limited, to the following target audiences and methods of dissemination:

<table>
<thead>
<tr>
<th>Vehicle</th>
<th>Target Audience</th>
<th>Method of Dissemination</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHCPL</td>
<td>Health care professionals and associations</td>
<td>Mail-out of printed copies (fax-out under exceptional circumstances e.g., urgency to communicate the safety information)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post on MAH, MedEffect™ Canada, and association Web sites</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disseminate to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters</td>
</tr>
<tr>
<td>NtoH</td>
<td>Canadian hospitals to the attention of Chiefs of Medical Staff and hospital pharmacies for distribution to relevant departments (e.g., Surgery, Emergency Medicine, Pharmacy, Paediatrics, Anaesthesia, Geriatrics, Internal Medicine, Nursing, Dentistry, Intensive Care) and other involved professional staff</td>
<td>Fax-out or mail-out of printed copies, with request to be posted in the institution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post on MAH, MedEffect™ Canada, and association Web sites</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disseminate to relevant professional associations to encourage posting on their Web sites and publication in their journals and newsletters</td>
</tr>
<tr>
<td>PC</td>
<td>Consumers, patients, and the general public</td>
<td>Canada Newswire Services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MedEffect™ Canada Web site</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post on MAH Web site</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(The PC is not disseminated to the same degree as the HPC)</td>
</tr>
</tbody>
</table>

The dissemination plan must be submitted with the draft and final versions of the HPC and PC and must be approved in advance of issuance of the HPC and PC.
2.5.2 Distributing the Health Professional Communications and the Public Communications
Upon receipt of Health Canada approval, the HPC should be disseminated in both official languages (and in other languages, if applicable) to the target audiences identified in the approved dissemination strategy. The PC should also be disseminated in both official languages (and in other languages, if applicable) 3 working days thereafter.

2.5.3 Posting the Health Professional Communications and the Public Communications on the Web
Health Canada will post the final version of the HPC and accompanying PC on the MedEffect™ Canada Web site and will release it to anyone who may request it. As a best practice for risk communications, Health Canada recommends that the MAH post the final documents on the company Web site. It is recommended the HPC remain on the Web site during the availability of the product.

Also, Health Canada encourages dissemination to relevant professional associations with electronic copies of the HPC for posting on their Web sites, or for publication in association journals and newsletters.

2.5.4 Submitting the List of Targeted Groups and Method of Dissemination
Within 14 days of issuing the HPC and accompanying PC, the MAH is asked to provide Health Canada with a list of targeted groups to whom the HPC was issued, including the date of issuance and the method of distribution that was used. Where Health Canada is not satisfied with the degree of distribution, a written request will be made to the MAH to correct the situation.

2.6 Follow-Up Documentation

Submitting an NC/SNDS/Licence Amendment
If Health Canada or the MAH determines that the issue requires a change in status or a labelling change a submission or application such as a SNDS, NC, or licence amendment may be required. See the Guideline on Preparation of Human New Drug Submissions at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/newdrug-drognouv/prephum-eng.php

The MAH should provide the submission or application to Health Canada within two weeks of the date on which the HPC is approved or a timeline agreed to by Health Canada. To avoid unnecessary processing delays, the submission should be flagged as “Urgent” and “Health Canada Requested.”

2.7 Monitoring

Submitting PSURs or Annual/Interim Summary Reports
In some cases, Health Canada may request the MAH to submit additional follow-up information (for example, the most recently available PSUR or annual/interim summary report) to monitor the situation. Such requests will describe the nature of the information requested and will include a time frame within which the response is to be submitted. If a follow-up summary report (or annual/interim summary report) is requested, the MAH should provide it within six months or within the time frame specified by Health Canada.
Appendix A: List of Abbreviations

AE: Adverse Event
AR: Adverse Reaction
CEO: Chief Executive Officer
DHCPL: Dear Health Care Professional Letter
DIN: Drug Identification Number
EU: European Union
FHH: Forum on Harmonization of Herbal Medicines
HPC: Health Professional Communication
HPFB: Health Products and Food Branch
ICH: International Conference on Harmonisation
MAH: Market Authorization Holder
MI: Medication Incident
MPR: Mandatory Problem Report
NC: Notifiable Change
NHP: Natural Health Product
NtoH: Notice to Hospitals
PC: Public Communication
PDF: Portable Document Format
PSUR: Periodic Safety Update Report
SNDS: Supplemental New Drug Submission
USA: United State of America
### Appendix B: Health Professional Communication and Public Communication Checklist

<table>
<thead>
<tr>
<th>Item</th>
<th>Recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Draft HPC and PC and Dissemination Strategy</strong></td>
<td></td>
</tr>
<tr>
<td>❑ First draft of DHCPL or NtoH</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Mock-up envelope (or justification in writing if not included)</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Dissemination strategy (distribution list and method of dissemination)</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Up-to-date list of medical literature references dealing with relevant AEs associated with this health product</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ References to be included with final HPC and accompanying PC</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Copies of any HPCs issued to date related to this health product within Canada or in other regulatory jurisdictions</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Translated version(s) should be provided with final drafts.</td>
<td>Health Canada</td>
</tr>
<tr>
<td><strong>Final Draft HPC and PC for Approval</strong></td>
<td></td>
</tr>
<tr>
<td>❑ Signed, dated, printed copy of the final draft of the HPC (DHCPL, NtoH, etc.) and PC in both official languages</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Final draft of the HPC (DHCPL, NtoH, etc.) and PC in both official languages (PDF and WordPerfect or Microsoft Word format)</td>
<td>Health Canada</td>
</tr>
<tr>
<td><strong>Dissemination and Notification</strong></td>
<td></td>
</tr>
<tr>
<td>❑ Printed copies</td>
<td>Targeted groups as indicated in Dissemination Plan</td>
</tr>
<tr>
<td>❑ Electronic copies</td>
<td>MAH Web site and relevant professional associations</td>
</tr>
<tr>
<td>❑ List of targeted groups and method of distribution, including date of issuance</td>
<td>Health Canada</td>
</tr>
<tr>
<td><strong>Follow-Up Documentation</strong></td>
<td></td>
</tr>
<tr>
<td>❑ SNDS/NC/licence amendment</td>
<td>Health Canada</td>
</tr>
<tr>
<td>❑ Revised labelling, product monograph, or patient package insert</td>
<td>MAH Web site</td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>❑ PSUR or annual/interim summary report</td>
<td>Health Canada</td>
</tr>
<tr>
<td>Activity</td>
<td>Time Taken&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>MAH prepares first draft HPC and submits to Health Canada.</td>
<td>4</td>
</tr>
<tr>
<td>Health Canada reviews first draft and requests revisions from MAH.</td>
<td>4</td>
</tr>
<tr>
<td>MAH makes requested revisions, and submits final draft HPC and PC to Health Canada.</td>
<td>2</td>
</tr>
<tr>
<td>Health Canada reviews and approves final drafts&lt;sup&gt;2&lt;/sup&gt;.</td>
<td>1</td>
</tr>
<tr>
<td>Health Canada verifies translation&lt;sup&gt;2&lt;/sup&gt;.</td>
<td>1</td>
</tr>
<tr>
<td>Health Canada notifies MAH of HPC and PC approval.</td>
<td>1</td>
</tr>
<tr>
<td>MAH disseminates HPC to target audience.</td>
<td>1</td>
</tr>
<tr>
<td>MAH distributes PC to public.</td>
<td>1</td>
</tr>
<tr>
<td>Health Canada posts HPC and PC on MedEffect&lt;sup&gt;TM&lt;/sup&gt; Canada Web site</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup> Time is reflected in business or working days.
<sup>2</sup> Each additional round of revision (request and response) will add two business days to the process.
Appendix D: Tips for Writing Public Communications

Warning
It is recommended the following language be added to the PC, in bold font:

“Warning: this Public Communication is not intended as medical advice. In order to understand the implications of this information to your health and before you modify the way you use this health product, it is important that you consult your doctor or health care professional.”

Minimum Level of Content
The following guidelines highlight the importance of clarity and relevance in risk communication.

- Briefly state the issue at hand. Explanatory detail should not be provided in the statement.
- Put key messages up front. Many readers will not read past the first few lines of content.
- Ensure that a clear distinction is made between the hazard and the risk: the “hazard” is what poses the threat of danger; the “risk” is the likelihood the danger will occur.
- Acknowledge that certain hazards may elicit fear or feelings of dread.
- Specify what is known about the hazard and how likely sensitive populations within the general public (e.g., children) are to be affected.
- Indicate how reliable the knowledge is on which the communication is based. Indicate whether the quality of this knowledge is expected to improve (e.g., through further research) and who is responsible for improving it.
- Provide a qualitative description of the uncertainties that may exist in the base of knowledge from which the content of the communication is drawn. Indicate what further steps may reduce these uncertainties.
- Provide a qualitative and quantitative description of the estimates of probability.
- Indicate what is thought to be an acceptable level of risk for the issue described in the communication. Provide a justification for this acceptable level.
- Provide a clear description of the actions taken to mitigate the risk. Provide a compelling justification for the action that was taken.
- Recommend actions to be taken by members of the public who are possibly affected by the risk. Provide a justification for these recommendations.
- Provide contact information to allow readers to easily obtain additional information and responses to questions.

Writing for a General Audience
Communicating health risk information to a general audience has inherent challenges that must be addressed.

Scientific Translation
The scientific basis behind the determination of a health risk must be translated into language that is understandable to the target audiences that have been identified as requiring the information to make informed decisions regarding their health. As established, a given message of this nature may need to be communicated to audiences along a continuum that ranges from those with little or no ability to consume scientific information to those who can be termed as “educated laypersons.” In the area of health, an educated layperson is an individual who attempts to maintain a basic level of awareness of issues that can affect his or her health, and who understands the basic principles of science.

Writing for any audience along this continuum, it involves a balance between simplifying a scientific concept while maintaining its technical integrity. Depending on the specific subject, its initial level of complexity, and the range of audiences to which the information must be communicated, achieving this balance can be a difficult but critical task in developing a public communication.

Plain Language
Plain language principles should be adhered to wherever possible. Underlying plain language writing is the principle that information should be written and organized as clearly as possible without compromising its accuracy. The answers to these questions will affect the approach to writing the document.

1. Who is the audience? Be sure that there is a clear idea of the key sub-audiences within the “general” public, if possible.
2. **What is being communicated?** Stay focused on the issue to be communicated. This avoids the clutter of irrelevant information and ensures that relevant information is emphasized. Avoid the temptation to provide too much detail. Also include a list of sources for additional information.

3. **What is the appropriate presentation?** Use templates, where possible, to help to develop the content.

**Tone and Voice**
The following tone and voice guidelines are recommended:

- Use a conversational tone, but avoid a tone that is too familiar or colloquial, as this will result in a document that loses credibility.
- Address the reader directly by using personal pronouns.
- Use the active voice. The subject of a sentence should be the doer of the action. Use the subject–verb–object word order and keep the subject and verb close to each other. However, the passive voice may be necessary if it is unclear who or what the subject is.

**Style**
The following style guidelines are recommended:

- Use short sentences. Studies have found that many people get lost in long sentences. Some guidelines recommend no more than 25 words per sentence, but no arbitrary rule can apply to all cases.
- Write simple sentences. The subject-verb-object word order is the simplest. Keep sentences to the point. If there is a related point, use another sentence. Break up long sentences into point form. However, do not sacrifice clarity to either sentence length or simplicity. Variety in both length and structure can help to keep the audience’s attention.
- Focus paragraphs on a single idea. In general, the first sentence should introduce the idea, the middle sentences should discuss it, and the last sentence should conclude it. However, it is sometimes difficult to determine where one idea ends and another one concludes. A complex idea may often need more than one paragraph to explain.
- Link ideas. Sentences should be held together with conjunctions and other connecting words. Paragraphs should be linked by having the concluding sentence of one paragraph lead into the introductory sentence of the following paragraph. Do not avoid providing the links just to keep sentences short or paragraphs focused.

**Consistency of Terms**
Use terms consistently. Use the same word whenever a reference is made to the same thing.

When difficult ideas or specialist information must be conveyed, there are plain language techniques for dealing with them.

Explain technical or specialist terms. Determine whether the word used is something that an educated layperson would understand and, if not, whether it is necessary. If a technical term must be used, define it the first time it is used and give sufficient context for those unfamiliar with it.

Explain complicated ideas. Acknowledge the complexity of research results and make the effort to explain them to the reader.

Avoid chains of nouns. Stringing nouns together to identify a complex concept does not work well in English. The reader will have to untangle the string, determine which word is the primary noun, and figure out how the rest relate to it. Instead, write a more expansive phrase or sentence that is easier to understand.

**Using Probabilities**
Probabilities associated with risk may be employed in the text of an advisory. Experts and the public alike are subject to biases when assessing probabilities. When using probabilities, perceived messages will depend on whether they are presented in absolute or relative terms. For example, in absolute terms the increase in the probability of an event occurring could be expressed as increasing from 5% to 10%. In relative terms, the probability has doubled. Doubling the probability sounds much more alarming than an increase of 5%, when in fact the actual numbers are the same.

When new information is provided to a general audience, baseline probabilities are often forgotten, and the focus of attention is squarely on the rate of change of the probability. While relative risks can be made to sound more interesting, they can seriously mislead the reader if the baseline risk is not made clear.
Word Choice
Plain language writing recommends the use of the clearest words possible. That may mean choosing a two-syllable word over a three-syllable word. Complex words, however precise, may need to be replaced by several simpler words.

The following word choice guidelines are recommended:

1. **Use familiar words.** Consumers, patients, and the general public have varying degrees of familiarity with medical language, and in some cases, may have only a basic understanding of English or French. To communicate a clear message to the target audience, avoid using a complex word when a simple word will do. For example:

<table>
<thead>
<tr>
<th>Instead of</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>determine</td>
<td>find, figure</td>
</tr>
<tr>
<td>terminate</td>
<td>end, stop</td>
</tr>
</tbody>
</table>

2. **Eliminate unnecessary words.** Elaborate phrases can also obscure a document’s meaning and lengthen it for no reason. For example:

<table>
<thead>
<tr>
<th>Instead of</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>in the event that/of</td>
<td>if</td>
</tr>
<tr>
<td>with respect to</td>
<td>on, about</td>
</tr>
</tbody>
</table>

3. **Avoid modifying parts of speech.** Do not change nouns into verbs, or verbs into nouns. In the former trend, “to have an impact on” becomes “impacted”; “to gain access to” becomes “accessed.” The latter trend results in passive sentences that sound important but are limp and difficult to read: “Several factors influence your health” becomes “Your health is impacted by several factors.”

4. **Avoid jargon.** Jargon is a trendy, short-form way of communicating. It tends to fall out of fashion quickly. Determine whether the term is a common one, or one that is only shared and understood within a certain milieu.


**Footnotes and References**


5. In some cases, labelling changes may precede or accompany the HPC

6. In some circumstances, other language translations may be required. These circumstances will be outlined where warranted. If other language translations are required, these translations must also be submitted for Health Canada review and approval. This should not delay the issuance of the English and French versions.

7. The World Health Organization (WHO) defines a serious adverse event or reaction as “any untoward medical occurrence that at any dose results in death; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; or is life-threatening.” To clarify the distinction between the terms “serious” and “severe,” the WHO clarifies that “seriousness (not severity) which is based on patient/event outcome or action criteria serves as a guide for defining regulatory reporting obligations.” Source: Glossary of terms used in Pharmacovigilance http://www.who-umc.org/graphics/15338.pdf.