Guidance on notifying Health Canada of foreign actions

Health Canada Santé Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Foreword

Guidance documents provide assistance to industry and healthcare professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. They 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 always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of other applicable guidance documents.

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Purpose

This guidance document:

- outlines the requirements for notifying Health Canada of foreign regulatory actions, as set out in sections C.01.050 (2)(a), (b) and (c) and C.01.050 (3) of the Food and Drug Regulations
- helps you, the market authorization holders (MAH), comply with these requirements

Note: the use of the term “market authorization holder” or “MAH” for the purposes of this guidance document refers to:

- the holder of one or more of the following therapeutic product authorizations:
    - a drug identification number that has been assigned under subsection C.01.014.2(1); and
    - a notice of compliance that has been issued under section C.08.004 or C.08.004.01.
- a person who holds an establishment licence and
    - imports a designated drug under section C.10.006, or
    - sells a designated drug under subsection C.10.007.1(1)

Many drugs may be marketed years in advance or prescribed in higher volume in other countries. For this reason, important safety signals may be detected earlier in a foreign jurisdiction.

The foreign notification provisions make it possible for us to know early on about regulatory actions taken in foreign jurisdictions.

With this knowledge, we can:

- better identify and assess risks to people in Canada throughout the life cycle of drug products **and**
- take appropriate action to mitigate those risks when warranted

We may seek further information about a regulatory action, if necessary.

Background

The regulation to notify us of foreign regulatory actions aims to put into operation certain safety provisions of the Protecting Canadians from Unsafe Drugs Act (also known as Vanessa's Law). This act received Royal Assent on November 6, 2014.

The regulations to which this guidance applies were published in the Canada Gazette, Part II on May 2, 2018.

The World Health Organization (WHO) describes pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. This activity takes place over the life cycle of a drug, including before, during and after marketing.

MAHs are responsible for the safety of their products throughout their life cycle and must comply with all Canadian legislative and regulatory requirements.

The management of safety signals is part of routine pharmacovigilance and is essential to ensuring that manufacturers and regulatory authorities have the most up-to-date information on a drug. The requirement to notify Health Canada of certain foreign actions supports these activities.

For MAHs, good pharmacovigilance practices involve:

- collecting and assessing drug safety information
- monitoring, detecting and managing safety signals
- analyzing or assessing signals that may indicate significant changes in a drug's benefits and risks (its risk-benefit profile)

- taking any follow-up actions that may be needed, based on the outcome of the assessment, such as:
    - recalling product
    - changing a product's label
    - preparing periodic summary reports (for example, annual), analysing safety information and reporting significant changes to us
    - updating risk management plans (RMP) as needed

For information on implementation including good vigilance practices, consult:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

For information on preparing summary reports, consult

- Guidance on preparing and submitting summary reports for marketed drugs and natural health products

For information on updating an RMP, consult:

- Submitting risk management plans guidance document

For information on reporting recalls in Canada, consult:

- Guidance: Drug, natural health product and biocide recall guide (GUI-0039)

Scope and application

The requirement to notify us of foreign regulatory actions applies throughout a product's life cycle for the following 3 classes of drugs that have been assigned a Drug Identification Number (DIN) (under C.01.014.2 (1)) or a Notice Of Compliance (NOC) (under C.08.004 or C.08.004.01):

1. prescription drugs
2. drugs that are required to be sold under a prescription by Part G of the Food and Drug Regulations, the Benzodiazepines and Other Targeted Substances Regulations or the Narcotic Control Regulations
3. drugs that are permitted to be sold without a prescription but that are to be administered only under the supervision of a practitioner

You are responsible for notifying us of foreign actions under section C.01.050 of the Food and Drug Regulations for as long as you hold a Canadian market authorization for the drug, whether in the form of a drug identification number or a notice of compliance.

The requirement applies to both human and veterinary drugs, if a foreign action is taken in respect of a serious risk of injury to human health.

These requirements begin when market authorization is granted in Canada and cease when the authorization is discontinued, regardless of marketing status.

Note: These requirements continue to apply even if the drug status changes to, for example, "approved" or "dormant" in the drug product database (DPD). However, the requirement does not apply to drugs still under review for market authorization.

Visit the regulations for more information:

- Benzodiazepines and Other Targeted Substances Regulations
- Narcotic Control Regulations
- Food and Drug Regulations

Interpretation

You must notify us within 72 hours after you receive or become aware of information that:

- involves a serious risk of injury to human health
- is relevant to the safety of the drug, and
- is associated with certain specific actions referred to in subsections C.01.050(2)(a), (b) and (c) taken in any of the specified foreign jurisdictions

The regulatory requirements in subsections C.01.050(2)(a), (b) and (c) only apply to foreign actions that have taken place, not foreign actions that are being considered.

For information on how global affiliates, cross-licensing and contractual agreements affect regulatory obligations, consult:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

What is "serious risk"

To determine whether a therapeutic product presents a serious risk of injury to human health, consult:

- Annex A to Guide to authorities under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

A qualified person must determine if the risk meets this threshold. The qualified person should have sufficient medical knowledge and appropriate training or experience, or should consult with someone who has the necessary expertise.

For information on personnel and training, including "qualified person," consult:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

You should contact us if you are not sure if the seriousness of a risk meets the threshold for notification.

Relevance to the safety of a drug

A qualified person must determine whether the action taken in a listed foreign jurisdiction is relevant to the safety of the drug.

GMP/product specific quality issues

If an action in respect of a serious risk of injury to human health arises from a foreign good manufacturing practices (GMP) issue, it is considered relevant if the GMP issue occurred at a manufacturing site listed in the Canadian product authorization or the establishment license.

Only one notification is required per GMP/product-specific quality-related issue (e.g. GMP issue results in a recall), even if the GMP issue affected more than one product or lot. If the GMP issue results in a product specific issue (e.g., recall), select both GMP/manufacturing site and product specific quality issue as source of risk in the form.

When a single event triggers both a C.01A.013 (DEL/GMP) notification and a C.01.050 (foreign regulatory action) notification for the same company, the company may submit one consolidated notification as long as:

- the notification includes all information necessary to satisfy the requirements under both C.01A.013 and C.01.050, as outlined in the applicable forms and guidance, and
- the strictest applicable timeline is met, and
- you retain sufficient documentation to demonstrate compliance with both requirements.

Comparable products

You are required to notify us of foreign actions that apply to your own products.

For generic and biosimilar products, you are required to notify us only of actions involving risks that would apply specifically to your own products with the same active ingredient or combination of active ingredients that was in scope of the foreign action.

Foreign actions explicitly involving class effects for products must be reported, but only those with a similar mode of therapeutic action (for example, systemic versus topical).

Foreign regulatory authorities covered under the requirements

The regulatory requirement only applies to those countries that appear in the three-part list of foreign regulatory authorities. This list is incorporated by reference in the Food and Drug Regulations.

Visit Scanning for foreign regulatory actions for guidance on environmental scanning, including monitoring frequency.

Foreign actions subject to notification

Not all foreign actions are subject to notification. The regulations require notification of a serious risk of injury to human health that is relevant to the safety of the drug and that is associated with certain specific actions referred to in subsections C.01.050(2)(a), (b) and (c) taken in any of the specified foreign jurisdictions.

Actions relating to communication of risks

A communication of risk referred to in C.01.050(2)(a) is only notifiable if all 4 of the following elements are met:

1. A risk has been publicly communicated by either
    a. a foreign regulatory authority on Part A of the list, or
    b. any person authorized to manufacture or sell a drug within the jurisdiction of a foreign regulatory authority on Part A of the list
2. The risk communicated is related to an authorized drug that is part of a class of drugs referred to in C.01.050(4) of the Food and Drug Regulations as being within the scope of foreign action notifications
3. The risk communicated is relevant to the safety of the drug
4. The risk communicated involved a serious risk of injury to human health

While it is normal for MAHs to discuss serious risks with regulatory authorities, such discussions do not always result in actions taken to mitigate them. A request for data from

a regulatory authority does not need to be reported to us. We interpret C.01.050(2)(a) to include only communications taken to mitigate risks and identify them publicly, such as:

- public warnings or advisories
- letters to health professionals or patient groups
- completed signal reviews or related information (such as a summary or key information) posted on regulatory web sites to identify and mitigate a serious risk of injury to human health

Examples include:

- A manufacturing issue that poses a serious risk of injury to human health is communicated by the foreign regulatory authority or a manufacturer in a safety notice.
- Serious risks related to a new contraindication or warning is communicated by the foreign regulatory authority or a manufacturer.
- Another country's regulatory authority issues a public warning about a prescription drug after learning about a serious, previously unknown safety issue when users take the drug along with certain foods.
- A public safety communication is issued about serious human health risks from accidental self-injection of a drug during administration to an animal.

Note: foreign actions involving communication of a decision that a risk should continue to be monitored as part of routine pharmacovigilance activities, or a publication where an adverse event is considered a potential signal are out of scope.

Actions relating to label changes

A label change referred to in C.01.050(2)(b) is only notifiable if all 5 of the following elements are met:

1. A change has been made to the labelling of the drug following approval by the foreign regulatory authority.

2. The label change is for an authorized drug that is part of a class of drugs referred to in C.01.050(4) of the Food and Drug Regulations as being within the scope of foreign action notifications.

3. The label change is relevant to the safety of the drug.

4. The safety issue addressed by the label change involved a serious risk of injury to human health.

5. The label change has either been

    a. communicated to a foreign regulatory authority on Part B of the list, or

    b. specifically requested by a foreign regulatory authority on Part B of the list

Examples include:

- change to dosages, indications, directions for use, warning statements, contraindications, interactions, changes to mitigate incorrect use made in response to a serious risk of injury to human health
- the label of a generic medication changed to include warnings about serious health effects in children under the age of 12
- the warnings section of the label for a veterinary topical product updated to mitigate serious human health risks associated with administering the product to animals

While it is normal for MAHs to discuss serious risks with regulatory authorities, such discussions do not always result in actions taken to mitigate them. A request from a regulatory authority for a label change or for information should not be reported to us unless all elements for notification are met.

Notification is still required even when the serious risk is already labelled in the Canadian product monograph. We will make an assessment to determine if the risk is adequately labelled in the appropriate section of the Canadian product monograph or whether foreign regulatory actions introduce new considerations for the Canadian context, such as additional mitigation measures, or emerging safety data.

Note: A risk being removed from a label because it is no longer believed to pose a serious risk to human health is not required to be notified under this provision.

Actions relating to recalls, reassessments and suspensions or revocations of authorizations including licenses

Actions relating to recalls, reassessments and suspensions or revocations of authorizations including licenses referred to in C.01.050(2)(c), are only notifiable if all 5 of the following elements are met:

1. One of the specified actions has taken place
2. The action is related to a drug that is part of a class of drugs referred to in C.01.050(4) of the Food and Drug Regulations as being within the scope of foreign action notifications
3. The action is relevant to the safety of the drug
4. The action was taken to address a serious risk of injury to human health
5. The action has taken place within the jurisdiction of any foreign regulatory authority on Part C the list

Examples include:

- Reassessments of market authorizations resulted in new or additional risk minimization measures or enhanced vigilance requirements for a drug.
- Equivalent to a Type I recall in Canada, a prescription drug is recalled in another jurisdiction because using or being exposed to it may cause serious adverse health consequences or death.
- The regulatory authority in another country suspends a manufacturer's licence for a non-prescription drug that's administered under healthcare professional supervision because a critical deficiency in good manufacturing practice poses a serious risk of injury to human health.
- Another country's regulatory authority revokes the licence of a prescription drug when a rare but serious adverse reaction is discovered after many years on the market.
- Another country's regulatory authority suspends a drug's marketing authorization pending a safety assessment of its risk profile due to its frequent off-label use.

- Suspending or revoking manufacturing authorizations, such as drug establishment licences, due to a noncompliance that introduced a serious risk.
- Suspending or revoking market authorizations due to unacceptable benefit-risk profile.

Multiple actions taken in multiple jurisdictions

An issue may give rise to more than one notification as different actions in different jurisdictions are taken in response to it. For example, a serious risk of injury may lead to a label change in one jurisdiction and a recall in another. In this case, the label change and the recall are each notifiable.

Where you become aware of multiple jurisdictions taking the same action, you must only notify us of the earliest action. Once you have notified us of an action taken in 1 country, you do not need to notify us of the same actions taken in other countries that:

- address the same issue **and**
- involve the same safety information

However, if multiple products or lots are affected by a single action related to GMP or quality issues, you may submit a single notification provided that it clearly identifies all affected product lots and relevant health risks.

If different actions are taken in multiple jurisdictions for the same issue, separate notifications are required, each with their own submission sequence. Examples of actions that are different and must each be reported include:

- a warning is added to a label in 1 jurisdiction and a public advisory is issued in another jurisdiction instead to address the same issue
- a recall is issued to the wholesale level in 1 jurisdiction and to the retail level in another jurisdiction
- a warning is added to a label in 1 jurisdiction and another jurisdiction issues a recall on the same issue

Content of notification

In order to comply with the regulations, you must provide the following information in your notification:

- name of the MAH and contact information and name of the Canadian importer, if different
- brand name(s) and DIN(s) of the relevant Canadian drug(s)
- name of the authorization holder in the foreign jurisdiction
- foreign jurisdiction involved in the action
- actions taken in the foreign jurisdiction in respect of serious risk of injury to human health
- information about the risk, including when it occurred
- for issues of serious risk related to GMP or manufacturing site, or product-specific quality issue, provide the foreign site where the issue took place (if different from the manufacturing site), if available and if known

You should also:

- provide the brand name of the foreign drug
- for issues of serious risk related to GMP or manufacturing site, or product-specific quality issue, provide batch/lot number(s) and expiration date(s) of the relevant Canadian drug(s), if applicable and known
- provide evidence that triggered the action, if available
- provide details of the actions taken in the foreign jurisdiction, including who took the specified action and reason for the action.
- provide available supporting information about the action taken by the foreign regulatory authority or by the MAH in the foreign jurisdiction
    - for example, a report, if available, from the foreign regulator, or information provided via an attachment or weblink

- list the actions taken in Canada following the serious risk
- give available details of follow-up actions you currently intend to take, and when, in Canada, such as:
    - file a submission to update the Canadian product monograph with supporting data
    - submit an updated RMP
    - issue a risk communication
    - discontinue the drug in Canada
    - recall relevant lots of the drug from the market and submit a recall notification
- provide a rationale for the follow-up actions you have taken or intend to take in Canada
- provide a concise scientific rationale if you decide not to take further action in Canada

Follow-up actions after the 72-hour deadline

You should continue to perform relevant signal management activities. If you do not make a decision about follow-up actions in Canada before the 72-hour deadline, you:

- must still report the foreign action before the deadline
- should indicate in your report that you have not yet decided on which follow-up actions to take in Canada

For issues relating to a safety signal or toxicity, adverse reactions or unsafe use, once you have made a decision regarding a follow-up action in Canada, you should notify us of your intended actions using the reporting form unless this has been done through other means (for example, by filing a submission or submitting an updated RMP).

Note: Follow-up reporting is not requested for GMP or manufacturing site, or product-specific quality issue notifications. However, C.01A.013 and C.01.051 notifications must still be submitted as required.

We will contact you if we need more information or if follow-up action requires further discussion.

How to provide required information

To provide information or follow-ups about foreign actions involving:

- safety signals or toxicity
- adverse reactions
- unsafe use

Relating to **human** pharmaceutical or biologic drugs or **veterinary** drugs, use the Notifying Health Canada of foreign actions in respect of a serious risk of injury to human health (safety signal or toxicity, adverse reactions, unsafe use) form.

The **form** is available upon request by emailing no-reply.MHPD.publications.DPSC.non-reponse@hc-sc.gc.ca. Ensure that only the exact text "Notifying Health Canada of foreign actions form" is in the subject line of the email.

Once complete, submit the PDF form in an electronic common technical document (eCTD) or non-eCTD format via the electronic submissions gateway (ESG) using the regulatory enrolment process (REP).

Note: a cover letter is not required with the initial filing of a submission containing the PDF form.

For information on transactions in eCTD or non-eCTD format, consult:

- Filing submissions electronically

Note: You may submit the PDF form via email, with an explanation, to meet the compliance requirement, but only if there are technical issues that prevent the submission of the PDF form within the 72-hour timeframe. This should be followed by notification through the ESG without delay. The ESG submission should include a copy of the email correspondence and the PDF form.

To provide information about foreign actions involving:

- GMP or manufacturing issues
- product-specific quality issue
- a product recall

Relating to either **human or veterinary drugs**, use this online form.

Upon submission of the information, you may maintain the following for your records:

- for notifications submitted using the PDF form as eCTD or non-eCTD transactions via the ESG, acknowledgement receipts that will be generated.
- for notifications submitted through the online form, an automatic confirmation that will be sent by email.
- for notifications submitted via email (due to technical issues), an acknowledgment email that will be provided

Language of notification

The notification of foreign action may be submitted in either English or French.

Other documents such as foreign recall notices and risk communications relating to the issue are not required by regulation. If we request them, they may be provided in their original language.

Information reports and public accessibility

Information submitted to us is subject to the Privacy Act.

These reports supplement existing regulatory monitoring. As such, they will be handled and shared according to the provisions in place for the results of safety reviews and establishment licensing decisions. These include:

- regulatory transparency and openness
- safety reviews
- powers to require and disclose information

Foreign action involving significant change

In determining whether a foreign action is relevant to the safety of your drug, you may conclude that the information provided about the foreign action also represents a significant change in what is known about the risks and benefits of the drug. If this occurs, the Food and Drug Regulations require you to notify us of both the foreign action and the significant change.

To avoid duplication and to ease burden, you may satisfy both requirements by notifying us of both the foreign action and the significant change without delay, within 72 hours, using the notification of foreign action form. You are responsible for retaining sufficient documentation to demonstrate compliance with both requirements.

For more information on the requirement to report a significant change, consult:

- Guidance on preparing and submitting summary reports for marketed drugs and natural health products

Scanning for foreign regulatory actions

Environmental scanning is a fundamental element of safety monitoring.

You are expected to collect safety information in ways that promote compliance with this regulation. This could include communicating regularly and often with your affiliates operating in the specified foreign jurisdictions. Communication could involve:

- ensuring the local affiliates make their global head office aware of the types of issues and products referred to in the regulation
- determining the relevance of the actions to products sold in Canada

If you are not affiliated with foreign companies, you are expected to:

- collect and assess information about safety issues and adverse events in conducting pharmacovigilance activities

- pay particular attention to information from listed authorities for relevant activities (for example, communication of risks, changes to labelling, recalls)
- scan for information that may inform an assessment of the seriousness of the risk to human health **and**
- determine relevance to prescription or non-prescription drugs that you sell in Canada and are administered under the supervision of a practitioner

Environmental scanning for relevant safety information is part of routine vigilance. It should be conducted regularly and documented. The timing, frequency, scope and method of scanning depend on such factors as the product's risk profile, known or specific emerging issues and the scheduling of the summary report.

Identified and potential safety issues, as well as knowledge gaps (for example, toxicity in vulnerable groups, interactions with other products, emergent use patterns) may require more active assessment.

The documented process should also include an assessment of whether the risk to human health meets the threshold for notifying us.

For more information on environmental scanning, global affiliates, cross-licensing and contractual agreements, consult:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

Assessing compliance

Documentation for receiving, assessing and reporting foreign regulatory actions is critical to show that you are complying with the regulations.

Documentation could include, for example:

- relevant quality documents, such as standard operating procedures or contractual agreements
- operational records that show information received and assessed, decisions and actions taken

We may:

- assess your ability to monitor and assess foreign regulatory actions, including determining relevance of the serious risk of injury to human health to safety of the drug, based on your systems, records and procedures and your performance in completing these activities
- verify compliance with these regulations by reviewing incoming reports against information we gather through other means, such as:
    - agreements with foreign regulatory authorities
    - our own environmental scans

Training records for qualified people should be documented and the training process described in a way that would enable internal and regulatory auditing.

For more information, consult:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

Contact us

Notifications of foreign actions should be submitted using the appropriate PDF or online forms.

Contact us if you have questions relating to this guidance as follows:

- Safety signals or toxicity, adverse reactions or unsafe use of human pharmaceuticals (non-biologic): mpb.rpm-gpr.bppc@hc-sc.gc.ca
- Safety signals or toxicity, adverse reactions or unsafe use of human biologics: bbrs.rpm-gpr.bbra@hc-sc.gc.ca
- Safety signals or toxicity, adverse reactions or unsafe use of veterinary drugs: pv-vet@hc-sc.gc.ca
- GMP and manufacturing issues: foreign.site-etranger@hc-sc.ca.ca

- Product specific quality issues or recalls: hpce-cpsal@hc-sc.gc.ca

For inquiries about this guidance document, include the phrase "Guidance on notifying Health Canada of foreign actions" in the subject line. Submit your request by email: mhpdpolicy-politiquesdpsc@hc-sc.gc.ca.