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Foreign risk notification for medical devices guidance document



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Également disponible en français sous le titre :
Lignes directrices sur la notification des risques survenus à l'étranger liés aux instruments médicaux

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Forward

Guidance documents provide assistance to industry and health care 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 must be 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 the Regulations and other applicable guidance documents.

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Background

This guidance document is to help holders of Canadian authorizations for medical devices understand and comply with the regulatory requirements on foreign risk notification (FRN). The requirements deal with serious risk of injury to human health and are set out in sections 61.2 and 61.3 of the *Medical Devices Regulations* (the Regulations).

The FRN requirements are intended to:

- improve the collection and assessment of new information concerning actions taken in response to any serious risk of injury to human health relevant to the safety of a medical device in certain foreign jurisdictions
- help determine an appropriate response in Canada to these risks

Important risks may be more likely to be detected in jurisdictions outside Canada where medical devices have been sold for a longer time or at a higher volume.

Under the FRN sections of the *Regulations*, actions by manufacturers or regulatory agencies to mitigate a serious risk in specified foreign jurisdictions must be reported to Health Canada. The reporting requirement applies to a medical device licence holder for a Class II to IV device, an establishment licence holder that imports Class II to IV devices (“importer”), and a holder of an authorization under subsection 83(1) of the Regulations (Investigational Testing Authorization). As a licence holder, a “private label manufacturer” (a person who sells a private label medical device under their own trademark) is responsible for complying with the requirement to submit FRN reports.

This requirement to notify Health Canada about foreign risks replaces the requirement for holders of Canadian authorizations for Class II to IV devices to report an incident that occurs outside of Canada, as required under the former section 59 of the Regulations.

Note: The FRN provisions under sections 61.2 and 61.3 don’t apply to holders of authorizations for the sale/import of Class I devices. However, the incident reporting requirements under subsection 59(1.1) apply to Class I manufacturers and importers.

Definitions

Notifiable action:

An action taken in one of the specified jurisdictions relating to the safety of a medical device for the purpose of mitigating or eliminating a serious risk of injury to human health. Notifiable actions include risk communications, recalls, label changes, reassessments of authorization, and suspensions or revocations of authorization to prevent serious risk of injury to human health. An action relating to the medical device may include issues regarding the quality, effectiveness or performance characteristics of the medical device, if safety was impacted.

Regulatory agency:

A government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements. (section 1, *Medical Devices Regulations*)

Revocation:

An action taken by an authority to revoke, cancel or indeterminately suspend an authorization designed to mitigate or eliminate a serious risk of injury to human health.

Serious risk of injury to human health:

A hazard associated with the medical device that is relevant to the safety of the medical device and that, without risk mitigation, would likely:

- be life-threatening
- result in persistent or significant disability or incapacity
- require inpatient hospitalization or prolonged hospitalization
- result in a serious health consequence such as loss of function or debilitating chronic pain
- result in death

For a discussion of “serious risk,” please refer to annex A of the [Amendments to the Food and Drugs Act: Guide to New Authorities](#).

Responsibilities and notifiable actions

Who's responsible for foreign risk notification

The reporting requirement applies to a medical device licence holder for a Class II to IV device, an establishment licence holder that import a Class II to IV device (“importer”), and a holder of an authorization under subsection 83(1) of the Regulations (Investigational Testing Authorization) for a Class II to IV device. As a licence holder, a “private label manufacturer” (a person who sells a private label medical device under their own trademark) is responsible for complying with the requirement to submit FRN reports. (See section 61.2 of the Regulations.)

The exception is if the manufacturer provides Health Canada with written authorization permitting the importer to report on its behalf. (See subsection 61.3(1) of the Regulations.) If a manufacturer wants to permit the importer of the device to submit FRN reports to Health Canada on the manufacturer’s behalf, Health Canada must be notified in writing, by email at: MDCU_UCIM@hc-sc.gc.ca.

The following form is recommended to be used to notify Health Canada that an importer has been permitted to submit FRN reports on a manufacturer’s behalf: “Authorization for medical devices mandatory problem, foreign risk notification, and recall reporting according to sections 61.1, 61.3, and 65.1 of the Medical Devices Regulations and/or designation to Act as the Canadian regulatory contact”. To receive a copy of the form, contact Health Canada’s Regulatory Operations and Enforcement Branch at MDCU_UCIM@hc-sc.gc.ca.

Note: Private label manufactures are considered to be “manufacturers” and, therefore, are responsible for complying with Section 61.3 of the Regulations. If a private label manufacturer wants to permit an importer to submit FRN reports on their behalf, Health Canada must be notified as described above.

Manufacturers are responsible for ensuring that information in FRN reports is complete and accurate. This is true even if the importer has been permitted to report on the manufacturer’s behalf.

Holders of a medical device establishment licence for distribution, but not for importation (i.e., “distributors”) are not responsible for submitting FRN reports.

Notifiable actions that require foreign risk notification

Medical device licence holders, importers, and Investigational Testing Authorization holders of Class II to IV devices must notify Health Canada when there’s a serious risk of injury to human health concerning a device authorized for sale in Canada and when:

- a notifiable action is taken by a foreign regulator of a certain jurisdiction or
- the authorization holder takes notifiable actions in certain foreign jurisdictions

Please refer to the [List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations](#).

Notifiable actions that constitute a serious injury to human health include:

- public risk communication
- labelling change that has been communicated to or requested by a relevant foreign regulatory agency
- recall (e.g., product withdrawal)
- reassessment of an authorization
- suspension or revocation of an authorization

Regulatory requirements and definitions may differ in various foreign jurisdictions and from those in Canada. The definition of the action in the foreign jurisdiction(s) should be used when determining whether an FRN

report must be submitted to Health Canada. For example, if an action in a foreign jurisdiction is considered a “recall” in that jurisdiction, but this same action is not considered a recall according to the Canadian Medical Devices Regulations, it is a “notifiable action” for the purposes of FRN reporting.

Note: Submission of a FRN report is **NOT** required if:

- The action taken is **not** in response to a serious risk of injury to human health
- The action was taken in a jurisdiction that is **not** included in the *List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations*
- A foreign notifiable action is being contemplated, but has not yet taken place
- **Within 72 hours**, another method has been or will be used to notify Health Canada of action(s) taken in Canada to mitigate or eliminate the serious risk. For example, this could include submission of a recall notification as required under sections 63-65 of the Regulations. If, however, action is being **planned** in Canada, but will not have taken place within the 72 hour FRN reporting requirement, a FRN report must be submitted.

Examples of notifiable actions where the device is authorized for sale in Canada:

- A regulatory agency undertakes a reassessment of the authorization for a medical device due to finding that there’s a potential new or increased serious risk of injury to health from using the device.
- The labelling of a medical device is misleading. This is identified as the cause of a new or increased serious risk of injury to health. As a result, the regulatory agency in the jurisdiction suspends the device authorization until the labelling is changed.
- A foreign regulatory agency or a manufacturer issues a communication informing the public that patients with certain characteristics shouldn’t use a medical device as there may be a new or increased serious risk of injury to health.
- A medical device company or regulatory agency in a foreign jurisdiction conducts a lot-specific recall to mitigate a potential serious risk of injury to human health (for example, death or hospitalization) from a medical device.
- A manufacturer identifies a new or increased serious risk of injury to health from the use of its medical device. As a result, it has recalled the product from the market in one or more foreign jurisdictions.

Examples that don’t require foreign risk notification:

- A manufacturer of a medical device issues a public communication about a product enhancement that has been implemented for reasons unrelated to mitigation or elimination of a serious risk of injury to health.
- A manufacturer of a Class II medical device has received complaints from users of its device, describing that hospitalization has taken place as a result of complications related to using it. The manufacturer concludes that it isn’t necessary or hasn’t been requested by the foreign regulatory agency to undertake any of the “notifiable actions” listed above.
- A manufacturer of a Class I device has received complaints from users of its device, describing that hospitalization has taken place, in any foreign jurisdiction, as a result of complications related to using it. Incident reporting under subsection 59(1.1) applies instead.
- A periodic review required by legislation in a foreign jurisdiction is submitted to one of the specified regulatory agencies or jurisdictions.
- A serious risk of injury to health is identified and a risk communication is issued in one of the specified foreign jurisdictions, but the device isn’t authorized for sale in Canada.
- A device is associated with an injury in one of the specified foreign jurisdictions, but neither the manufacturer nor the regulatory agency has yet to take action to manage or mitigate future risk.
- A licence is suspended in one of the specified foreign jurisdictions for a reason that is not relevant to the safety of the device, such as not paying the required processing fee.

What, when and how to submit

Information to submit

To comply with the Regulations, licence holders, importers and/or investigational testing authorization holders of Class II to IV medical devices must provide the following information:

- the foreign regulatory agency that took the notifiable action and/or the foreign jurisdiction in which the action was taken
- the action taken by the foreign regulatory agency or by the company in the jurisdiction

Where applicable, authorization holders should also provide the following information:

- name and contact information of the medical device authorization holder submitting the report
- brand name and manufacturer of the foreign product
- brand name of the relevant Canadian product
- Canadian authorization number (e.g., medical device licence number)
- product identifier, part number or catalogue number
- lot number
- a description of the reasons for the action, including information about the serious risk being mitigated and what is known about the root cause
- a description of any actions being planned in Canada in response to the identified serious risk
 - provide reference numbers if available
- give a rationale explaining why action isn't warranted if no action is planned in Canada

It isn't necessary to provide the original documents that are issued to health care professionals or to the public as part of the foreign action, such as:

- recall notices
- risk communications
- notifications of label change

However, when describing the notifiable action taken, give enough detail, including how the action taken was communicated. It's important that Health Canada has sufficient information to understand what was shared with health care professionals or the public in the foreign jurisdiction. Health Canada may ask for copies of these documents later.

FRN reports must be in either English or French. Additional documents (for example, recall notices, risk communications) relating to the issue aren't required but may be requested by Health Canada at a later date. These too must be in English or French.

Timelines

An FRN report must be provided within 72 hours of when the authorization holder **receives or becomes aware of** a notifiable action. This will allow Health Canada to consider the situation and understand whether risk mitigation measures should be taken in Canada.

An authorization holder is responsible for identifying and implementing actions to be taken in Canada in order to comply with the Regulations. Submission of a FRN report does not replace the implementation of risk mitigation actions in Canada by authorization holders.

As a reminder, submission of a FRN report is required when the following three conditions have been met:

1. There's a **serious** risk of injury to human health concerning a class II to IV device authorized for sale in Canada;
2. A notifiable action **has been taken** for the purpose of mitigating or eliminating the serious risk; and
3. The action took place within the jurisdiction(s) of one or more regulatory agencies that is included in the *List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations*.

In some cases, one or more notifiable actions in response to a serious risk of injury to human health may be taken in more than one foreign jurisdiction set out in the *List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations*. Similarly, different or additional actions may be taken in different jurisdictions or as more is learned about the risk(s).

A **single FRN report** should be submitted to Health Canada related to serious risk of injury to human health, even if more than one notifiable action is taken and/or if notifiable actions are taken in more than one foreign jurisdiction. If different actions were taken in different jurisdictions, there would be an opportunity on the FRN form to provide a brief description.

Of note, however, a FRN report must be submitted to Health Canada within 72 hours after the holder receives or becomes aware of information that a notifiable action has taken place in response to a serious risk. Therefore, as more is learned about the risk, it is possible that **additional actions** will be taken or that actions will be taken in **additional jurisdictions** following the submission of an initial FRN report.

In this situation, **additional FRN reports** must be submitted to Health Canada within 72 hours. Any additional reports should:

- refer to a previously submitted relevant FRN report; and
- only include information specific to the new information (i.e., additional actions and/or jurisdictions).

How to submit

The [Medical Device Foreign Risk Notification Form](#) includes all necessary fields and instructions to support the submission of information required by sections 61.2 and 61.3 of the Regulations (Serious Risk of Injury to Human Health).

FRN reports should be submitted to Health Canada by email (as an attachment) at:

mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca.

In the subject line of the email, it should be specified that a "FRN report" is being submitted.

Health Canada will follow up with the submitter only if a FRN report is incomplete or if additional information is necessary to understand the situation.

Monitoring, compliance and enforcement

Monitoring

Authorization holders are encouraged to collect safety information in ways that promote compliance with the requirement to notify Health Canada of notifiable actions. This may include facilitating timely communication between themselves and their counterparts operating in the relevant jurisdiction.

For example, the monitoring process authorization holders may include:

- monitoring information sources from listed regulatory agencies for relevant actions (for example, communicating risks, making changes to labelling, recalls)
- scanning for information on “serious risk of injury to human health” related to the safety of a medical device

However, actions that are monitored, should be consistent and follow a documented procedure in a way that promotes compliance with the Regulations.

Compliance and enforcement

The new amendments to the *Medical Devices Regulations* will not alter existing compliance and enforcement mechanisms under the provisions of the Regulations.

Health Canada will work with authorization holders to achieve compliance with all regulations by addressing issues and providing the necessary guidance documents and templates.

The manufacturer and importer should have in place and maintain records of a monitoring process, which Health Canada may assess when verifying compliance. Records could include, for example:

- a documented process for the receipt, assessment and reporting on notifiable actions (includes relevant quality documents, such as standard operating procedures)
- complete operational records so the regulator is able to determine compliance (for example, showing information received and assessed, decisions and actions taken)

Health Canada may also verify compliance by reconciling incoming reports with the information we collect through other means. Information may include mutual recognition agreements with foreign regulatory authorities or environmental scans done by Health Canada.

In the case of non-compliance, we may take compliance and enforcement action in accordance with the risk-based approach outlined in the [compliance and enforcement policy for health products \(POL-0001\)](#). If non-compliance isn't resolved, Health Canada may apply the provisions of the *Food and Drugs Act* and its associated regulations (sections 61.2 and 61.3 of the Regulations, and outlined in the policy).

When determining which enforcement measures are appropriate, for the purposes of sections 61.2 and 61.3 of the Regulations, we consider whether non-compliance poses a serious health risk to Canadians.