Health Canada Santé Canada

Foreign risk notification for medical devices guidance document

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Lignes directrices sur les communications étrangères relatives aux risques liés aux instruments médicaux

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Background

This guidance document is to help manufacturers and importers of 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 FRN requirements are intended to:

- improve the collection and assessment of new information concerning 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 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 and an establishment licence holder that imports Class II to IV devices.

This requirement to notify Health Canada about foreign risks replaces the requirement for manufacturers and importers of 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 establishment licences for the sale/import of Class I devices. However, the incident reporting requirements under section 59(1.1) apply to Class I manufacturers and importers.

Note about guidance documents in general

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.

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, 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 deterioration in 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

Both the medical device licence holder and holder of an establishment licence to import Class II to IV medical devices are responsible for providing Health Canada with information under the FRN requirements. (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 section 61.3(1) of the *Regulations*.)

Manufacturers are still responsible for ensuring that the information in the report is complete and accurate.

Notifiable actions that require foreign risk notification

Medical device licence holders and importers 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 licence holder and importer take 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, including product withdrawal
- reassessment
- suspension or revocation of an authorization

Note: The regulatory requirements only apply when a foreign action has taken place, not when action is being contemplated.

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

- A regulatory agency requires a manufacturer to reassess 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 section 59(1.1) applies.
- 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 and/or importers of Class II to IV medical devices must provide the following information:

- 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, licence holders and/or importers should also provide the following information:

- name and contact information of the medical device licence holder and/or importer
- brand name and manufacturer of the foreign product
- brand name of the relevant Canadian product
- Canadian 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 and/or already taken in Canada by the manufacturer 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 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

A foreign risk notification (FRN) report must be provided within 72 hours of when the manufacturer or importer receives or becomes aware of a notifiable action. This will allow Health Canada to consider the situation and determine whether adequate risk mitigation measures have also been taken in Canada.

A manufacturer or importer is responsible for identifying and implementing actions to be taken in Canada in order to comply with the *Regulations*. Submission of a FRN does not replace the implementation of risk mitigation actions in Canada by authorization holders.

How to submit

Reporting can be submitted online using an electronic form. This form will be available on Canada.ca

Monitoring, compliance and enforcement

Monitoring

Manufacturers and importers 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 for manufacturers and importers 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 *Regulation*s.

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 manufacturers 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 we 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, 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.