QUESTIONS & ANSWERS

Sections 61.2 to 61.3 – Serious Risk of Injury to Human Health Foreign Risk Notification

Q14: As specified in the Regulations under section 61.2(2)(c), the following are included among the "notifiable actions" with respect to FRN reporting requirements: recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device. What constitutes a "reassessment of an authorization"?

Q15: As specified in the Regulations under section 61.3, a manufacturer may permit the importer of the device to submit FRN reports to Health Canada on the manufacturer's behalf. How must the manufacturer notify Health Canada that permission has been given?

Q16: If a manufacturer already allows the importer to submit Mandatory Problem Reports and recalls on their behalf (under sections 61.1 and 65.1, respectively), does Health Canada still need to be notified that the same permission is granted for submission of FRN reports (under section 61.3)?

Q17: Do FRN requirements apply to a device that is authorized in Canada for investigational testing involving human subjects, under Part 3 of the Regulations?

Q18: As specified in Section 61.2(2) of the Medical Devices Regulations, the FRN requirements apply when there is a "serious risk of injury to human health". Should probability of occurrence be considered among the factors used when making a determination about serious risk?

Q19: If an authorization holder has a very large number of authorizations and/or devices relevant to a notifiable action, this may require the submission of a large number of FRN reports. Are there alternative options for reporting in this situation?

Q1: Who is responsible for submitting foreign risk notification (FRN) reports?

Holders of therapeutic product authorizations are responsible for submitting FRN reports. As specified in sections 61.2(1) and 88.1 of the Medical Devices Regulations (the Regulations), this includes holders of:

1. a Medical Device Licence;
2. a medical device establishment licence to import Class II, III or IV medical devices (i.e., "**importers**"); and
3. an authorization issued under subsection 83(1): investigational testing involving human subjects

As defined in the Medical Devices Regulations, a "**manufacturer**" means a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

A "private label manufacturer" who holds a Medical Device Licence is considered to be a manufacturer and, therefore, is responsible for complying with the Medical Devices Regulations.

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

Q2: Where is the FRN form available?

The form will be made available by email request. Please contact Health Canada's Medical Devices Directorate at mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca to request a blank FRN form.

Q3: Must a FRN report be submitted to Health Canada for any "notifiable action" that has taken place outside of Canada (i.e., communication, labelling change, recall, reassessment, and suspension or revocation of authorization)?

No. Submission of a FRN report is not always required when a notifiable action has taken place outside of Canada (such as a labelling change or a recall).

If one or both of the following situations apply, submission of a FRN report to Health Canada is not required:

- The action was **not** taken in response to a "serious risk of injury to human health"
- The action was **not** taken in a jurisdiction is included in the *List of regulatory agencies and foreign jurisdictions*

Submission of a FRN report **is** required when the following **three conditions** have been met:

1. There is a "serious risk of injury to human health" concerning a device authorized for sale in Canada;
2. A notifiable action **has been taken** in a foreign jurisdiction 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 and foreign jurisdictions*.

Note: Submission of a FRN report is **not** required if, **within 72 hours** of receipt or awareness of a notifiable action, **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 (e.g., submission of a recall notification).

Q4: Regulatory requirements and definitions may differ in various foreign jurisdictions and from those in Canada. What definitions of notifiable actions should be used when determining whether a FRN report must be submitted to Health Canada?

The definition of the action **in the foreign jurisdiction(s)** should be used.

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.

When describing any actions being planned in Canada in response to the identified serious risk, there would be an option on the FRN form to indicate whether a different action will be taken in compliance with Canadian regulatory requirements.

Q5: Section 61.2(3) specifies, "The information shall be submitted to the Minister within 72 hours after the holder receives or becomes aware of it, whichever occurs first." Does the 72 hours refer to business hours or actual hours?

The requirement to inform the Minister within 72 hours refers to **actual hours**.

Q6: Section 61.2(3) specifies, "The information shall be submitted to the Minister within 72 hours after the holder receives or becomes aware of it, whichever occurs first." When does the clock start?

The 72-hour clock starts when the therapeutic product authorization holder **receives or becomes aware** (whichever occurs first) of information that one or more notifiable actions outlined in section 61.2(2)(a)(b)(c) **has taken place**. Therefore, if an action is being considered, but has not yet begun, the clock has not started.

Q7: In some cases, one or more notifiable actions in response to a serious risk of injury to human health may be taken in one or more foreign jurisdictions set out in the List of regulatory agencies and foreign jurisdictions. In such situations, must separate FRN reports be submitted for each jurisdiction and/or for each action?

No. 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. In this situation, there would be an option on the FRN form to select all jurisdictions and actions that apply. If different actions were taken in different jurisdictions, there would also 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 **update reports** should:

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

Q8: Does the submission of a FRN report include preliminary and final reports?

No. Unlike for mandatory problem reporting of incidents, the requirement to submit a FRN report does not include a separate preliminary and final report. A single FRN report should be submitted to Health Canada.

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 **update reports** should:

- refer to a previously submitted relevant FRN report (i.e., date submitted and licence numbers
- only include information specific to the new actions or jurisdictions.

Q9: Must a FRN report be submitted to Health Canada if action (e.g., recall) has already been taken in Canada in response to the identified serious risk of injury to human health?

No. Submission of a FRN report is not required if, **within 72 hours** of receipt or awareness of a notifiable action, **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, in compliance with the Medical Devices Regulations.
For example, if an action, such as a recall, has already taken place in Canada to mitigate the serious risk, a separate FRN report would not be required. Through notification to Health Canada under Section 64 of the Regulations ("Recall"), Health Canada would determine whether any further actions are necessary.

Q10: Must a FRN report be submitted to Health Canada if action (e.g., recall) is planned in Canada in response to the identified serious risk of injury to human health?

Yes. Submission of a FRN report would be required even if action is planned in Canada in response to the same serious risk. In this situation, the FRN form would allow the reporter to describe the type(s) of action(s) that have been planned in Canada, and to provide a brief description, the anticipated dates of initiation and completion, and any relevant reference numbers.

Q11: Must a FRN report be submitted to Health Canada if the serious risk being eliminated or mitigated in a foreign jurisdiction is not relevant in Canada (e.g., the risk is associated with an indication that is not authorized in Canada)?

Yes. Submission of a FRN report would be required even if the serious risk being mitigated in a foreign jurisdiction is not interpreted to be relevant in Canada.

When describing actions being planned in Canada in response to the serious risk, there would be an option on the FRN form to indicate "no action" and to provide a brief rationale.

For example, the rationale may be that the serious risk is related to an indication that is not authorized in Canada. Sufficient information should be provided to allow Health Canada to understand why action is not considered to be necessary in Canada.

Q12: If a medical device authorization (i.e., licence, establishment licence, or Investigational Testing Authorization) has been issued for a Class II, III or IV medical device, but products have not yet been sold or imported in Canada, do the FRN requirements apply?

Yes. Holders of a Medical Device Licence (MDL) (including private label manufacturers), holders of a medical device establishment licence (MDEL) to import Class II, III, or IV medical device ("importers"), and holders of an authorization for investigational testing must submit a FRN report when the three conditions outlined in the Medical Devices Regulations have been met:

1. There is a "serious risk of injury to human health" concerning a device authorized for sale in Canada;
2. A notifiable action **has been taken** in a foreign jurisdiction 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 and foreign jurisdictions*.

It is required to report in this situation because products that are authorized for sale in Canada must continue to meet safety and effectiveness requirements as specified by the Medical Devices Regulations. Certain actions taken to mitigate serious risk of injury to human health, such as changes to the labelling, would be important to the safety of Canadians in anticipation of initiation of sale or importation. Other actions, such as risk communication or product withdrawal, may not be considered relevant in Canada if sale or importation has not yet occurred. In this situation, there would be an opportunity on the FRN form to explain why action is not planned in Canada.

Q13: As specified in section 59(1) of the Regulations, Mandatory Problem Reporting of incidents that occur outside of Canada will continue to be required for class I medical devices once FRN reporting requirements have come into force for class II to IV medical devices on June 23, 2021. How does the requirement to submit FRN reports (class II-IV) differ from the requirement to submit Mandatory Problem Reports of foreign incidents (class I)?

As of June 23, 2021, Mandatory Problem Reporting of foreign incidents by medical device authorization holders is **no longer required** for class II, III, or IV medical devices.

Mandatory Problem Reporting of foreign incidents continues to be required for **class I** medical devices when the following conditions have been met:

- An **incident** comes to their attention involving a device that is sold in Canada and that:
  - is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and
  - has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

Unlike the Mandatory Problem Reporting requirements, FRN reporting requirements are **not** based on awareness of the occurrence of individual incidents. Rather, the submission of a FRN report is required when the following **three conditions** have been met:

1. There is a "serious risk of injury to human health" concerning a device authorized for sale in Canada;
2. A notifiable action **has been taken** in a foreign jurisdiction 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 and foreign jurisdictions*.

Q14: As specified in the Regulations under section 61.2(2)(c), the following are included among the "notifiable actions" with respect to FRN reporting requirements: recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device. What constitutes a "reassessment of an authorization"?

For the purposes of section 61.2(2)(c) of the Medical Devices Regulations, a "*reassessment of an authorization"* is considered to be an assessment that is carried out to determine whether the product continues to meet requirements for authorization and that:

- includes information that has become available since the time of initial authorization and that is related to safety, effectiveness, and/or quality; and
- is undertaken with the objective of determining whether there has been a change to what is known about the benefits and/or risks of a product compared to what was known at the time of authorization.

Q15: As specified in the Regulations under section 61.3, a manufacturer may permit the importer of the device to submit FRN reports to Health Canada on the manufacturer's behalf. How must the manufacturer notify Health Canada that permission has been given?

A manufacturer (including a private label manufacturer) may permit the importer of the device to submit FRN reports to Health Canada on the manufacturer's behalf **if the information that the manufacturer and the importer must submit is identical**.

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.

To notify Health Canada or to receive a copy of the form "**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**", contact Health Canada's Regulatory Operations and Enforcement Branch at MDCU_UCIM@hc-sc.gc.ca.

Q16: If a manufacturer already allows the importer to submit Mandatory Problem Reports and recalls on their behalf (under sections 61.1 and 65.1, respectively), does Health Canada still need to be notified that the same permission is granted for submission of FRN reports (under section 61.3)?

Yes. Health Canada requires that specific permission be provided for FRN reporting. This is because some manufacturers may choose to allow the importer to submit to Health Canada mandatory problem reports and/or recall information on their behalf, but not to grant this same permission with respect to FRN reports (or vice versa).

Updated permission information can be submitted to Health Canada at any time. To update Health Canada or to receive a copy of the form "**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**", contact Health Canada's Regulatory Operations and Enforcement Branch at MDCU_UCIM@hc-sc.gc.ca.

Q17: Do FRN reporting requirements apply to a device that is authorized in Canada for investigational testing involving human subjects, under Part 3 of the Regulations?

Yes. As specified in Section 88.1 of the Regulations, the FRN provisions (61.2(2), 61.2(3), and 61.3) apply in respect of medical devices to which Part 3 of the Regulations applies: "Medical Devices for Investigational Testing Involving Human Subjects". It is further specified in Section 88.1 that references to a "holder of a therapeutic authorization" in Sections 61.2 and 61.3 shall be read as "references to a holder of an authorization issued under subsection 83(1)". Therefore, **the FRN requirements apply to holders of Investigational Testing Authorizations in Canada for Class II-IV medical devices**.

Q18: As specified in Section 61.2(2) of the Medical Devices Regulations, the FRN requirements apply when there is a "serious risk of injury to human health". Should probability of occurrence be considered among the factors used when making a determination about serious risk?

Yes. In Annex A of the document "Amendments to the Food and Drugs Act: Guide to new authorities", considerations are listed to help in the determination of whether a therapeutic product presents a serious risk of injury to human health. As noted, the **probability** of the serious adverse health consequence posed by the medical device should be considered as **one of several elements** when making a determination about seriousness. It is also specified that such a determination is complex, that it should be conducted on a case-by-case basis, and that it should include additional contextual elements when appropriate. Each element included in the determination of serious risk may have a different influence or "weight". When in doubt about the determination of "serious risk", the submission of a FRN report to Health Canada is advised.

Q19: If an authorization holder has a very large number of authorizations and/or devices relevant to a notifiable action, this may require the submission of a large number of FRN reports. Are there alternative options for reporting in this situation?

Yes. A single form can be used to submit for up to three (3) medical devices if they are authorized:

- under a single Medical Device Licence number;
- under a single Medical Device Licence number *as well as* one or more Investigational Testing Authorization numbers; or
- only for Investigational Testing (i.e., no Medical Device License), even if there is more than one Investigational Testing Authorization number.

If more than one (1) Medical Device Licence number or more than three (3) devices are implicated, submit additional forms.

If, however, a **very large** number of authorizations and/or devices are implicated, please contact Health Canada for further guidance at: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca. An alternative approach may be possible, such that the burden on the reporter is reduced while continuing to ensure that the required information is provided for timely review by Health Canada.