Medical Devices Regulations

Post-Market Requirements

Medical Devices Directorate
June 2021
(Updated December 2021)

Santé Canada Health Canada

Outline

- New post-market regulations
- Foreign Risk Notification
  - Objective
  - When to submit a report
  - Implementation details
- Next steps

New post-market regulations

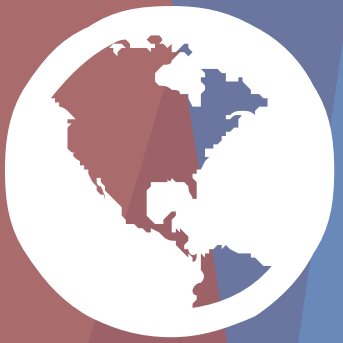
Vanessa's Law Authorities under the Food and Drugs Act

- **61.2 - 61.3:** Requirement for manufacturers to **notify Health Canada of foreign actions** taken in response to serious risk of injury to human health
- **S62.1:** Authority to compel manufacturers to conduct **assessment**
- **S62.2:** Authority to compel manufacturers to **compile information, conduct tests or studies, or monitor experience**

Requirements related to monitoring and surveillance

- **S25(1) & S39:** Authority to request that manufacturers complete **issue-related analysis**
- **S61.4 - 61.5:** Authority to require that manufacturers to conduct **summary reporting & notify of changes** to what is known about benefits and/or risks

Foreign risk notification (FRN)



Submit **information in respect of any serious risk of injury to human health** that the holder receives or becomes aware of and that is relevant to the safety of the device, regarding:

a) **risks that have been communicated by:**
   - **any regulatory agency** that is set out in the *List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations*, or
   - by **any person who is authorized to manufacture or sell** a medical device within the jurisdiction of such a regulatory agency

b) **changes that have been made to the labelling** and that **have been communicated to or requested by any regulatory agency** that is set out in the list

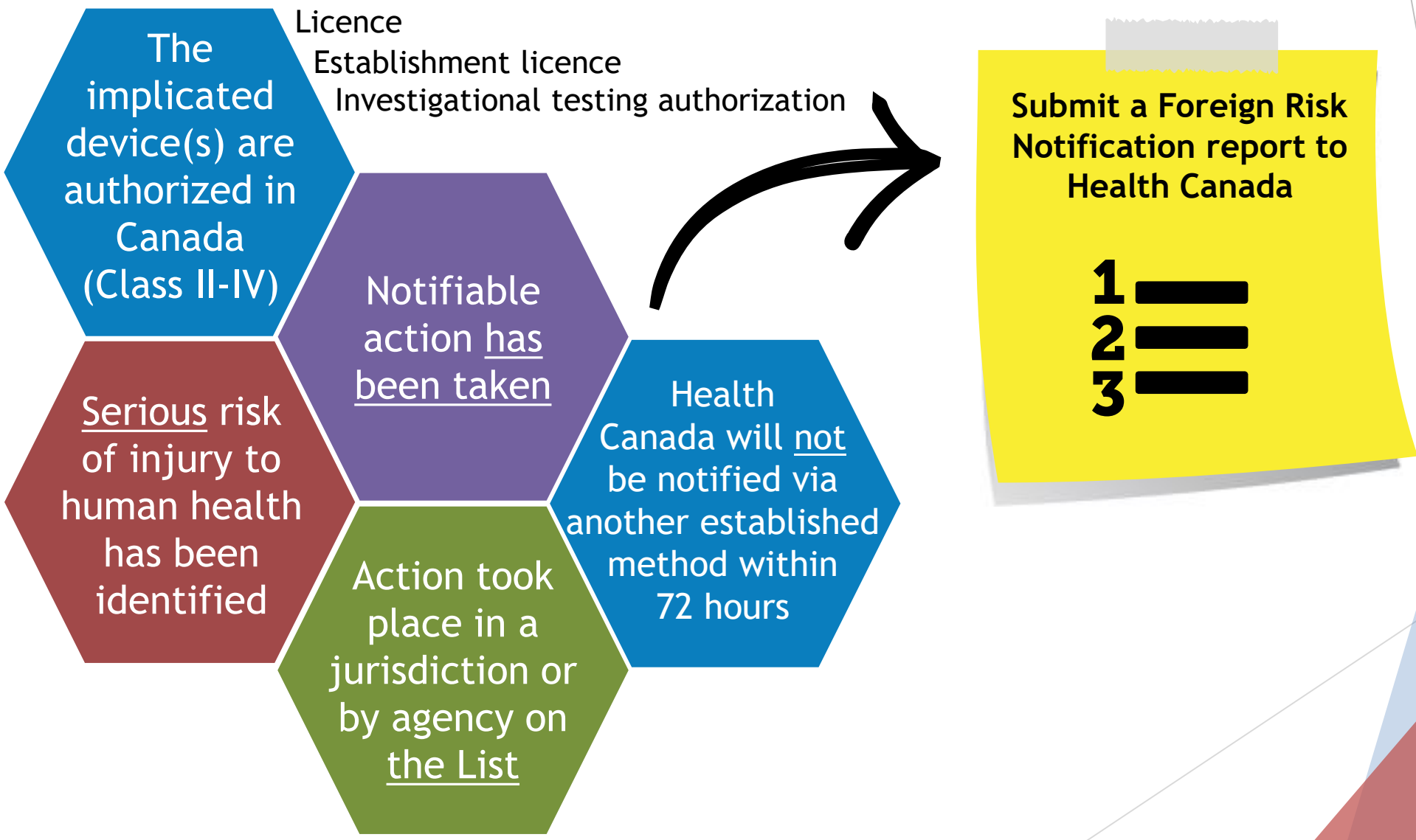
c) **recalls**, **reassessments of authorizations** and **suspensions or revocations of authorizations**, that have taken place within the jurisdiction of any regulatory agency that is set out in the list

FRN: Objectives for Health Canada

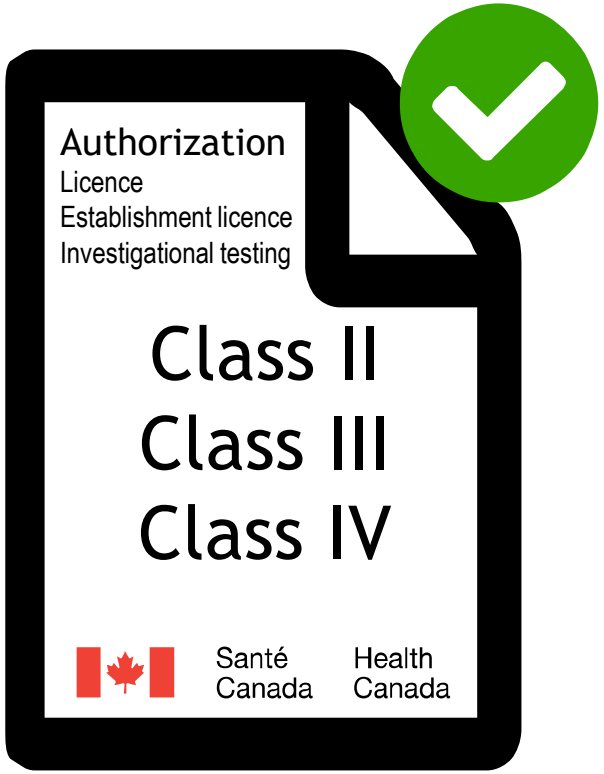
- Improve the collection and assessment of new information concerning serious risk of injury to human health
- Provide oversight of the response in Canada
- Better anticipate the need to provide a regulatory perspective and/or to take additional action

- Hinder industry's timely response to eliminate or mitigate an identified serious risk
- Require the collection and submission of information that has limited value in terms of protecting the health and safety of Canadians

When to submit a FRN report



What medical devices are in scope?



- Certain notifiable actions, such as changes to the labelling, would be important 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. (This could be indicated on the FRN form.)

Note: Even if an authorized device has not yet been sold or imported in Canada, it is in scope.

What is a “serious risk”?

For the purposes of FRN reporting:

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 (e.g., loss of function or chronic pain)
- result in death

Whether the risk is actual or potential, if a notifiable action was taken to eliminate or mitigate the risk, the risk should be considered in scope.

Must a FRN report be submitted for <u>any</u> notifiable action outside of Canada?

Notifiable actions*

- Risk communications
- Recalls
- Label changes
- Reassessments of authorization
- Suspensions or revocations of authorization

Do **not** submit a FRN report if the action:

1. was **not** taken in response to a "serious risk of injury to human health"
2. was **not** taken in a jurisdiction that is included in the "List of regulatory agencies and foreign jurisdictions"

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

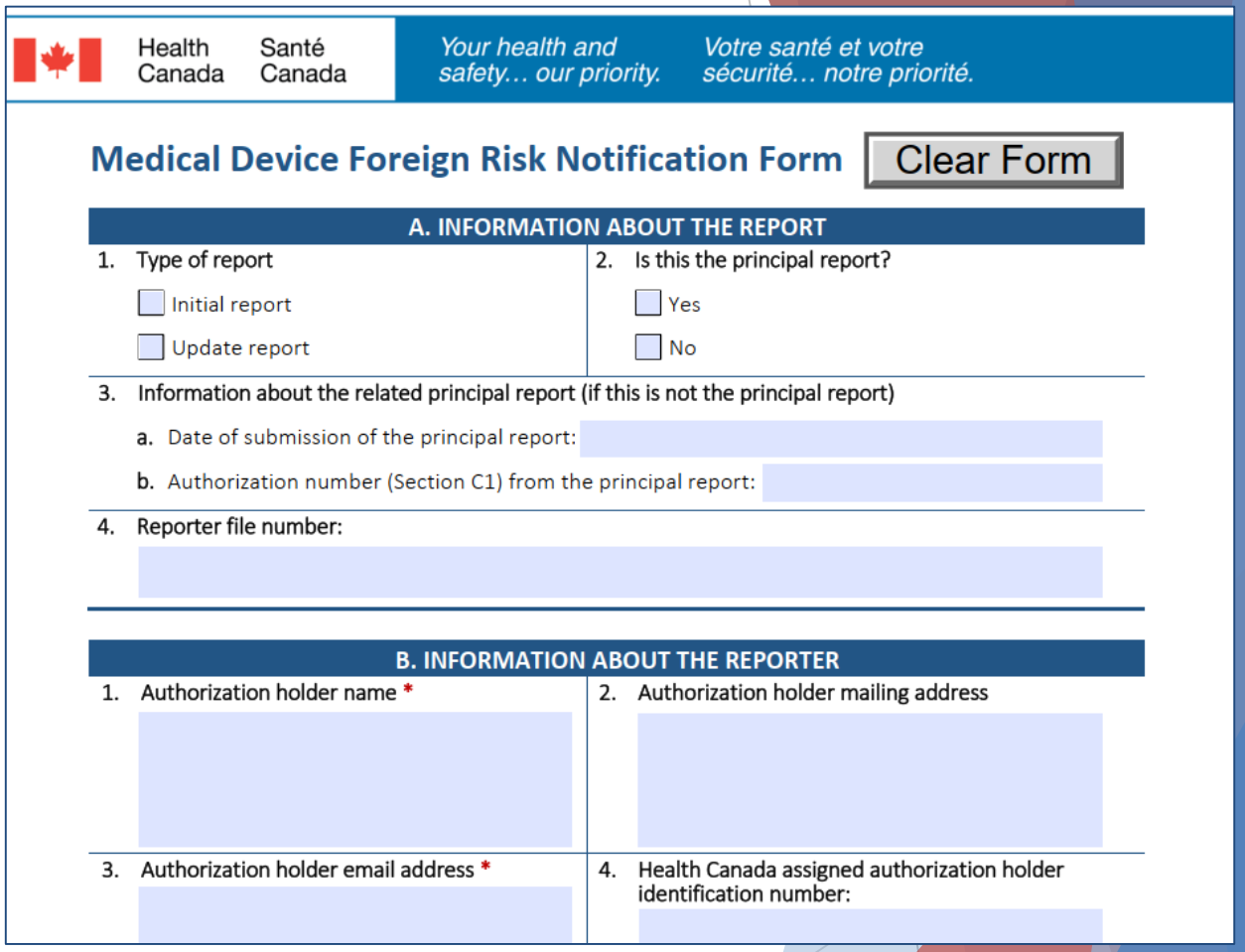
Must a FRN report be submitted if action has already been taken in Canada?

- **No.** Submission of a FRN report is not required if, **within 72 hours** of receipt or awareness of a notifiable action, **another established 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.
- Examples include:
  - Recall notification
  - Licence amendment application

If action has been planned in Canada, but Health Canada will not be notified within the 72-hour FRN timeline, a FRN report must be submitted.

FRN Form

- Six sections:
  - About the report
  - About the reporter
  - About the medical device(s)
  - About the serious risk(s)
  - About the notifiable action(s)
  - About actions planned in Canada
- Fillable PDF
- Web posting is underway



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Medical Device Foreign Risk Notification Form Clear Form

A. INFORMATION ABOUT THE REPORT

1. Type of report
   - ☐ Initial report
   - ☐ Update report
2. Is this the principal report?
   - ☐ Yes
   - ☐ No
3. Information about the related principal report (if this is not the principal report)
   - a. Date of submission of the principal report:
   - b. Authorization number (Section C1) from the principal report:
4. Reporter file number:

B. INFORMATION ABOUT THE REPORTER

1. Authorization holder name *
2. Authorization holder mailing address
3. Authorization holder email address *
4. Health Canada assigned authorization holder identification number:

To receive a blank form, send an email with subject "**FRN Form Request**" to: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca

Must separate FRN reports be submitted for each jurisdiction and/or for each action?

- **No.** The form includes options to select all jurisdictions and actions that apply.

E. INFORMATION ABOUT THE FOREIGN NOTIFIABLE ACTION(S) TAKEN

1. Jurisdiction(s) in which the manufacturer or importer has taken a notifiable action and/or the regulatory agency/agencies that has/have taken or been notified of a notifiable action *
   Select all that apply.

☐ Australia	☐ Therapeutic Goods Administration (TGA)
☐ Austria	☐ Austrian Agency for Health and Food Safety (AGES)
☐ Belgium	☐ Federal Agency for Medicines and Health Products (FAMHP)
☐ Brazil	☐ National Health Surveillance Agency (ANSIVA)
☐ Bulgaria	☐ Bulgarian Drug Agency

2. Type(s) of notifiable action(s) taken *
   Select all that apply.
   - ☐ Risk communication
   - ☐ Label change that has been communicated to or requested by a relevant regulatory agency
   - ☐ Recall, including product withdrawal
   - ☐ Reassessment of authorization
   - ☐ Suspension or revocation of authorization

Must separate FRN reports be submitted for each implicated medical device?

- **No.** 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
  - Only for Investigational Testing (i.e., no Medical Device License), even if there is more than one Investigational Testing Authorization number

A review was conducted of **foreign mandatory problem reports** received by Health Canada:

- ~93% included only 1 licence
- ~97% included 3 devices or less

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

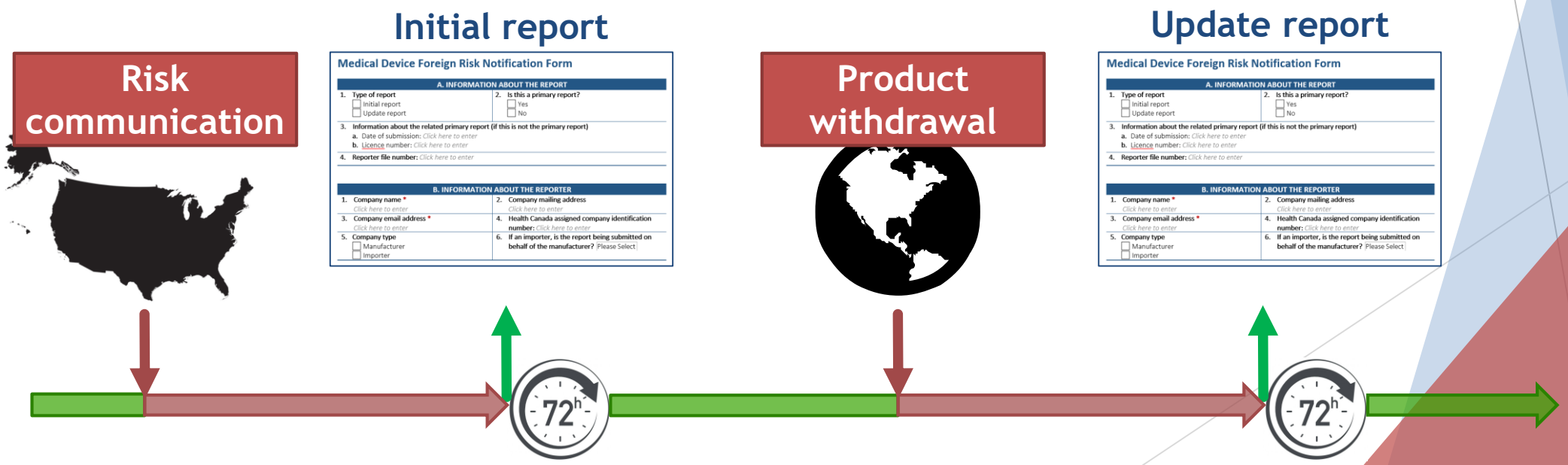
When should a FRN report be submitted?

- Within 72 hours after the authorization holder receives or becomes aware of “it”, whichever occurs first
  - “It” is information in respect of any serious risk of injury to human health
  - For the purposes of FRN, the information is regarding a notifiable action that <u>has been taken</u>

If a notifiable action has not yet been taken, a FRN report does not yet need to be submitted.

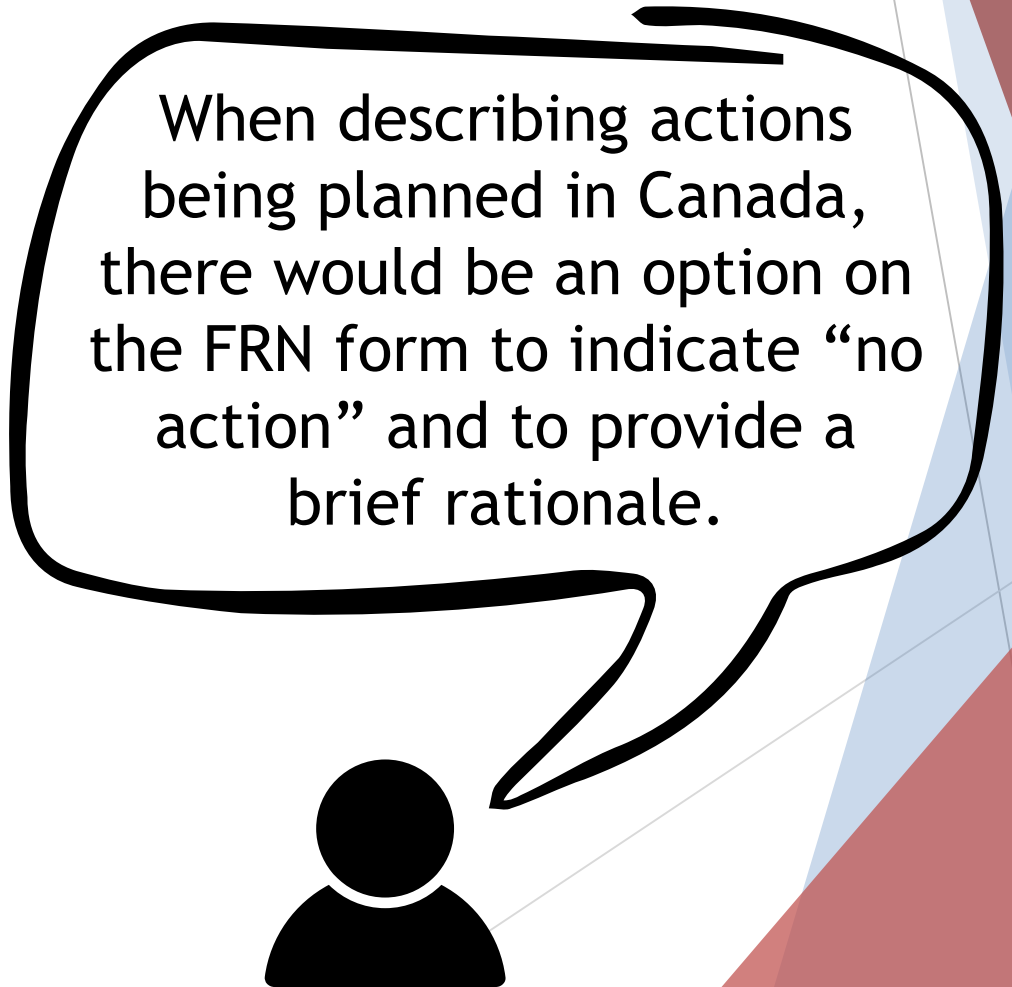
What happens if additional actions are taken after a FRN report is submitted?

- As more is learned about an identified serious risk, it is possible that **additional actions** will be taken or that actions will be taken in **additional jurisdictions**
- **Update FRN reports** must be submitted within 72 hours
  - Refer back to the “principal report” that was submitted initially



Must a FRN report be submitted if the serious risk being mitigated in a foreign jurisdiction is not relevant in Canada?

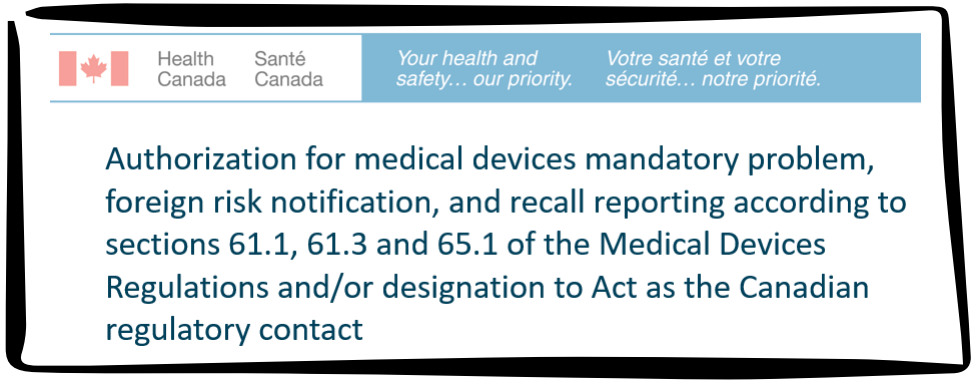
- **Yes.**
  - Health Canada could become aware of a serious risk in a foreign jurisdiction due to media communication, collaboration with foreign regulators, etc.
  - Receipt of a FRN report from industry would help Health Canada understand and explain why Canada may not be impacted.



How does a manufacturer authorize an importer to report on their behalf?

A 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.

Notify Health Canada in writing: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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 notify Health Canada at any time or to receive a copy of the form, contact Health Canada's Regulatory Operations and Enforcement Branch at: MDCU_UCIM@hc-sc.gc.ca

Permission must be provided for each of the applicable regulatory requirements, as some manufacturers may not wish to grant the same permission for each requirement.

Next steps

- FRN will come into force on June 23, 2021
  - Additional materials will be made available as soon as possible:
    - FRN form
    - Questions and answers document
    - Updated guidance document
- Summary reporting will come into force on December 23, 2021
  - A similar exercise is underway to develop additional materials and identify any necessary changes or clarifications

Need more information?

Health Canada's Medical Devices Directorate – Post-market
mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca