Health Canada Santé Canada

Canada

Medical Devices Regulations

Summary Reports: Tips and Tricks for Success

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- Objective of summary reports
- Required information
- Tips and tricks (what we have seen)

Summary reports: Objectives for Health Canada

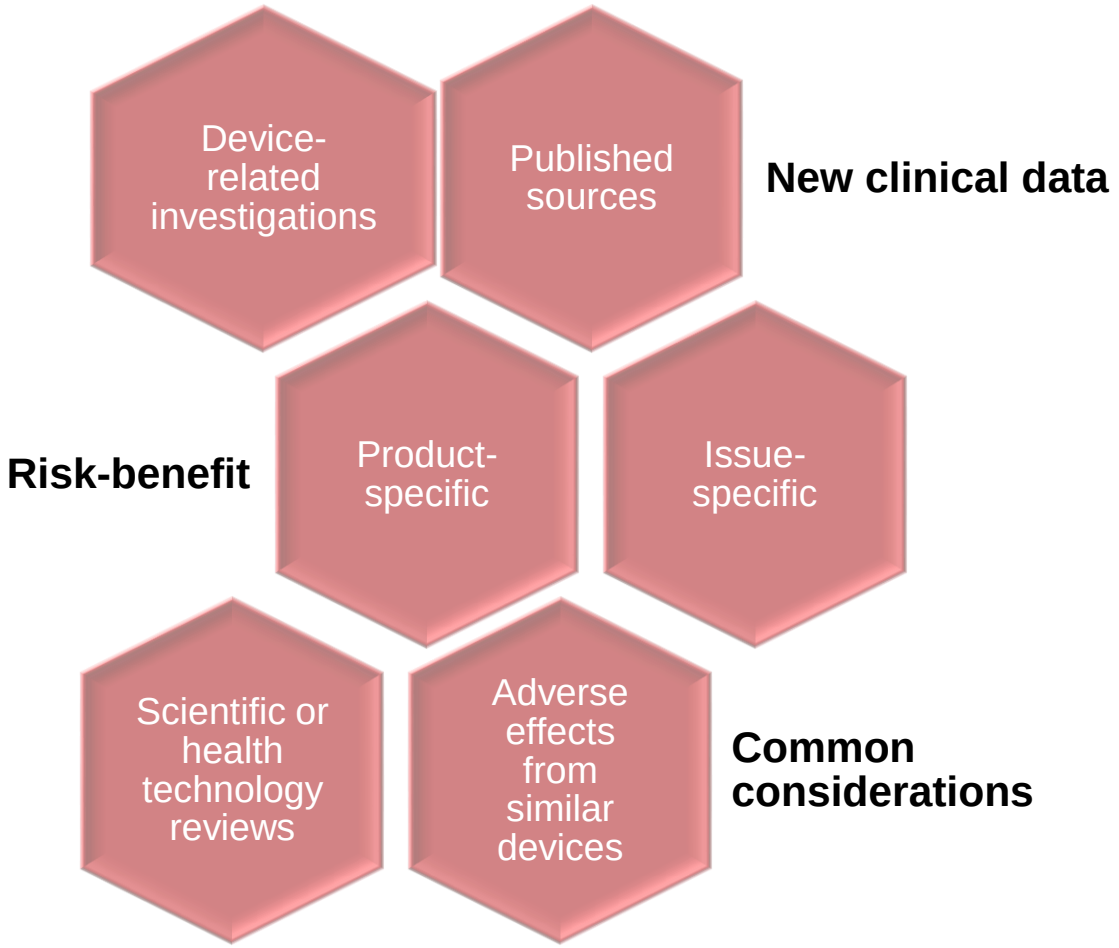
- ✓ Support a lifecycle approach to the regulation of medical devices in Canada
- ✓ Strengthen monitoring after a device is authorized for sale in Canada to determine if requirements related to safety and effectiveness continue to be met

- ✗ Notification to Health Canada is not required if there are no changes to the benefits and risks of a medical device
- ✗ Prescriptive (the intent was to facilitate flexibility)

Regulation – Must contain (Adverse effects)

Adverse effects

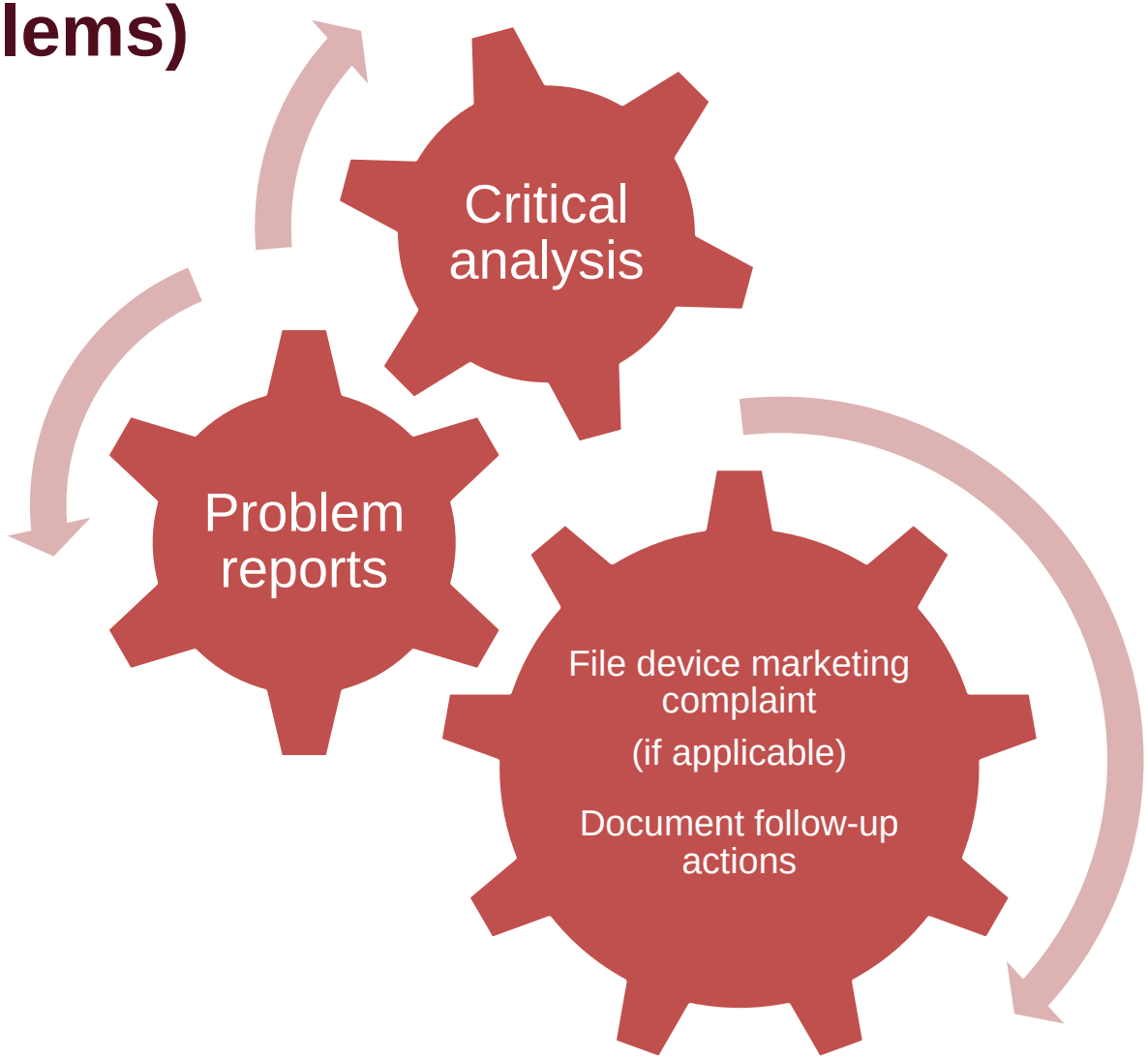
- This is the only required information in summary reports that has not been defined in regulation.



Regulation – Must contain (Problems)

Problems referred to in paragraph 57(1)(a):

Reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Canada.

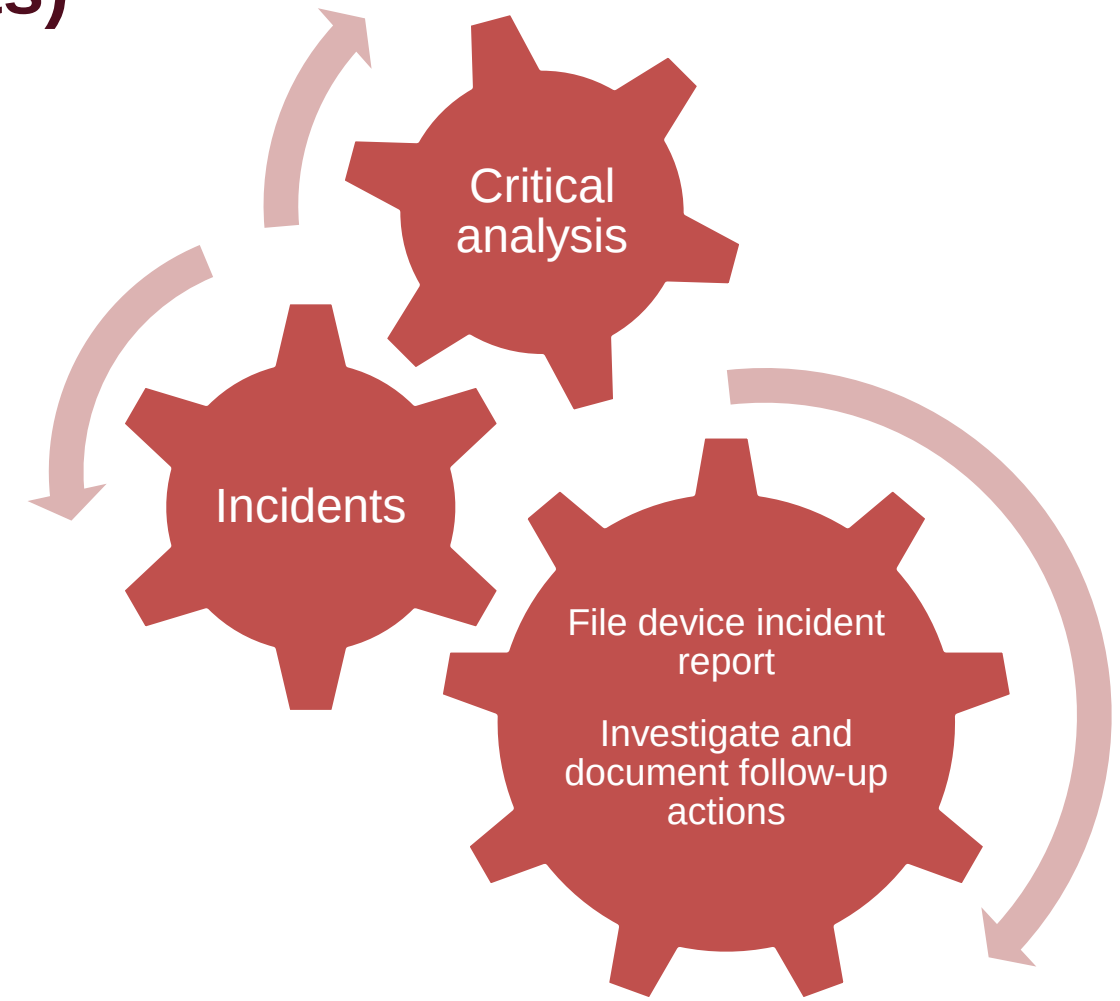


Regulation – Must contain (Incidents)

Incidents referred to in subsection 59(1):

The manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring in Canada that involves the device if the device is sold in Canada; and the incident

- Is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its direction 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 where the incident to recur.



Regulation – Must contain (Foreign Risk Notification)

Serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in subsection 61.2(2):

The holder of a therapeutic product authorization issued in respect of a medical device shall submit to the Minister 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

- Risks that have been communicated by any regulatory agency that is set out in the List of Regulatory Agencies (the List);
- Changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory agency set out in the List; and
- Recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device that have taken place within the jurisdiction of any regulatory agency set out in the List.

Regulation – Must contain (Concise critical analysis)

Using:

Prepare a concise critical analysis that identifies:

- If any of the benefits could be less
- If the risk is more likely to occur, or,
  if the consequences of the risk could be more serious
- If a new risk has been identified

Tips and tricks

Objective: To determine if the safety and effectiveness requirements continue to be met

- Administrative information is valuable
  - Indicate the licence(s) addressed by the summary report
  - Include a rationale that outlines why licences that are grouped together (if applicable)
  - Indicate the period of time covered by the summary report

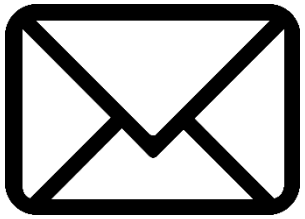
- Clear information will support the conclusion
  - Consider using language outlined in the regulations
  - Review alignment of summary report information with authorized labelling claims that support benefit-risk
  - If leveraging an EU PSUR, validate that the authorized benefit-risk of the device are aligned in Canada and the EU

Tips and tricks

Objective: To determine if the safety and effectiveness requirements continue to be met

- Consult (your) experts in ISO 14971 and ISO 13485
  - You may already have existing analyses that can be used to prepare the summary report
- Change history over the reporting period will support benefit-risk assessments
  - Changes, such as through licence amendments or completed recalls, support your conclusion
- Consider the Canadian device risk classification
  - Whether or not the Canadian device risk classification aligns with the EU device risk classification, Canadian regulatory requirements still apply

Questions, comments, or need support?



Health Canada’s Medical Devices Directorate – Post-market

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