Health Canada Santé Canada

Canada

Medical Devices Regulations

Summary Reports

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- New post-market regulations
- Summary reports
  - Objective
  - When to submit a summary report
  - Implementation details
- Next steps

New post-market regulations

Vanessa's Law Authorities under the Food and Drugs Act

- Requirement for manufacturers to notify Health Canada of foreign actions taken in response to serious risk of injury to human health
- Authority to compel manufacturers to conduct assessment
- Authority to compel manufacturers to compile information, conduct tests or studies, or monitor experience

Monitoring and Surveillance Authorities

- Authority to request that manufacturers complete issue-related analysis
- Authority to require that manufacturers conduct **summary reporting & notify of changes** to what is known about benefits and/or risks

Summary Report

The summary report shall:

- contain a concise critical analysis of the matters to be covered

- The licence holder shall determine **whether what is known about the benefits and risks associated with the device has changed** in one or more of the ways described in subsections 61.4(4)(a) to (c) :
  - any of the benefits could be less;
  - in respect of any of the risks;
    - the risk is more likely to occur, or
    - if the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and
  - a new risk has been identified

- If, in preparing the summary report, the licence holder concludes that what is known about the benefits and risks associated with the medical device **has changed**, they shall **notify the Minister, in writing, within 72 hours** after having reached the conclusion, unless that has already been done.

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)

Summary reports are part of ongoing post-market monitoring

- This information should increase knowledge about the benefits and risks associated with the use of a device in real-world situations.

- Licence holders are required to prepare summary reports for as long as their device is licensed in Canada.

- A summary report is required for each medical device licence. However, it may be reasonable to combine certain devices when preparing a summary report, even if they're not included in the same licence.

- A licence amendment application or a recall does not replace a summary report. While a summary report may inform the need to submit a licence amendment application, it is a different regulatory requirement.

Summary Reports – Preparation and maintenance

61.4 (1) The holder of a medical device licence shall prepare a summary report

Who is responsible for preparing, maintaining, and if requested, submitting summary reports to Health Canada?

- The holder of a Class II, III or IV medical device licence (MDL) is responsible to prepare, maintain records of and, if requested, submit summary reports to Health Canada.
- A private label manufacturers that hold MDLs for Class II, III or IV devices, must comply with sections 61.4 to 61.6.
- Medical Device Establishment Licence (MDEL) holders that **do not** hold a Class II, III or IV MDL are **not** required to comply with Summary Reporting requirements.

Summary Reports - Frequency

61.4 (1) (a) in the case of a **Class II** medical device, on a **biennial basis**

61.4 (1) (b) in the case of a **Class III or IV** medical device, on an **annual** basis

When must the first summary and subsequent reports be prepared?

- Licence holders may choose the cut-off date for data to be included in the summary report as long as the report falls within the required reporting timeframe.
- The intent of summary reporting is to have **no gaps in the data**.

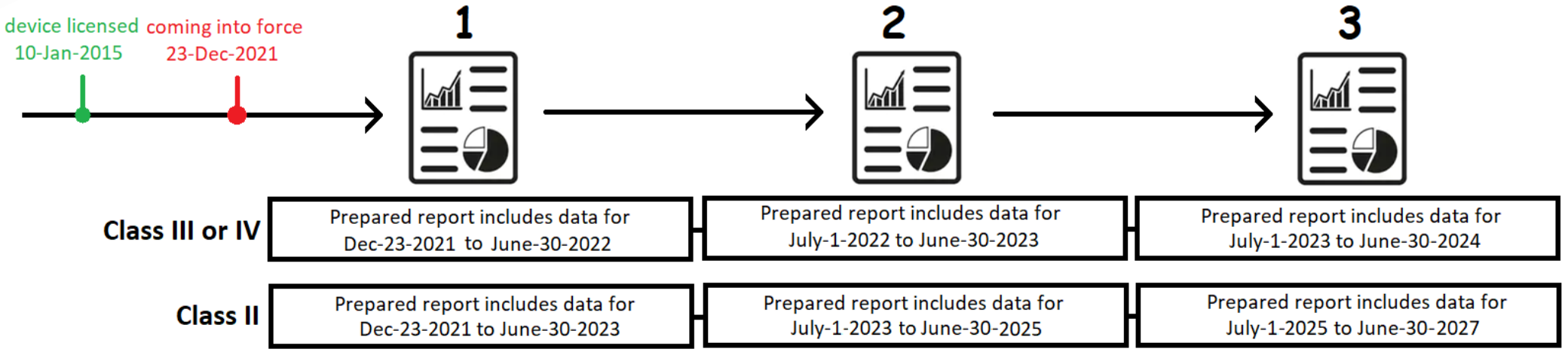
First Summary Report – Frequency for existing licences

When must the first summary and subsequent reports be prepared? (continued)

- For Class III or IV licences issued on or before December 23, 2021, the **first** summary report must be prepared **on or before** December 23, 2022. **Subsequent** summary reports must cover intervals of 12 months.

- For Class II licences issued on or before December 23, 2021, the **first** summary report must be prepared **on or before** December 23, 2023. **Subsequent** summary reports must cover intervals of 24 months.

Example



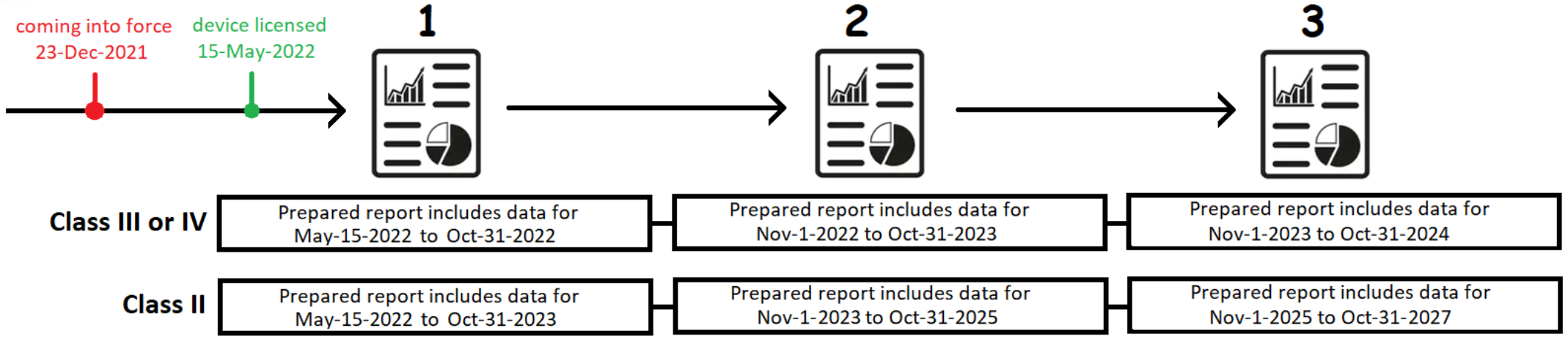
First Summary Report – Frequency for new licences

When must the first summary and subsequent reports be prepared? (continued)

- For Class III or IV licences issued after December 23, 2021, the **first** summary report must be prepared **within one (1) year** of the date of issuance. **Subsequent** summary reports must cover intervals of 12 months.

- For Class II medical device licences issued after December 23, 2021, the **first** summary report must be prepared **within two (2) years** for of the date of issuance. **Subsequent** summary reports must cover intervals of 24 months.

Example



Summary Reports - Content

61.4 (2) The matters to be covered by the summary report are

(a) adverse effects;

(b) problems referred to in paragraph 57(1)(a);

(c) incidents referred to in subsection 59(1); and

(d) 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).

61.4 (3) The summary report shall contain a concise critical analysis of the information referred to in subsection (1).

Should domestic and foreign information be included in the summary report?

- Both Canadian and international findings should be included in the summary report. It is recommended that Canadian adverse effects, problems and incidents be discussed separately.

Will Health Canada accept a European Union (EU) Periodic Safety Update Report (PSUR) as a summary report?

- Various formats are acceptable for a summary report so long as the report includes the required information outlined in the Canadian regulations. Information specific to the Canadian context is an important part of the summary report.

What's in a critical analysis?

- Information to support the analysis comes from:
  - Adverse effects
  - Problems reported to the manufacturer, importer or distributor of the device, including consumer complaints
  - Incidents that have come to the attention of the manufacturer or importer
  - Serious risks of injury to human health that were identified outside of Canada
  - Misuse or off-label use of the medical device resulting in changes to what is known about the benefits or risks associated with the device

- If available, include the following types of evidence in the analysis:
  - Clinical evidence updates (published sources, ongoing clinical studies, device-related investigations)
  - Information on safety or effectiveness (including published reports)
  - Product or issue-specific information
  - Information on similar devices, including those using similar materials and/or technology

Summary Reports – No change or no sales in Canada

61.4 (4) In preparing the summary report, the licensee shall determine, on the basis of the analysis referred to in subsection (3), whether what is known about the benefits and risks associated with the medical device has changed as described in any of the following paragraphs:

(a) any of the benefits that may be obtained by patients through the use of the medical device could be less;

(b) in respect of any of the risks,

(i) the risk is more likely to occur, or

(ii) if the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and

(c) a new risk has been identified

Does a summary report need to be prepared and maintained if there has been no change to the benefit-risk profile or if there have been no sales in Canada?

- Yes. Class II, III or IV medical device licence holders are responsible for preparing and maintaining summary reports regardless of the conclusion, or whether or not the medical device was sold in Canada during the reporting period.

Change in the benefit-risk profile

- If the licence holder determines that there has been a change in the benefit-risk profile of a device and has already notified the Minister, it is recommended to include the following information in the summary report:
    - Any preventive or corrective actions that have been taken to address the change in the benefit-risk profile of the device, and
    - How Health Canada was notified, including specific reference to the notification, such as the associated amendment application number and/or the recall ID.

If you determined that there was no change to the benefits and risks of your medical device since the previous reporting period, you do **not** need to submit the summary report to Health Canada.

Summary Reports – When to notify Health Canada

61.4 (5) The licensee shall include the conclusions they reach under subsection (4) in the summary report.

61.4 (6) If, in preparing the summary report, the licensee concludes that what is known about the benefits and risks associated with the medical device has changed as described in any of paragraphs (4)(a) to (c), they shall notify the Minister, in writing, within 72 hours after having reached the conclusion, unless that has already been done.

How can a licence holder notify Health Canada if there is a change ?

- Submission of the summary report, or
- Notification by email (mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca), or
- Notification of a recall of the impacted device(s)*, or
- Submission of an application for a medical device licence amendment*

* Acceptable only if the recall/amendment occurred prior to completion of the summary report and such that the recall/amendment addresses all the identified changes related to the change in benefit-risk profile.

Summary Reports – Available upon request

61.5 (1) The Minister may, for the purposes of determining whether a medical device meets the applicable requirements of sections 10 to 20, request that the holder of a medical device licence issued in respect of the device submit, on or before the day specified in the request, any of the following:

(a) summary reports; or

(b) information on the basis of which summary reports were prepared.

61.5 (2) The licensee shall submit to the Minister the summary reports or information, or both, that the Minister requests not later than the day specified in the request.

Should all summary reports be submitted upon completion, or only when requested by Health Canada?

- Summary reports are not required to be submitted to Health Canada unless requested by the Minister.

Summary Reports - Records

61.6 (1) The holder of a medical device licence shall maintain records of the summary reports and the information on the basis of which those reports were prepared.

61.6 (2) The licensee shall retain the records for seven years after the day on which they were created.

Are importers and distributors required to have copies of the summary reports, in case of Health Canada inspection?

- Yes, if they hold a Class II, III or IV medical device licence, importers and distributors are responsible for preparing, maintaining or submitting summary reports. However, importers and distributors are not responsible for preparing, maintaining or submitting summary reports if they **only** hold an MDEL to import or sell medical devices.

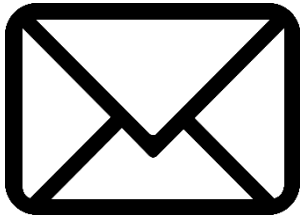
Can MDSAP auditors or Health Canada's inspectors ask to see summary reports?

- Yes. Information and summary reports may be reviewed during both MDSAP audits and Health Canada inspections of licence holders (during compliance verifications or inspections to prevent non-compliance, for example).

Next steps

- The summary reports requirement will come into force on December 23, 2021.
  - Additional materials will be made available as soon as possible
    - Questions and answers document on the GCwiki page
    - Updated guidance document (planned for winter 2022)

Questions, comments, or need support?



Health Canada's Medical Devices Directorate – Post-market

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