QUESTIONS & ANSWERS

Sections 61.4 to 61.6– Summary Report

Q1: 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.

Class I device manufacturers do not hold MDLs. As such, they are not responsible for preparing, maintaining or submitting summary reports to Health Canada.

Importers and distributors are not responsible for preparing, maintaining or submitting summary reports if they only hold a Medical Device Establishment Licence (MDEL) to import or sell medical devices.

Manufacturers holding an authorization for a COVID-19 medical device under Interim Order No. 2 Respecting the importation and sale of medical devices for use in relation to COVID-19 are not required to prepare, maintain or submit summary reports to Health Canada.

Q2: Can importers and distributors assist the MDL holder to prepare or maintain summary reports?

Importers and distributors play a key role in supplying safe and effective medical devices in Canada and ensuring products meet their regulatory requirements. Although the responsibility to comply with summary report requirements rests with MDL holders, importers and distributors are encouraged to work with their manufacturer suppliers that hold MDLs (e.g. establish communications, procedures, supply contracts, etc.) to assist these manufacturers in remaining compliant with the Medical Devices Regulations (MDR). Importers and distributors may be able to provide unique Canadian derived information and data to foreign manufacturers holding MDLs for the purpose of preparing the summary reports.

Q3: Do private label manufacturers have to prepare, maintain, and if requested, submit summary reports?

Yes. Private label manufacturers that hold a MDL for a Class II, III or IV device must comply with the applicable requirements of the MDR, including sections 61.4 to 61.6.

Although private label manufacturers may depend on the original manufacturer to prepare summary reports, in part or in full, it is ultimately the private label manufacturers' responsibility to ensure that they comply with the summary reporting requirements for their authorized private label device. As such, to comply with the requirements, a private label manufacturer should establish processes to ensure timely and effective communication with the original manufacturer and ensure that they remain compliant with the MDR.

If, in preparing the summary report, it is concluded that what is known about the benefits and risks associated with the medical device has changed, as described in any of paragraphs 61.4(4)(a) to (c) and elaborated in the supporting guidance document, the private label manufacturer must notify the Minister within 72 hours after the conclusion has been reached (see also Q5).

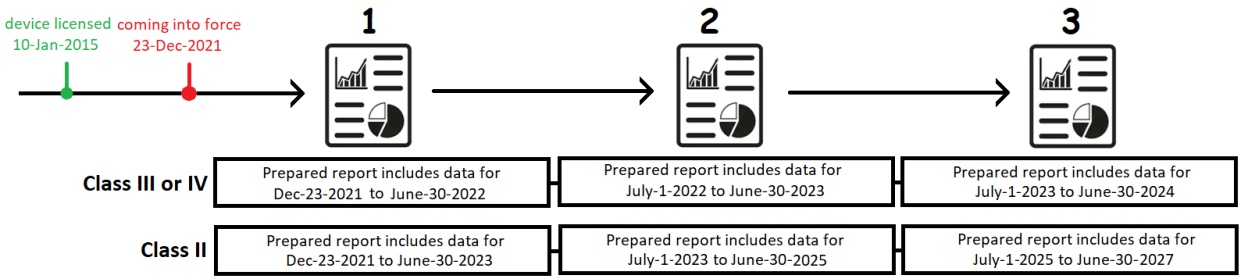
Q4: When must the first and subsequent summary reports be prepared?

The amendment to the MDR to include the new summary report provisions (sections 61.4 to 61.6) will come into force on December 23rd, 2021. MDL 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. With this flexibility, MDL holders are able to use the same timeline for both the Canadian summary report and similar reports created to meet the requirements of international jurisdictions.

In the case of a Class III or IV medical device, the MDL holder must prepare a summary report on an annual basis. For licences issued **on or before** December 23rd, 2021, the **first** summary report must be prepared on or before December 23rd, **2022.** For licences issued **after** December 23rd, 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** with new information that pertains to the matters referred to in subsection 61.4(2), that the MDL holder received or became aware of.

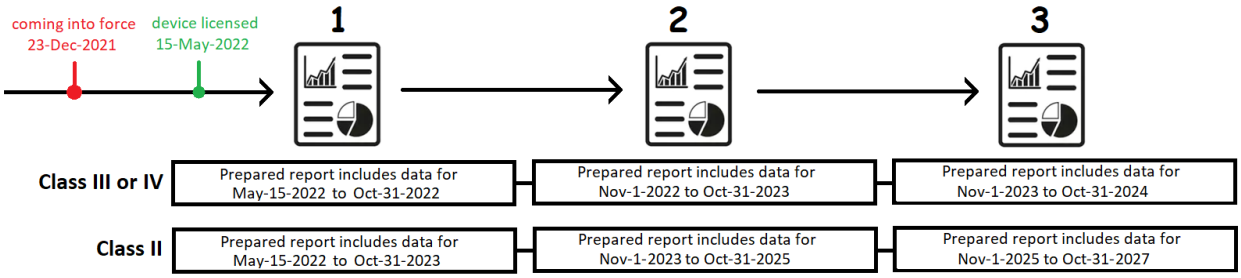
In the case of a Class II medical device, the MDL holder must prepare a summary report on a biennial basis (i.e., every two (2) years). For licences issued **on or before** December 23rd, 2021, the **first** summary report must be prepared on or before December 23rd, **2023**. For licences issued **after** December 23rd, 2021, the first summary report must be prepared within two (2) years of the date of issuance. **Subsequent** summary reports must cover **intervals of 24 months** with new information that pertains to the matters referred to in subsection 61.4(2), that the MDL holder received or became aware of.

The intent of summary reporting is to have no gaps in the data, i.e. that the summary report information is continuous over the reporting periods. The following examples are acceptable scenarios.



Example 1: The holder of a Class III or IV MDL issued prior to or on December 23rd, 2021, stops collecting new information in support of the summary report on June 30th, 2022, and prepares their first summary report. The subsequent reports must be prepared on an annual basis, therefore the second report must include data for July 1st, 2022, through June 30th, 2023. Similarly, the holder of a Class II MDL stops

collecting new information in support of the summary report on June 30th, 2023, and prepares their first summary report. The subsequent reports must be prepared on a biennial basis, therefore the second report must include data for July 1st, 2023, through June 30th, 2025.



Example 2: The holder of a Class III or IV MDL issued on May 15th, 2022, stops collecting new information in support of the summary report on October 31st, 2022, and prepares their first summary report. The subsequent reports must be prepared on an annual basis, therefore the second report must include data for November 1st, 2022, through October 31st, 2023. Similarly, the holder of a Class II MDL stops collecting new information in support of the summary report on October 31st, 2023, and prepares their first summary report. The subsequent reports must be prepared on a biennial basis, therefore the second report must include data for November 1st, 2023, through October 31st, 2025.

Q5 a): Should all summary reports be submitted to Health Canada upon completion, or only when requested by Health Canada?

While summary reports must be prepared on an annual basis for a Class III or IV medical device and on a biennial basis for a Class II medical device, they **are not required** to be submitted to Health Canada **unless one of the following criteria** has been met:

1. The Minister requests that the MDL holder submit the report (and/or the information on the basis of which the summary report was prepared) for the purpose of determining whether a medical device meets the applicable requirements of sections 10 to 20 of the MDR, (see subsection 61.5(1) of the MDR), or
2. If, in preparing the summary report, the MDL holder concludes that what is known about the benefits and risks associated with the medical device has changed (see subsection 61.4(4) of the MDR), the MDL holder must notify the Minister in writing, within 72 hours after having reached the conclusion (e.g. by submitting the summary report) (see subsection 61.4(6) of the MDR).

Despite the above, if the MDL holder has already notified the Minister of the change in the benefit-risk profile of the device, they are **not required** to submit the summary report or otherwise notify the Minister under subsection 61.4(6) of the MDR if this information would be redundant. Nevertheless, the MDL holder should document the following information in their 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.

Q5 b): How can a MDL holder notify Health Canada if there is a change in the benefit-risk profile of the device(s) included in a summary report?

If, in preparing the summary report, the MDL holder concludes that there has been a change in the benefit-risk profile of a device, they must notify Health Canada in writing within 72 hours after having reached the conclusion, unless that has already been done. The following actions are acceptable methods to notify the Minister:

- Submission of the summary report, or
- Notification by email (mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca) of the change in the benefit-risk profile. The email should include any preventive or corrective actions that are planned to address the identified change, or
- Notification of a recall of the impacted device(s) (sections 63 to 65 of the MDR) if the recall notification occurred prior to the completion of the summary report and such that the recall addresses all the identified changes related to the change in benefit-risk profile, or
- Submission of an application for a medical device licence amendment (section 34 of the MDR) if submitted prior to the completion of the summary report and the amendment addresses all the identified changes related to the change in benefit-risk profile.

Q6: Will Health Canada communicate whether a submitted summary report complies with the requirements?

Health Canada understands there may be uncertainty as to what amount of detail is required in summary reports to be considered compliant with the MDR. The Guidance on summary reports and issue-related analyses for medical devices provides manufacturers with information to consider when preparing summary reports. Specific questions may be submitted to Health Canada using the following email address: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca.

If the MDL holder took all reasonable measures to prepare a summary report in a manner consistent with the MDR and guidance, but upon consideration, Health Canada deems more information was needed, we will request for the provision of additional information and provide a reasonable amount of time to address this request. If, however, the MDL holder is found to be non-compliant with the MDR or the information needed is deemed urgent to address health risks to Canadians, Health Canada may take compliance and enforcement action in accordance with our Compliance and Enforcement Policy.

Q7: Does a summary report need to be prepared and maintained if there has been no change to the benefit-risk profile of the medical device?

Yes. All Class II, III or IV MDL holders are responsible for preparing and maintaining summary reports regardless of the conclusion. Records of the summary reports and the information used to prepare these

reports must be retained for seven (7) years after the day they were created (subsection 61.6(2) of the MDR).

Q8: Can a summary report replace a licence amendment application or vice-versa?

No. A summary report is a comprehensive assessment of new information on the benefits and risks of a licensed Class II, III or IV medical device. While a summary report may inform the need to submit a licence amendment application, it is a different regulatory requirement.

Q9: Is the MDL holder subject to sections 61.4 to 61.6 if there have been no sales in Canada during the reporting period?

Yes. The requirement to prepare, maintain and, if requested, submit summary reports applies whether or not the medical device was sold in Canada during the reporting period. This is required because devices that are authorized for sale in Canada must continue to meet safety and effectiveness requirements as specified by the MDR. Certain actions taken to mitigate 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.

When a summary report is being prepared for one or more devices that were not sold in Canada during the reporting period, the information used to inform the analysis and conclusions may come from data collected outside of Canada.

Q10: 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 MDL holders (during compliance verifications or inspections to prevent non-compliance, for example). Section 61.6 of the MDR requires MDL holders to maintain copies of the summary reports and the information on the basis of which those reports were created for a period of seven years.

Q11: Will Health Canada accept a European Union Periodic Safety Update Report (PSUR) as a summary report?

Yes, so long as the report includes the required information outlined in subsections 61.4(1) to 61.4(5) of the Canadian MDR, various formats are acceptable for a summary report, including those from other jurisdictions. For example, the Periodic Safety Update Report (PSUR) format as required in the European Union regulations may be an acceptable approach to fulfilling the summary report requirement in Canada. In this case, the PSUR prepared for the same device(s) may meet the Canadian summary report requirements, and therefore, the MDL holder would not need to create an additional report. However, information specific to the Canadian context is an important part of the summary report (see Q12).

Q12: Should domestic and foreign information be included in the summary report?

The matters to be covered by the summary report include analysis of both domestic and foreign information, and include:

- adverse effects associated with using the medical device,
- reported problems as described in paragraph 57(1)(a) of the MDR,
- mandatory incident reporting as described in subsection 59(1), and
- serious risks of injury to human health as described in subsection 61.2(2).

In addition, it is recommended that the summary report include analysis of misuse or off-label use of the medical device resulting in changes to what is known about benefits or risks associated with the device.

Information specific to the Canadian context is an important part of the summary report. Thus, it is recommended that information, including that related to Canadian adverse effects, problems and incidents be included in the analysis, but also discussed separately so as to be able to support a conclusion about both the Canadian as well as global findings.

In addition to documenting domestic and foreign incidents in summary reports, MDL holders must continue to comply with sections 59 through 61.1(2) of the MDR concerning incident reporting. For more information, refer to Health Canada's guidance document on Incident reporting for medical devices.