Health Canada regulatory spotlight on medical device post-market surveillance

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On December 23, 2020, Health Canada published SOR/2020-262 – Regulations Amending the Food and Drug Regulations and the Medical Device Regulations (Post-market Surveillance of Medical Devices) in the Canada Gazette. This new regulation amends the *Food and Drug Regulations* and the *Medical Device Regulations* (MDR) by adding provisions aimed at strengthening Health Canada's ability to collect post-market safety information on medical devices. In this article, we summarize the two phases of these amendments:

Phase I – June 2021 amendments

The first slate of amendments came into force on June 23, 2021. For medical device manufacturers and importers, these amendments clarified and added reporting requirements in respect of incidents occurring both inside and outside of Canada. Under the new regime, the MDR requires medical device license holders and importers of Class II, III, and IV medical devices to advise Health Canada of relevant information pertaining to a serious risk to human health posed by a device on the Canadian market. This obligation is triggered when:

- A designated foreign regulatory agency or foreign manufacturer communicates that a device poses a serious risk to human health;[1]
- Changes are made to a medical device's labelling and that change is communicated to or requested by the foreign regulatory agency;[2] or
- A medical device is recalled or reassessed, or its authorizations (such as its licence) is suspended or revoked in the foreign regulatory agency's jurisdiction.[3]

Licensees or importers must advise Health Canada within 72 hours of receiving the above information.[4] Health Canada expects medical device licence holders and importers for Class II, III, and IV medical devices to establish monitoring systems in the relevant foreign jurisdiction to ensure that it receives timely safety information. In total, there are 39 relevant jurisdictions. These include the 27 member countries of the European Union, the U.S. , Mexico, the United Kingdom, China, Japan, South Korea, Singapore, Australia, New Zealand, Switzerland, Luxembourg, and Russia.[5]

Phase II – December 2021 amendments

On December 23, 2021, the second slate of amendments on medical device annual and biennial reporting requirements will come into force. Health Canada will require medical device licence holders to prepare and retain summary reports that address:

- A device's adverse effects;[6]
- Reported problems relating to the performance characteristics or safety of the device. This includes any consumer complaints that the manufacturer, importer or distributor receives after the device was first sold in Canada;[7]
- Any incidents relating to a device's failure, a deterioration in its effectiveness, or any inadequacy in its labelling or directions for use;[8]
- Any incidents that led to the death or serious deterioration of the state of health of a patient, user, or other person, or if such an incident could lead to one of these outcomes if it were to happen again;[9] and
- Serious risks of injury to human health that are relevant to the safety of the medical device. These are risks communicated by authorized foreign regulatory agencies or manufacturers and associated with relabelling, recalls, reassessments, or suspensions, or revocations of medical device authorizations.[10]

Holders of Class II licences must prepare these summary reports every two years based on information they received or became aware of in the prior 24 months.[11] For holders of Class III and IV licences, this requirement is an annual one based on information from the previous 12 months.[12] The amendments require licensees to maintain a record of the report for seven years following the report's creation date.[13]

These summary reports must also contain a short analysis of the above information and set out conclusions on medical device safety and efficacy. If the analysis leads a licensee to the conclusion that the known benefits and risks associated with its medical device have changed, the licensee must notify Health Canada within 72 hours.[14] The December 23, 2021 amendments do not otherwise create any other positive reporting requirements for licensees. Health Canada does not require licensees to submit these reports at regular intervals – licensees are only required to *prepare* and *retain* the reports.[15] However, licensees should still diligently prepare their summary reports, in the event the regulator requests production.[16]

Looking ahead

The new and upcoming MDR amendments require Canadian medical device licence holders to continue to carefully examine their post-market surveillance policies and procedures to ensure compliance. As of June 23, 2021, Health Canada expects holders of Class II, III, and IV medical devices licences to have sufficient systems in place to meet their obligation of reporting foreign risk information. Specifically, these companies should ensure they are conducting diligent surveillance with respect to incidents involving their Class II, III, IV devices in the relevant foreign jurisdictions listed above. Finally, in preparation for December 23, 2021, medical device licence holders should prepare for the creation and retention of the newly required summary reports.

If you have any questions or would like to learn more about the Health Canada medical device regulatory amendments, please reach out to any of the authors or key contacts listed below.

[1] See *Medical Device Regulations*, SOR/98-282, s. 61.2(2)(a).

[2] *Ibid*, s. 61.2(2)(b).

[3] *Ibid*, s. 61.2(2)(c).

[4] *Ibid*, s. 61.2(3).

[5] Health Canada's intention was to limit the list of relevant foreign jurisdictions to those that have a Memorandum of Understanding with Health Canada.

[6] See *Medical Device Regulations*, SOR/98-282, s. 61.4(2)(a) [Coming into force date: 23 December 2021].

[7] *Ibid*, ss. 61.4(2)(b) and 57.1(a).

[8] *Ibid*, ss. 61.4(2)(c) and 59(1).

[9] *Ibid*.

[10] *Ibid*, ss. 61.4(2)(d) and 61.2(2).

[11] *Ibid*, s. 61.4(1).

[12] *Ibid*.

[13] *Ibid*, s. 61.6(2).

[14] *Ibid*, s. 61.4(6).

[15] *Ibid*, ss. 61.4–61.6.

[16] *Ibid*.

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