November 27, 2020

To: Small- and medium-sized manufacturers of medical devices

Re: *Regulations relating to the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 beyond March 2021*

The purpose of this letter is to provide a high-level overview of the proposed new interim order and proposed transition regulations being developed by Health Canada.

Background

The *Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19* (the IO) is set to expire in March 2021. It provides a faster way to authorize the importation and sale in Canada of medical devices that are used to diagnose, treat, mitigate or prevent COVID-19. With the COVID-19 pandemic still ongoing, Health Canada intends to maintain the flexibilities and regulatory oversight provided by the IO through a second interim order that would last until at least fall 2021 (the end of the interim order period).

In the absence of transition regulations following the expiry of the second interim order, all IO-authorizations would cease to have effect. Manufacturers of IO-authorized devices would need to reapply under the Medical Devices Regulations (MDR), and their devices would not be authorized for importation or sale until new licences are issued.

Health Canada is developing transition regulations that would take effect at the end of the interim order period and would remain in place for two years. The proposed transition regulations would permit the continued importation and sale of authorized devices during the transition period while the manufacturer is seeking a regular medical device licence or Medical Device Establishment Licence (MDEL). Some regulated parties would need to come into compliance with the MDR before the end of the two-year transition period.

Approach

Policy change proposed under the second interim order (March 2021 through fall 2021)

While the second interim order would maintain most of the flexibilities of the current IO, two changes would be introduced to address potential risks to the health and safety of Canadians:

- Importers and distributors of IO-authorized devices will be required to hold a Medical Device Establishment Licence (MDEL), as required under the MDR

- Manufacturers of all classes of devices are required to comply with additional labelling provisions from the MDR, including providing bilingual labelling under certain circumstances

In both cases, the deadline for compliance would be six months following the anticipated coming into force of the second interim order in March 2021.

Policy changes proposed as part of the transition regulations (anticipated to begin in fall 2021)

Class I medical devices

Upon the start of the transition period, active interim order authorizations for Class I devices would be deemed as 'temporary Class I licences' and would be valid for up to 18 months.

During the 18 months following the end of the interim order period, manufacturers of Class I devices with a temporary Class I licence would not need to hold an MDEL or import or distribute exclusively through an MDEL holder.

To continue importing or selling the device past those 18 months, the manufacturer of an IO-authorized Class I device would need to comply with the MDR by doing one of the following:

a. obtaining an MDEL to import/distribute the Class I device, or
b. importing or distributing solely through an existing MDEL holder.

Note that a fee would be charged for the examination of an MDEL application, as set out in the *Fees in Respect of Drugs and Medical Devices Order*.

Class II to IV medical devices

Active interim order authorizations granted for Class II to IV devices would be deemed as medical device licences under the MDR.[1] In other words, those devices would continue to be authorized for importation, sale and distribution in Canada subject to the requirements associated with their interim order authorization and for a period not exceeding two years.

For those devices to continue to be authorized after the two-year transition period, regular medical device licences must be obtained within that period by meeting the requirements below and by submitting the relevant information to Health Canada for review:

[1] Class II to IV manufacturers will also be given an option to 'opt out' if they do not want a medical device licence.

- Manufacturers must receive a Medical Device Single Audit Program Quality Management System certificate within two years of the expiry of the interim order provisions;
- Manufacturers must submit a report to Health Canada demonstrating that they have completed or made satisfactory progress on any terms and conditions placed on their interim order authorization; and
- Manufacturers of Class III and IV devices must submit additional evidence to meet requirements under the MDR, building on information already submitted under the interim order provisions (for example, this could include clinical evidence, a marketing history report, and an assessment of post-market data).

Health Canada would be actively risk-managing these devices during the two-year transition period through the authority to place terms and conditions on a licence and the ability to request additional information. Manufacturers would be required to comply with post-market provisions under the MDR, including requirements around incident reporting, distribution records, complaint handling, and recalls.

When a regular medical device licence is issued under the MDR, all applicable fees and performance standards from the *Fees in Respect of Drugs and Medical Devices Order* would apply.

Applications in queue

For Class I to IV device manufacturers who have applied for an authorization under the IO or under the second interim order but have not received a decision by the end of the second interim order, Health Canada would continue to review their pending device applications under the transition regulations against the criteria established under the IO provisions. If upon completing the review a determination is made that the IO requirements have been met, the Minister would issue a temporary Class I licence for Class I devices or a transitional medical device licence for Class II to IV devices.

Consultation document

The policy document [Annex A] explains in detail the policy intent behind the second interim order and transition regulations. The cost and benefit questionnaire seeks to explore how the proposed approach could impact stakeholders.

Next steps

We ask that you please review the attached documents and provide your feedback. Your responses will be carefully considered to help inform the development of the transition regulations. They will also help us to adjust the regulatory proposal to minimize costs. While we welcome qualitative description in your responses, quantitative data would be most helpful in supporting our analysis.

You will also be consulted in the future about a draft guidance document that will explain how the proposed changes would be applied.

Health Canada will use all the input received to develop its approach, including the development of guidance documents on the proposed changes.

Contact us

If you have any questions, please contact Health Canada at hc.lrm.consultations-mlr.sc@canada.ca.

Additional Resources

- Applications for medical devices under the Interim Order for use in relation to COVID-19: Guidance document
- Authorized medical devices for uses related to COVID-19: List of authorized testing devices
- Interim order respecting the importation and sale of medical devices for use in relation to COVID-19
- Medical Devices Regulations