Cassels

Health Canada Expedites Access to Medical Devices

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To assist with Canada's response to COVID-19, the Minister of Health (the Minister) has signed the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* (the Interim Order).[1] The Interim Order will allow expedited access to COVID-19 medical devices for use by healthcare providers, including diagnostic test kits. According to Health Canada, the Interim Order will help ensure quicker and more flexible approval of the importation and sale of COVID-19 medical devices.[2]

Exemptions for Some Regulatory Requirements

Under the Interim Order, if the Minister determines that there is an urgent public health need for the importation or sale of a COVID-19 medical device, the manufacturer of such device may submit an application for authorization of importation or sale. Once issued, an authorization for importation or sale would exempt the manufacturer from most requirements under Part I of the *Medical Devices Regulations*.[3] The manufacturer would still need to comply with certain record keeping, recall and some labeling requirements.

Eligible Devices

The Interim Order defines a COVID-19 medical device as a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Interim Order further establishes a List of Medical Devices for Expanded Use that is to be maintained and updated by the federal government (to date no devices are listed). Any product on this list would be permitted to expand their use as set out in the list.

Required Information

Section 5 of the Interim Order provides that the Minister must issue an authorization for importation or sale if the following requirements are met:

(a) the applicant has submitted an application to the Minister that meets the requirements set out in subsection 4(1) and, if applicable, subsection 4(2);

(b) the applicant has submitted to the Minister all additional information or material, including samples, requested under section 9;

(c) the Minister has sufficient evidence to support the conclusion that the benefits associated with the COVID-19 medical device outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the urgent public health need; and

(d) the Minister determines that the health or safety of patients, users or other persons will not be unduly affected.[4]

An application for an authorization for importation or sale must contain sufficient information and material to enable the Minister to determine whether to issue an authorization.[5] Section 4(1) of the Interim Order lists the information required in an application for importation or sale, including, but not limited to, the name of the device, the class of the device, and the diagnosis, treatment, mitigation or prevention for which the device is required.[6] Additional information is required in an application for importation or sale in respect of a Class III or IV COVID-19 medical device.[7]

Fees Waived

To remove impediments for manufacturers, Health Canada has waived all application fees for COVID-19 medical devices, as well as the requirement to obtain an MDSAP certificate prior to submitting an application.[8]

Time Frame

Once issued, an authorization for importation or sale is only valid for so long as the Interim Order is in effect. The Interim Order will expire after a one-year period but may be subject to renewal based on the ongoing public health need.[9]

Conclusion

Manufacturers and distributors of medical devices or products that may have utility as a medical device in the current crisis may be eligible to take advantage of this program to get their products sold in Canada without the same regulatory scrutiny while providing much need items in these difficult times.

For more information, please see:

- Announcement: *Applications for medical devices under the Interim Order for use in relation to COVID-19 - Guidance document*
- Announcement: *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19*
- News Release: *Health Canada expedites access to COVID-19 diagnostic laboratory test kits and other medical devices*

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1 *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*, made pursuant to the *Food and Drugs Act*, RSC 1985, c F-27, s 30.1(1).
2 Government of Canada, News Release, "Health Canada expedites access to COVID-19 diagnostic laboratory test kits and other medical devices" (18 March 2020) https://www.canada.ca/en/health-canada/news/2020/03/health-canada-expedites-access-to-covid-19-diagnostic-laboratory-test-kits-and-other-medical-devices.html.
3 Government of Canada, Guidance Document, "Applications for medical devices under the Interim Order for use in relation to COVID-19 – Guidance document" (6 April 2020) https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19/guidance-medical-device-applications.html#a1.
4 *Supra* note 1 at s 5.
5 *Ibid* at s 4(1).
6 *Ibid*.
7 *Ibid* at s 4(2).
8 *Supra* note 3.
9 *Ibid*.
