Interim order respecting the importation and sale of medical devices for use in relation to COVID-19

Whereas the Minister of Health believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment;

Therefore, the Minister of Health, pursuant to subsection 30.1(1) [i] of the *Food and Drugs Act* [ii], makes the annexed *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*.

Ottawa, March 18, 2020
Minister of Health
Patty Hajdu

Interpretation

Definitions

1 The following definitions apply in this Interim Order.

COVID-19 medical device means a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). (*instrument médical destiné à être utilisé à l'égard de la COVID-19*)

foreign regulatory authority means a government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements. (*autorité réglementaire étrangère*)

incident means any incident involving a COVID-19 medical device that

a. is related to a failure of the device or a deterioration in its quality or effectiveness, or any inadequacy in its labelling or in its directions for use; or
b. has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur. (*incident*)

List of Medical Devices for Expanded Use means the *List of Medical Devices for Expanded Use in Relation to the COVID-19 Pandemic* that is published by the Government of Canada on its website, as amended from time to time. (*Liste d'instruments médicaux destinés à un usage supplémentaire*)

Regulations means the *Medical Devices Regulations*. (*Règlement*)

Words and expressions

2 Unless the context requires otherwise, words and expressions used in this Interim Order have the same meaning as in the Regulations.

Importation and sale

3 Part 1 of the Regulations, with the exception of sections 52 to 56 and 63 to 65.1, does not apply to the importation or sale of a COVID-19 medical device if the following conditions are met:

a. the Minister determines that there is an urgent public health need for the importation or sale of the device;
b. the manufacturer of the device has filed with the Minister an application for the authorization of importation or sale of the device in a form established by the Minister;
c. the Minister has issued the authorization; and
d. the authorization has not been cancelled.

Application

4 (1) An application for the authorization of importation or sale of a COVID-19 medical device must contain sufficient information and material to enable the Minister to determine whether to issue the authorization and must include the following:

a. the name of the device;
b. the class of the device;
c. the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
d. the name and address of the manufacturer as it appears on the device label;
e. the address where the device is manufactured, if different from the one referred to in paragraph (d);
f. the diagnosis, treatment, mitigation or prevention for which the device is required;
g. the known information in relation to the quality, safety and effectiveness of the device;
h. the directions for use, unless directions are not required, for the device to be used safely and effectively;

i. an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls; and
j. a copy of the label of the device.

Class III and IV devices

(2) An application in respect of a Class III or IV COVID-19 medical device must contain, in addition to the information and material referred to in subsection (1), the following:

a. a description of the materials used in the manufacture and packaging of the device; and
b. a list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries.

Foreign regulatory authority

(3) Despite subsection (1) and, if applicable, subsection (2), the application need not include the information and material referred to in paragraph (1)(g) and, if applicable, paragraphs (2)(a) and (b) if the applicant provides information that demonstrates that the sale of the COVID-19 medical device is authorized by a foreign regulatory authority and has not been suspended.

Issuance

5 The Minister must issue the 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.

Amendment

6 A person must not sell a COVID-19 medical device in respect of which an authorization for importation or sale has been issued and has not been cancelled if any of the matters referred to in subsection 4(1) and, if applicable, subsection 4(2) are significantly different from the information or material contained in the application, unless

a. the manufacturer has filed with the Minister an application to amend the authorization;
b. the Minister determines that the requirements set out in paragraphs 5(b) to (d) are met; and
c. the Minister amends the authorization.

Terms and conditions

7 The Minister may, at any time, impose terms and conditions on the authorization for importation or sale of a COVID-19 medical device or amend those terms and conditions.

Cancellation

8 The Minister may cancel the authorization for importation or sale of a COVID-19 medical device, giving reasons, if

a. the Minister determines that the requirements under paragraphs 5(c) and (d) are no longer met;
b. the Minister determines that the terms and conditions imposed under section 7 are not met;
c. a medical device licence has been issued for the COVID-19 medical device under section 36 of the Regulations; or
d. the authorization for sale of the COVID-19 medical device that has been issued by a foreign regulatory authority is suspended or cancelled.

Additional information and material

9 The Minister may request a person that has submitted an application for the issuance of an authorization for importation or sale of a COVID-19 medical device or a holder of such an authorization to submit any additional information or any material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or cancel the authorization.

Labelling

10 A person must not import or sell a COVID-19 medical device unless the device has a label that sets out the following information:

a. the name of the device;
b. the name and address of the manufacturer;
c. the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical

device family or device group family;

d. in the case of a Class III or IV device, the control number;
e. if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
f. an indication that the device is sterile, if the manufacturer intends the device to be sold in a sterile condition;
g. the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
h. unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use;
i. the directions for use, unless directions are not required, for the device to be used safely and effectively; and
j. any special storage conditions applicable to the device.

Importation — copy of authorization

11 Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of the authorization for importation.

Incident reporting

12 The holder of an authorization for importation or sale of a COVID-19 medical device must, within 10 days after becoming aware of an incident in Canada, report the incident to the Minister and specify the nature of the incident and the circumstances surrounding it.

Expanded use

13 Part 1 of the Regulations does not apply to the importation or sale of a medical device or a COVID-19 medical device that is set out in column 1 of the *List of Medical Devices for Expanded Use* for the expanded use set out in column 2 if the following conditions are met:

a. the Minister determines that there is an urgent public health need for the expanded use of the medical device or the COVID-19 medical device;
b. the Minister has evidence to support the conclusion that the benefits associated with the expanded use outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the urgent public health need; and
c. the Minister determines that the health or safety of patients, users or other persons will not be unduly affected.

Supplementary information

14 The Minister must publish on a Government of Canada website supplementary information pertaining to the expanded use of a medical device or a COVID-19 medical device, including

a. a statement of the expanded use;
b. a statement of the known and potential benefits and the known and potential risks; and
c. any supplement to the directions for use, unless a supplement is not required, for the device to be used safely and effectively.

Information request

15 (1) The Minister may request from the holder of a medical device licence or the holder of an authorization for importation or sale of a COVID-19 medical device, in respect of a device set out in column 1 of the *List of Medical Devices for Expanded Use*, any information in relation to its expanded use set out in column 2 that the holder possesses or has reasonable access to.

Form and manner

(2) The holder of the licence or authorization must provide the information in the time, form and manner specified by the Minister.

Footnotes

i S.C. 2004, c. 15, s. 66

ii R.S., c. F-27

Related links

- Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19 - Guidance Document [2020-03-26]

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