Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose 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) [1] of the *Food and Drugs Act* [2], makes the annexed *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19*.

Ottawa, March 30, 2020
Patty Hajdu
Minister of Health

Interpretation

Other words and expressions

1 Unless the context otherwise requires, words and expressions used in this Interim Order have the meanings assigned to them by the *Food and Drug Regulations* or the *Medical Devices Regulations*, as the case may be.

Drugs

Interpretation

Definition of drug

2 In sections 3 to 14, ***drug*** does not include

(a) a veterinary health product;
(b) a *natural health product* as defined in subsection 1(1) of the *Natural Health Products Regulations*;
(c) a *cell, organ or tissue* as defined in section 1 of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*; and
(d) *blood* as defined in section 1 of the *Blood Regulations*.

Exceptional Importation and Sale

Definitions

3 The following definitions apply in this section and sections 4 to 10.

designated drug means a drug that is set out in the *List of Drugs for Exceptional Importation and Sale* or a drug that is part of a class of drugs that is set out in that list. (*drogue désignée*)

List of Drugs for Exceptional Importation and Sale means the *List of Drugs for Exceptional Importation and Sale* that is published on a Government of Canada website, as amended from time to time. (*Liste des drogues destinées aux importations et aux ventes exceptionnelles*)

Non-application

4 Subject to section 5 and subsection 6(1), the following provisions of the *Food and Drug Regulations* do not apply to a designated drug that is imported:

(a) sections A.01.044, A.01.051 and A.01.060; and

(b) the provisions of Part C other than

(i) sections C.01.020.1, C.01.040.3 to C.01.049 and C.01.051, and

(ii) the provisions of Divisions 1A and 2 of Part C.

Prohibition — sale

5 (1) The prohibition set out in section C.01.016 of the *Food and Drug Regulations* applies to the sale of a designated drug that is imported.

Serious adverse drug reaction reporting

(2) Despite subsection (1), the manufacturer of the designated drug is required to comply only with the requirements set out in sections C.01.017 and C.01.019 of those Regulations.

Finished product testing

6 (1) Section C.02.019 of the Food and Drug Regulations does not apply to an importer in respect of a designated drug that they import.

Timing of testing

(2) An importer of a designated drug must perform the finished product testing on a sample of the drug that is taken either

(a) after receipt of each lot or batch of the drug on their premises in Canada; or

(b) before receipt of each lot or batch of the drug on their premises in Canada if the following conditions are met:

(i) the importer has evidence satisfactory to the Minister to demonstrate that drugs sold to them by the vendor of that lot or batch are consistently manufactured in accordance with and consistently comply with the specifications for those drugs, and

(ii) the drug has not been transported or stored under conditions that may affect its compliance with the specifications for that drug.

Visual inspection

(3) If the importer receives on their premises in Canada a lot or batch of a drug the useful life of which is more than 30 days, the importer must visually inspect the lot or batch to confirm the identity of the product.

Non-application

(4) Subsections (2) and (3) do not apply to the importer if the designated drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building and both of the following requirements are met:

(a) the address of the building is set out in their establishment licence; and

(b) they retain a copy of the batch certificate for each lot or batch of the drug that they receive.

Information request

7 (1) The Minister may request from an importer of a designated drug, in writing, any of the information referred to in paragraphs C.02.020(1)(a), (b) and (d) of the *Food and Drug Regulations*.

Time, form and manner

(2) The importer must provide the information in the time, form and manner determined by the Minister.

Non-application

8 Subsections 6(2) and (3) and section 7 do not apply in respect of a drug that is not subject to Division 2 of Part C of the *Food and Drug Regulations*.

Notification

9 (1) An importer of a designated drug must notify the Minister at least five days before the day on which the drug is imported.

Content

(2) The notification must be made in the form and manner determined by the Minister and contain the following information:

(a) the importer's name and contact information;
(b) the name and contact information of each fabricator, packager/labeller and tester of the drug and the address of each building in which the drug is fabricated, packaged/labelled or tested,
(c) in respect of the drug that is intended to be imported,
(i) its brand name,
(ii) its medicinal ingredients,
(iii) its dosage form,
(iv) its strength,
(v) its route of administration, and
(vi) its identifying code or number, if any, assigned in the country in which the drug is authorized for sale;
(d) a detailed description of the drug's conditions of use;
(e) the intended port of entry into Canada;
(f) the estimated date of arrival of the shipment of the drug;
(g) the customs identification number for the shipment; and
(h) the total quantity of the drug that is intended to be imported.

Accessibility of information

10 An importer of a designated drug that sells it must ensure that the information referred to in paragraph 9(2)(d) is available in a manner that permits the safe use of the drug.

Interpretation

Definitions

11 The following definitions apply in this section and sections 12 to 14.

biocide means a drug that is not a pest control product and that

(a) is intended to destroy or irreversibly inactivate the number of pathogenic viruses on

(i) the surface of a medical device that is intended to come into contact with intact skin only, or

(ii) a hard surface, other than the surface of a medical device; or

(b) is intended to reduce or inactivate pathogenic microorganisms on human skin. (*biocide*)

pest control product has the same meaning as in sub-section 2(1) of the *Pest Control Products Act*. (*produit antiparasitaire*)

Drug Identification Number

Non-application — application

12 (1) Paragraph C.01.014.1(2)(m.1) of the *Food and Drug Regulations* does not apply in respect of an application for a drug identification number for a biocide that is made under subsection C.01.014.1(1)

Written text of labels

(2) Paragraph C.01.014.1(2)(m) of those Regulations applies in respect of the application and is to be read without reference to the words "in the case of a drug for veterinary use".

Notice of Compliance

Non-application — submission

13 (1) Paragraph C.08.002(2)(j.1) of the *Food and Drug Regulations* does not apply in respect of a new drug submission for a biocide that is submitted under subsection C.08.002(2).

Drafts of labels

(2) Paragraph C.08.002(2)(j) of those Regulations applies in respect of the submission and is to be read without reference to the words "in the case of a new drug for veterinary use"

Establishment Licence

Non-application

14 The provisions of Division 1A of Part C of the *Food and Drug Regulations* do not apply to a person who conducts one or more activities referred to in Table I to section C.01A.008 of those Regulations only in respect of drugs that are not pest control products and that are intended to reduce or inactivate pathogenic microorganisms on human skin.

Medical Devices

Medical Device Shortages — Notification

Definitions

15 The following definitions apply in this section and in sections 16 to 19.

List of Medical Devices — Notification of shortages means the *List of Medical Devices — Notification of Shortages* that is published on a Government of Canada website, as amended from time to time. (*Liste d'instruments médicaux — avis de pénuries*)

shortage means a situation in which the manufacturer of a medical device is unable to meet the demand for the device or for its components, accessories, parts or consumable materials. It does not include a situation in which a substitute device, component, accessory or part is available. (*pénurie*)

specified medical device means a medical device that is set out in the *List of Medical Devices — Notification of Shortages* or a medical device that is part of a category of medical devices that is set out in that List (*instrument médical inscrit*)

Shortage — information

16 (1) If a shortage of a specified medical device — or of its components, accessories, parts or consumable materials — exists — or is likely to occur, the manufacturer and the importer of the device must each submit the following information to the Minister in both English and French in the form and manner determined by the Minister:

(a) the name and contact information of the manufacturer and of the importer;
(b) in the case of a Class II, III or IV device, the medical device licence number;
(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 of the device and of any component or accessory of the device, including, if applicable, the model name;
(e) a description of the device;
(f) the date when the shortage began or is anticipated to begin; and

(g) the anticipated date when the manufacturer will be able to meet the demand for the device if that date can be anticipated.

Timing

(2) The information must be submitted

(a) within five days after the day on which the manufacturer or importer becomes aware of the shortage; or

(b) within five days after the day on which the manufacturer or importer anticipates the shortage.

Updates

(3) If any of the information that was submitted by the manufacturer or importer changes, the manufacturer or importer must submit the new information to the Minister within two days after the day on which they make or become aware of the change.

End of shortage

(4) Within two days after the day on which the manufacturer is able to meet the demand for the medical device — or for its components, accessories, consumable materials or parts — the manufacturer or importer must notify the Minister in writing to that effect.

Permission

17 (1) Despite subsection 16(1), the manufacturer of a specified medical device may permit an importer of the device to submit the information referred to in that subsection on the manufacturer's behalf if the information that the manufacturer and importer must submit is identical.

Notification

(2) The manufacturer must notify the Minister in writing if the manufacturer has permitted an importer to submit the information on the manufacturer's behalf.

Publication of information

18 The Minister must publish the information that he or she receives under section 16 on a Government of Canada website.

Information request

19 (1) The Minister may request from the manufacturer or importer of a specified medical device any information, other than the information referred to in section 16, that relates to a shortage of the device or of its components, accessories, parts or consumable materials.

Time, form and manner

(2) The manufacturer or importer must provide the information in the time, form and manner determined by the Minister.

Exceptional importation and sale

Definitions

20 The following definitions apply in this section and in sections 21 to 23.

designated medical device means a medical device that is set out in the *List of Medical Devices for Exceptional Importation and Sale* or a medical device that is part of a category of medical devices that is set out in that List. (*instrument médical désigné*)

List of Medical Devices for Exceptional Importation and Sale means the *List of Medical Devices for Exceptional Importation and Sale* that is published on a Government of Canada website, as amended from time to time. (*Liste*

d'instruments médicaux destinés aux importations et aux ventes exceptionnelles)

Non-application

21 The provisions of the *Medical Devices Regulations* — other than sections 44 to 65.1 — do not apply to a medical device if the device is

(a) a designated medical device for which no country of manufacture is specified in the *List of Medical Devices for Exceptional Importation and Sale*; or

(b) a designated medical device for which a country of manufacture is specified in the *List of Medical Devices for Exceptional Importation and Sale* and the device is manufactured in that country.

Notification

22 (1) An importer of a designated medical device must notify the Minister at least five days before the day on which the device is imported.

Content

(2) The notification must be made in the form and manner determined by the Minister and contain the following information:

(a) the importer's name and contact information;

(b) in respect of the designated medical device that is intended to be imported

(i) the name of the device and of any component or accessory of the device, including, if applicable, the model name,

(ii) 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,

(iii) the name and contact information of the manufacturer of the device as it appears on the device label, and

(iv) the name and address of the establishment where the device is manufactured, if different from the information referred to in subparagraph (iii);

(c) a detailed description of 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;

(d) the intended port of entry into Canada;

(e) the estimated date of arrival of the shipment of the device;

(f) the customs identification number for the shipment; and

(g) the total number of units of the device that are intended to be imported.

Accessibility of information

23 An importer of a designated medical device that sells it must ensure that the information referred to in paragraph 22(2)(c) is available in a manner that permits the safe use of the device.

Food

Exceptional Importation and Sale

Definitions

24 The following definitions apply in this section and in sections 25 to 27.

designated food for a special dietary purpose means a food for a special dietary purpose that is set out in the *List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale* or such a food that is part of a

class of foods for a special dietary purpose that is set out in that List. (*aliment à des fins diététiques spéciales désigné*)

food for a special dietary purpose means a food that has been specially processed or formulated

(a) to meet the particular requirements of an individual in whom a physical or physiological condition exists as a result of a disease, disorder or abnormal physical state; or
(b) to be the sole or primary source of nutrition for an individual. (*aliment à des fins diététiques spéciales*)

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 a food for a special dietary purpose within its jurisdiction and that may take enforcement action to ensure that such foods marketed within its jurisdiction comply with the applicable legal requirements. (*autorité réglementaire étrangère*)

List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale means the *List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale* that is published on a Government of Canada website, as amended from time to time. (*Liste d'aliments à des fins diététiques spéciales destinés aux importations et aux ventes exceptionnelles*)

Non-application

25 (1) Sections A.01.014 and A.01.016 of the *Food and Drug Regulations*, — the provisions of Part B of those Regulations — other than sections B.24.100 and B.24.300 — and the provisions of Part D of those Regulations do not apply to a food for a special dietary purpose that is imported if the food is

(a) a designated food for a special dietary purpose for which no country of manufacture is specified in the *List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale*; or
(b) a designated food for a special dietary purpose for which a country of manufacture is specified in the *List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale* and the food is manufactured in that country.

Exemptions

(2) A food for a special dietary purpose that is imported is exempt from the application of paragraphs 4(1)(a) and (d) of the *Food and Drugs Act* in respect of the use or presence of any of the following substances or materials if the applicable condition in subsection (1)(a) or (b) is met:

(a) food additives;
(b) any nutritive material that is used as an ingredient of the food;
(c) vitamins, mineral nutrients and amino acids;
(d) agricultural chemicals;
(e) food packaging materials and components of those materials;
(f) drugs recommended for administration to animals that may be consumed as food; and
(g) any other substance specified in the *List of Foods for a Special Dietary Purpose for Exceptional Importation and Sale* in respect of the food.

Notification

26 (1) An importer of a designated food for a special dietary purpose must notify the Minister at least five days before the day on which the food is imported.

Content

(2) The notification must be made in the form and manner determined by the Minister and contain the following information:

(a) the importer's name and contact information;
(b) information that demonstrates that the sale of the food is authorized by a foreign regulatory authority, if such an authorization is required within its jurisdiction;
(c) the name and contact information of the manufacturer of the food as it appears on the food's label;
(d) the name and address of each establishment in which the food is manufactured;
(e) in respect of the food that is intended to be imported,
(i) a copy of the food's labels,
(ii) the special dietary purpose for which the food is represented,
(iii) a list of the food's ingredients,
(iv) the warnings, if applicable,
(v) directions for the preparation, use and storage of the food,
(vi) the expiration date, and
(vii) the lot number of the food, if applicable;
(f) the intended port of entry into Canada;
(g) the estimated date of arrival of the shipment of the food;
(h) the customs identification number for the shipment; and
(i) the total quantity of the food that is intended to be imported.

Accessibility of information

27 An importer of a designated food for a special dietary purpose that sells it must ensure that the information referred to in subparagraphs 26(2)(e)(ii) to (vii) is available in a manner that permits the safe preparation and use of the food.

Footnotes

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

2 R.S., c. F-27

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