Interim Order Respecting the Importation, Sale and Advertising of Drugs 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) [1] of the *Food and Drugs Act* [2], makes the annexed *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.

Ottawa, September 16, 2020

Minister of Health
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Interpretation

Definition

1 (1) The following definitions apply in this Interim Order.

authorization

means an authorization issued under section 5. (autorisation)

Chief Public Health Officer

means the Chief Public Health Officer appointed under subsection 6(1) of the *Public Health Agency of Canada Act*. (administrateur en chef de la santé publique)

COVID-19

means the coronavirus disease 2019. (COVID-19)

COVID-19 drug

means a drug that is manufactured, sold or represented for use in relation to COVID-19. (drogue contre la COVID-19)

drug

means a drug other than

a. a veterinary health product; or
b. a natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations*. (drogue)

foreign drug

means a drug that is set out in the *List of Foreign Drugs*. (drogue étrangère)

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 drugs within its jurisdiction and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with the applicable legal requirements. (autorité réglementaire étrangère)

List of Foreign Drugs

means the *List of Foreign Drugs in Relation to the COVID-19 Pandemic* that is published on a Government of Canada website, as amended from time to time. (*Liste des drogues étrangères*)

List of New Drugs for Expanded Indication

means the *List of New Drugs for Expanded Indication in Relation to the COVID-19 Pandemic* that is published on a Government of Canada website, as amended from time to time. (*Liste des drogues nouvelles à indication supplémentaire*)

notice of compliance

means a notice of compliance issued under section C.08.004 or C.08.004.01 of the Regulations. (avis de conformité)

Regulations

means the *Food and Drug Regulations*. (Règlement)

submission

means any of the following:

a. a new drug submission that is filed under section C.08.002 of the Regulations;
b. an extraordinary use new drug submission that is filed under section C.08.002.01 of the Regulations;
c. an abbreviated new drug submission that is filed under section C.08.002.1 of the Regulations; or
d. an abbreviated extraordinary use new drug submission that is filed under section C.08.002.1 of the Regulations. (*présentation*)

supplement

means a supplement to a submission that is filed under section C.08.003 of the Regulations. (*supplément*)

Other words and expressions

(2) Unless the context otherwise requires, words and expressions used in this Interim Order have the meanings assigned by the Regulations.

Interpretation

(3) For the purposes of the definition *innovative drug* in subsection C.08.004.1(1) of the Regulations, a medicinal ingredient in a COVID-19 drug is not considered to be approved in a drug by the Minister by reason of the Minister having issued or amended an authorization in respect of the COVID-19 drug.

Authorizations

Non-application

2 (1) The provisions of the Regulations — other than the following provisions — do not apply to a COVID-19 drug if an authorization is issued in respect of the drug and the authorization is not suspended or revoked:

a. sections A.01.014, A.01.015, A.01.022 to A.01.043, A.01.050, A.01.051 and A.01.060.1 to A.01.068;
b. sections C.01.004 to C.01.011, C.01.014.9, C.01.014.10, C.01.017 and C.01.019, subsection C.01.020(1), sections C.01.020.1, C.01.040.3 to C.01.053, C.01.064 to C.01.069 and C.01.401;
c. the provisions of Division 1A of Part C;
d. the provisions of Division 2 of Part C with the exception of section C.02.019;
e. sections C.03.202, C.03.203 and C.03.206 to C.03.209; and
f. sections C.04.013 to C.04.016, C.04.019 and C.04.020.

Clarification

(2) For greater certainty, an authorization issued in respect of a COVID-19 drug authorizes the sale and advertising of the drug in accordance with this Interim Order.

Application for authorization

3 (1) Subject to section 4, an application for an authorization in respect of a COVID-19 drug must be in a form established by the Minister and contain sufficient information and material to enable the Minister to determine whether to issue the authorization, including

a. the applicant's name and contact information and, in the case of a foreign applicant, the name and contact information of their representative in Canada;
b. a description of the drug and a statement of its proper name or its common name if there is no proper name;
c. a statement of the brand name of the drug or the identifying name or code proposed for the drug;
d. a list of the ingredients of the drug, stated quantitatively;
e. the specifications for each of the drug's ingredients;
f. a description of the facilities and equipment to be used in the manufacture, preparation and packaging of the drug;
g. details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the drug;
h. details of the tests to be applied to control the potency, purity, stability and safety of the drug;
i. the names and qualifications of all the investigators to whom the drug has been sold;
j. a draft of every label to be used in connection with the drug, including any package insert and any document that is provided on request and that sets out supplementary information on the use of the drug;
k. a statement of all the representations to be made for the promotion of the drug respecting
    i. the recommended route of administration of the drug,
    ii. the proposed dosage of the drug,
    iii. the drug's indications, and

iv. the contra-indications and side effects of the drug;

l. a description of the dosage form that is proposed for the sale of the drug;

m. evidence that all test batches of the drug used in any studies conducted in connection with the application were manufactured and controlled in a manner that is representative of market production;

n. in the case of a drug intended for administration to food-producing animals, the withdrawal period of the drug; and

o. the known information in relation to the quality, safety and effectiveness of the drug.

Incomplete application – plan

(2) If, at the time an application is initially submitted to the Minister, the applicant is unable to provide information or material referred to in any of paragraphs (1)(g) to (k) and (m) to (o) or that information or material is incomplete, the applicant must include in the initial part of the application a plan as to how and when they will provide the Minister with the missing information or material.

Application based on comparison

(3) A person may submit an application for an authorization in respect of a COVID-19 drug under this section on the basis of a direct or indirect comparison to another drug only if

a. the person notifies the Minister of their intention to submit the application and provides information to the Minister to establish that the following requirements are met:

i. a notice of compliance or authorization is issued in respect of the other drug, and

ii. the other drug is not offered for sale in Canada or is offered for sale in Canada but not in sufficient quantities to address the urgent public health need related to COVID-19;

b. the Minister, after receiving the notification and information referred to in paragraph (a), provides the manufacturer of the other drug with, having regard to the urgent public health need related to COVID-19, an opportunity to make representations to the Minister as to whether the requirement set out in subparagraph (a)(ii) is met; and

c. the Minister determines that the requirements set out in subparagraphs (a)(i) and (ii) are met and notifies the person in writing of that determination.

Application for authorization – foreign drug

4 (1) An application for an authorization in respect of a COVID-19 drug may be based on a comparison to a foreign drug if the sale of the foreign drug is authorized by a foreign regulatory authority on the basis of information submitted to the authority in relation to the quality, safety and effectiveness of that drug.

Content

(2) The application must be in a form established by the Minister and contain the following information and material:

a. the information and material described in paragraphs 3(1)(a) to (d), (f), (j) to (l) and, if applicable, (n);

b. an attestation, signed and dated by an individual who has authority to bind the applicant in Canada, certifying that the applicant has access to the information referred to in paragraph 3(1)(o) that was submitted to the relevant foreign regulatory authority in order for the foreign drug to be authorized to be sold;

c. information that demonstrates that the drug is identical to, and is manufactured, prepared and packaged in the same manner as, the foreign drug;
d. information that demonstrates that the sale of the foreign drug is authorized by the foreign regulatory authority referred to in paragraph (b); and
e. any labels that are approved by the foreign regulatory authority referred to in paragraph (b) for use in connection with the foreign drug.

Issuance

5 The Minister must issue an authorization in respect of a COVID-19 drug if the following requirements are met:

a. the applicant has submitted an application to the Minister that meets the requirements set out in subsection 3(1) or 4(2);
b. the applicant has provided the Minister with all information or material, including samples, requested under subsection 13(1) in the time, form and manner specified under subsection 13(2); and
c. the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

Prohibition – significant difference

6 (1) It is prohibited to sell a COVID-19 drug to which an authorization relates if any of the matters referred to in subsection 3(1) or subsection 4(2) — other than in paragraph 3(1)(i) or 4(2)(e), as the case may be — are significantly different from the information or material contained in the application, unless the Minister amends the authorization.

Amendment

(2) The Minister must amend the authorization if the following requirements are met:

a. the holder of the authorization has submitted an application to the Minister to amend it;
b. the holder has provided the Minister with all information or material, including samples, requested under subsection 13(1) in the time, form and manner specified under subsection 13(2); and
c. the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

Drug identification number

7 (1) When the Minister issues or amends an authorization, he or she must assign a drug identification number for each distinct combination of dosage form, strength and route of administration for the COVID-19 drug to which the authorization relates.

Deeming – holder

(2) Any reference to a person that holds a drug identification number in sections C.01.050, C.01.052, C.01.053 and C.01A.003 of the Regulations is deemed to include a reference to the holder of an authorization.

Deeming – drug identification number

(3) Any reference to a drug identification number in the provisions of Divisions 1 and 1A of Part C of the Regulations — other than in sections C.01.050, C.01.052, C.01.053 and C.01A.003 — is deemed to include a

reference to a drug identification number assigned under subsection (1).

Notification of first sale

8 The holder of an authorization must, within 15 days after the day on which the COVID-19 drug to which the authorization relates is first sold in Canada, notify the Minister, in writing, of the date of that first sale.

Notification of discontinuance

9 The holder of an authorization must, within 15 days after the day on which they permanently discontinue the sale in Canada of the COVID-19 drug to which the authorization relates, notify the Minister, in writing, of the date on which the sale was permanently discontinued.

Terms and conditions

10 The Minister may, at any time, impose terms and conditions on an authorization or amend those terms and conditions.

Suspension

11 (1) The Minister may suspend an authorization, in whole or in part, giving reasons, if

a. the Minister determines that the requirement set out in paragraph 5(c) is no longer met;
b. the Minister has reasonable grounds to believe that the holder of the authorization has contravened, in relation to the COVID-19 drug to which the authorization relates, any provision of this Interim Order, the Regulations or the *Food and Drugs Act* or any order made under that Act; or

c. in the case of an authorization that was issued on the basis of an application submitted under section 4, the Minister becomes aware that the foreign regulatory authority has revoked or suspended the authorization to sell the foreign drug.

Reinstatement

(2) The Minister must reinstate a suspended authorization if the holder provides to the Minister, in the time, form and manner specified by the Minister, information or material that demonstrates that the situation giving rise to the suspension did not exist or has been corrected.

Discretionary revocation

12 (1) The Minister may revoke an authorization, in whole or in part, giving reasons, if the holder of the authorization has not provided to the Minister, in the time, form and manner specified by the Minister, the information or material referred to in subsection 11(2).

Mandatory revocation

(2) The Minister must revoke an authorization if the holder of the authorization requests it.

Request for information or material

13 (1) The Minister may request that a person that has submitted an application for an authorization in respect of a COVID-19 drug or the holder of such an authorization provide any information or material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or suspend the authorization.

Time, form and manner

(2) The person or holder, as the case may be, must provide the information, material or samples in the time, form and manner specified by the Minister.

Comparison – submission or supplement

14 (1) Despite sections C.08.002, C.08.002.01, C.08.002.1 and C.08.003 of the Regulations and subject to subsection (2), a manufacturer of a new drug is not permitted to file a submission or supplement for the new drug on the basis of a direct or indirect comparison to a COVID-19 drug in respect of which an authorization is issued.

Clarification

(2) In the case where both a notice of compliance and an authorization are issued in respect of a COVID-19 drug, subsection (1) does not prevent a manufacturer of a new drug from filing a submission or supplement for the new drug in respect of the matters that are approved under the notice of compliance.

Expanded indication

15 Section C.08.003 of the Regulations does not apply to the sale of a new drug — in respect of which a notice of compliance is issued and that is set out in the *List of New Drugs for Expanded Indication* — in relation to the expanded indication that is set out in the List in respect of the new drug if the Minister

a. determines that the expanded indication of the new drug is necessary to address the urgent public health need related to COVID-19; and
b. has evidence to support the conclusion that the benefits associated with the expanded indication outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

Supplementary information

16 The Minister must publish on a Government of Canada website supplementary information pertaining to the expanded indication of a new drug that is set out in the *List of New Drugs for Expanded Indication*, including

a. a statement of the expanded indication;
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 new drug to be used safely and effectively.

Information request

17 (1) If a new drug for which a notice of compliance is issued is set out in the *List of New Drugs for Expanded Indication*, the Minister may request the manufacturer to which the notice of compliance is issued to provide any information that it possesses or has reasonable access to in relation to the expanded indication that is set out in the List in respect of the drug.

Time, form and manner

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

Shortages or discontinuation of sale

18 Despite the definition *drug* in section C.01.014.8 of the Regulations, sections C.01.014.9 and C.01.014.10 of the Regulations apply, with any modifications that may be necessary, to the holder of an authorization in respect of the COVID-19 drug to which the authorization relates.

Records

19 (1) The holder of an authorization must maintain records of the following in relation to the COVID-19 drug to which the authorization relates:

a. any substitution of another substance for the drug or any mixing of another substance with the drug;
b. any error in the labelling of the drug or in the use of the labels designed for the drug;
c. any bacteriological or any significant chemical or physical or other change or deterioration in any lot of the drug;
d. any failure of one or more distributed lots of the drug to meet the specifications established for the drug; and
e. any unusual failure in efficacy of the drug.

Provision to Minister

(2) The holder of the authorization must provide to the Minister

a. a summary of a record respecting any information referred to in paragraphs (1)(a) to (c), immediately after the holder establishes the record; or
b. a summary of a record respecting any information referred to in paragraph (1)(d) or (e), within 15 days after the day on which the holder establishes the record.

Establishment licences

Application for establishment licence

20 (1) A person that submits an application for an establishment licence under section C.01A.005 of the Regulations that relates solely to one or more activities set out in Table I of section C.01A.008 of the Regulations in

respect of a COVID-19 drug may include a statement to that effect in the application.

Application for amendment

(2) A person that submits an application for the amendment of their establishment licence under section C.01A.006 of the Regulations that relates solely to one or more activities set out in Table I of section C.01A.008 of the Regulations in respect of a COVID-19 drug may include a statement to that effect in the application.

Deeming

(3) In the case of an application referred to in subsection (1) or (2) that includes the relevant statement, any reference to information and documents in sections C.01A.006 and C.01A.008 of the Regulations is deemed to include that statement.

Information and material

21 For the purposes of section C.01A.008 of the Regulations, the Minister must, in determining whether he or she has received the information and material required by sections C.01A.005 to C.01A.007 of the Regulations in relation to an application referred to in subsection 20(1) or (2) that includes the statement referred to in the applicable subsection, also take into consideration the necessity of addressing the urgent public health need related to COVID-19.

Terms and conditions

22 (1) Despite subsection C.01A.008(4) of the Regulations and subject to subsection (2), the Minister may, at any time, including when issuing an establishment licence, impose terms and conditions on an establishment

licence that is issued or amended under section C.01A.008 of the Regulations on the basis of an application referred to in subsection 20(1) or (2) that includes the statement referred to in the applicable subsection.

Duration

(2) Any terms and conditions that the Minister imposes on an establishment licence under subsection (1) cease to apply to the licence immediately before this Interim Order ceases to have effect.

Scope

(3) For greater certainty, terms and conditions that may be imposed under subsection (1) are not limited to those described in paragraphs C.01A.008(4)(a) and (b) of the Regulations.

Amending terms and conditions

23 Despite section C.01A.012 of the Regulations, the Minister may, at any time, amend any terms and conditions that are imposed on an establishment licence under section 22.

Verification – holder or importer

24 (1) If the holder of an authorization receives a lot or batch of the COVID-19 drug to which the authorization relates — or an importer receives a lot or batch of such a COVID-19 drug — on their premises in Canada the useful life of which is more than 30 days, the holder or importer must visually inspect the lot or batch to confirm its identity.

Verification – packager/labeller

(2) If a packager/labeller receives a lot or batch of a COVID-19 drug on their premises in Canada the useful life of which is more than 30 days, the packager/labeller must test the lot or batch for identity and must confirm the identity of the lot or batch after it is packaged/labelled.

Exception – holder

(3) Subsection (1) does not apply to the holder of the authorization if the COVID-19 drug is fabricated, packaged/labelled and tested in Canada by a person that holds an establishment licence that authorizes those activities in respect of that drug.

Exception – holder or importer

(4) Subsection (1) does not apply to the holder of the authorization or the importer if the following requirements are met:

a. the COVID-19 drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building;
b. the address of the building is set out in their establishment licence; and
c. they retain a copy of the batch certificate for each lot or batch of the drug that they receive.

Non-application – records

25 (1) Paragraphs C.02.020(1)(a), (b) and (d) of the Regulations do not apply to an importer in respect of a COVID-19 drug to which an authorization relates.

Deeming – holder

(2) Any reference in section C.02.020 of the Regulations to a distributor referred to in paragraph C.01A.003(b) of the Regulations is deemed to include a reference to the holder of an authorization.

Cancellation

26 (1) Any establishment licence that the Minister has issued under section C.01A.008 of the Regulations on the basis of an application referred to in subsection 20(1) that includes the statement referred to in that subsection is cancelled immediately before this Interim Order ceases to have effect.

Amendment ceasing to have effect

(2) Any amendment that the Minister has made to an establishment licence that was issued under section C.01A.008 of the Regulations before this Interim Order is made ceases to have effect immediately before this Interim Order ceases to have effect if the Minister made the amendment on the basis of an application referred to in subsection 20(2) that included the statement referred to in that subsection.

Pre-positioning of COVID-19 drugs

Application

27 Sections 28 to 30 apply in respect of a COVID-19 drug if the following conditions are met:

a. a notice of compliance has not been issued in respect of the drug;
b. an authorization has not been issued in respect of the drug; and
c. Her Majesty in right of Canada has entered into a contract for the procurement of the drug.

Importation

28 (1) The holder of an establishment licence may import a COVID-19 drug if the following conditions are met:

a. the Chief Public Health Officer provides the Minister with
    i. information indicating that
        A. the drug is the subject of an application submitted under section 3 or 4,
        B. the drug is the subject of a submission, or
        C. an application has been submitted to a foreign regulatory authority to authorize the sale of a foreign drug that is identical to, and is manufactured in the same manner as, the drug,
    ii. the name of the drug and a description of it,
    iii. the name and contact information of the drug's manufacturer,
    iv. information specifying the quantity of the drug to be imported,
    v. the name and contact information of the holder of an establishment licence who is proposed to import the drug, and
    vi. the civic address of the place where the drug will be stored after importation;
b. the holder provides the Minister with
    i. the name and contact information of each fabricator, packager/labeller and tester of the drug and the civic address of each building at which the drug will be fabricated, packaged/labelled or tested, specifying for each building
        A. the activities referred to in Table I to section C.01A.008 of the Regulations that apply to the drug,
        B. the categories referred to in Table II to that section that apply to the drug, and

C. for each category, the dosage form classes, if any, and whether the drug will be in a sterile form, and

ii. a certificate from an inspector indicating that each fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of the provisions of Divisions 2 to 4 of Part C of the Regulations or, alternatively, other evidence establishing that those requirements are met; and

c. the holder is specified in the information that the Chief Public Health Officer provides under subparagraph (a)(v).

Exception

(2) Paragraph (1)(b) does not apply to the holder of an establishment licence in respect of a building referred to in subparagraph (1)(b)(i) if

a. the building is listed in the licence; and

b. the information referred to in clauses (1)(b)(i)(A) to (C) that the holder submitted in respect of the building in their application for the licence under section C.01A.005 of the Regulations, or in an application for an amendment to the licence under section C.01A.006 of the Regulations, as the case may be, has not changed.

Letter

(3) If the conditions set out in subsection (1) are met, the Minister must send a letter to the Chief Public Health Officer to that effect.

Non-application – importation

29 Sections A.01.040 and C.01.004.1, subsection C.01A.004(1) and section C.01A.006 of the Regulations and the provisions of Divisions 2 to 4 of Part C of the Regulations, except for the following provisions, do not apply in

respect of the importation of a COVID-19 drug by the holder of an establishment licence under section 28:

a. sections C.02.003.1, C.02.004 and C.02.006, as they apply to the storage of the drug by the holder;
b. subsection C.02.012(1);
c. sections C.02.013 and C.02.014;
d. section C.02.015, as it applies to the storage and transportation of the drug by the holder;
e. subsection C.02.021(1), as it applies to the storage of the drug by the holder;
f. subsection C.02.022(1);
g. section C.02.023;
h. subsection C.02.024(1);
i. section C.03.013; and
j. section C.04.001.1, as it applies to the storage of the drug by the holder.

Distribution of imported drug

30 Despite anything in the Regulations, the holder of an establishment licence may distribute a COVID-19 drug that they have imported under section 28 if the following conditions are met:

a. the Chief Public Health Officer provides the Minister with the name of the drug and the civic address of the place where the drug will be stored after the distribution; and
b. the drug is distributed to a person who will store it at the place.

Footnotes

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

2 R.S., c. F-27

Date modified:
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