Government of Canada / Gouvernement du Canada

Interim Order respecting clinical trials for medical devices and drugs relating 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) [a] of the *Food and Drugs Act* [b], makes the annexed *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*.

Ottawa, May 23, 2020

Minister of Health
Patricia Hajdu

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Interpretation

Definition

1 The following definitions apply in this Interim Order.

COVID-19 means the coronavirus disease 2019. (COVID-19)

COVID-19 drug means a drug for human use that is manufactured, sold or represented for use in relation to COVID-19. *(drogue utilisée en lien avec la COVID-19)*

COVID-19 drug authorization means an authorization to do any of the following activities:

a. import or sell a COVID-19 drug that is to be tested in a clinical trial; and
b. conduct a clinical trial in respect of such a drug. *(autorisation relative à une drogue utilisée en lien avec la COVID-19)*

COVID-19 medical device means a medical device that is manufactured, sold or represented for use in relation to COVID-19. *(instrument médical utilisé en lien avec la COVID-19)*

COVID-19 medical device authorization means an authorization to do any of the following activities:

a. import or sell a COVID-19 medical device that is to be tested in a clinical trial; and
b. conduct a clinical trial in respect of such a device. *(autorisation relative à un instrument médical utilisé en lien avec la COVID-19)*

incident means any incident involving a COVID-19 medical device that is tested in a clinical trial 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 its directions for use; or
b. has led to the death or a serious deterioration in the state of health of a clinical trial subject, user or other person or could do so were it to recur. *(incident)*

qualified investigator means a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care under their licence in that province and who

a. conducts a clinical trial; or
b. in the case of a clinical trial conducted by a team, is the responsible leader of that team. *(chercheur compétent)*

research ethics board means a body that is not affiliated with an applicant for a COVID-19 medical device authorization or a COVID-19 drug authorization, or a holder of such an authorization, and whose principal mandate is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being. *(comité d'éthique de la recherche)*

Words and expressions

2 (1) Unless the context requires otherwise, words and expressions used in this Interim Order have the same meaning as in the *Medical Devices Regulations* and the *Food and Drug Regulations*, as applicable.

Definition of clinical trial

(2) Despite subsection (1), ***clinical trial*** has the same meaning as in section 2 of the Act, except as otherwise provided.

Application

3 (1) This Interim Order applies to the importation and sale of a COVID-19 medical device, other than a Class I device, that is to be tested in a clinical trial, to the importation and sale of a COVID-19 drug, other than a drug that is described in Schedule C to the Act, that is to be tested in a clinical trial and to the conduct of a clinical trial in respect of such a device or drug.

Non-application — COVID-19 medical device

(2) The *Medical Devices Regulations* do not apply to the importation and sale of a COVID-19 medical device that is to be tested in a clinical trial and to the conduct of a clinical trial in respect of such a device if those activities are

authorized by a COVID-19 medical device authorization and the authorization has not been revoked.

Non-application — COVID-19 drug

(3) The following regulations do not apply to the importation and sale of a COVID-19 drug that is to be tested in a clinical trial and to the conduct of a clinical trial in respect of such a drug if those activities are authorized by a COVID-19 drug authorization and the authorization has not been revoked:

a. the *Food and Drug Regulations*, other than sections A.01.022 to A.01.024, A.01.026, A.01.041, A.01.042, A.01.050, A.01.067, A.01.068, C.01.015, C.01.036, C.01.037 to C.01.040, C.01.040.2, C.01.051, C.01.064 to C.01.067, C.01.070, C.01.131, C.01.133 to C.01.136 and C.01.435 and Divisions 2 and 4 of Part C; and
b. the *Blood Regulations*.

Part 1 COVID-19 Medical devices

Application

4 (1) An application for a COVID-19 medical device authorization must be submitted to the Minister in the form and manner specified by the Minister.

Content

(2) The application 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 and contact information of the applicant and, if applicable, the importer;
b. the name and class of the device;

c. a description of the device and of the materials used in its manufacture and packaging;
d. a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented, including its performance specifications if those specifications are necessary for proper use;
e. 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;
f. the name and contact information of the manufacturer as they appear on the device label;
g. the address where the device is manufactured, if the address is different from the one provided in the contact information under paragraph (f);
h. the diagnosis, treatment, mitigation or prevention for which the device is required;
i. 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 of any recalls of the device in those countries;
j. the known information in relation to the quality, safety and effectiveness of the device;
k. the directions for use, unless directions are not required for the device to be used safely and effectively;
l. an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls;
m. a copy of the label of the device;

n. the name of the qualified investigator and their qualifications, including their training and experience;
o. the name and contact information of the institution at which the clinical trial is proposed to be conducted;
p. the protocol of the proposed clinical trial, including the number of clinical trial subjects, the number of units of the device proposed to be used for the clinical trial, the hypothesis for and objective of the clinical trial, the period of time during which the clinical trial will be conducted and a copy of the informed consent form;
q. a written undertaking from the qualified investigator to:
    i. conduct the clinical trial in accordance with the protocol provided by the applicant,
    ii. inform each clinical trial subject of any risks and benefits associated with the use of the device and obtain the subject's informed consent for its use, and
    iii. not permit the device to be used by any other person except under the direction of the qualified investigator; and
r. in the case of a Class III or IV device, for each clinical trial site, the name and contact information of the research ethics board that approved the protocol and informed consent form referred to in paragraph (p), if known at the time of submitting the application.

Class II devices

(3) Despite subsection (2), if the application for the authorization is in respect of a Class II COVID-19 medical device, the information and material set out in paragraphs (2)(c), (h) to (j), (n) and (q) may be omitted from the application.

Issuance

5 The Minister must issue a COVID-19 medical device authorization if the following requirements are met:

a. the applicant has submitted to the Minister an application that meets the requirements set out in section 4;
b. the applicant has submitted to the Minister any additional information or material requested under subsection 10(1) in the time, form and manner specified under subsection 10(2); and
c. the Minister determines that:
    i. the use of the device that is to be tested in the clinical trial will not unduly affect the health or safety of clinical trial subjects, users or other persons,
    ii. the clinical trial is not contrary to the best interests of clinical trial subjects, and
    iii. the objectives of the clinical trial are achievable.

Research ethics board approval

6 A holder of a COVID-19 medical device authorization must not import or sell a COVID-19 medical device for which the authorization has been issued or conduct a clinical trial in respect of such a device unless the holder has obtained, for each clinical trial site, the approval of a research ethics board in respect of the protocol and informed consent form referred to in paragraph 4(2)(p).

Terms and conditions

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

Amendment

8 A holder of a COVID-19 medical device authorization must not import or sell a COVID-19 medical device for which the authorization has been issued or conduct a clinical trial in respect of such a device if the substance of any of the information or material referred to in subsection 4(2) and, if applicable, submitted under subsection 10(1), is significantly different from the substance of the information or material contained in the application, unless:

a. the holder has filed with the Minister an application to amend the authorization;
b. the Minister determines that the requirements set out in subparagraphs 5(c)(i) to (iii) are met;
c. the holder has submitted to the Minister any additional information or material requested under subsection 10(1) in the time, form and manner specified under subsection 10(2); and
d. the Minister amends the authorization.

Suspension

9 (1) The Minister may suspend, in whole or in part, a COVID-19 medical device authorization by notice, giving reasons, if:

a. the Minister determines that any of the requirements set out in subparagraphs 5(c)(i) to (iii) is no longer met;
b. the holder of the authorization has not provided to the Minister any additional information or material requested under subsection 10(1) in the time, form and manner specified under subsection 10(2); or
c. the holder of the authorization has contravened this Interim Order or any provisions of the Act relating to the device.

Reinstatement

(2) The Minister must reinstate a COVID-19 medical device authorization if the holder of the authorization 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.

Additional information and material

10 (1) The Minister may request an applicant for a COVID-19 medical device authorization or a holder of such an authorization to submit any additional information or material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or suspend the authorization.

Form and manner

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

Discontinuance

11 If a holder of a COVID-19 medical device authorization discontinues, in whole or in part, the clinical trial for which the authorization has been issued, the holder must, without delay:

a. notify the Minister, in writing, of the discontinuance and the reasons for it;
b. inform all qualified investigators, in writing, of the discontinuance and the reasons for it and advise them, in writing, of any potential risks to the health of clinical trial subjects, users or other persons; and
c. in respect of each clinical trial site at which the trial is discontinued, stop the importation or sale of the device as of the date of the

discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the device that have been sold.

Discretionary revocation

12 (1) The Minister may revoke, in whole or in part, a COVID-19 medical device authorization by notice, 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 9(2).

Mandatory revocation

(2) The Minister must revoke, in whole or in part, the authorization if the Minister has received a notice of discontinuance referred to in paragraph 11(a).

Labelling

13 (1) A person must not import or sell a COVID-19 medical device for which a COVID-19 medical device authorization has been issued or conduct a clinical trial in respect of such a device unless the device has a label that sets out the following information:

a. the name of the device;
b. the name and contact information 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. a statement indicating that the device is sterile, if the device is to be sold in a sterile condition;
g. the expiry date of the device, if the device has one;
h. the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including its performance specifications 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;
j. any special storage conditions applicable to the device;
k. a statement indicating that the device is an investigational device;
l. a statement indicating that the device is to be used by qualified investigators only; and
m. in the case of an *in vitro* diagnostic device, a statement indicating that the performance specifications of the device have not been established.

Presentation of information

(2) The information required by subsection (1) to be set out on the label must be in English and in French.

Incident reporting

14 A holder of a COVID-19 medical device authorization must, within 10 days after becoming aware of an incident inside or outside Canada involving a COVID-19 medical device for which the authorization has been issued, report the incident to the Minister and specify the nature of the incident and the circumstances surrounding it.

Records

15 (1) A holder of a COVID-19 medical device authorization must record, handle and store all information in respect of the clinical trial for which the authorization has been issued in a manner that allows for the complete and accurate reporting as well as the interpretation and verification of the information.

Content

(2) The holder of the authorization must maintain complete and accurate records in respect of a COVID-19 medical device for which the authorization has been issued in order to establish that the clinical trial is conducted in accordance with this Interim Order and that include the information and material referred to in subsection 4(2).

Retention period

(3) The holder of the authorization must retain all records for the period during which this Interim Order is in force.

Distribution records

16 (1) A holder of a COVID-19 medical device authorization must maintain a distribution record in respect of each device that is imported, sold or tested under the authorization.

Withdrawal

(2) The distribution record must contain sufficient information to permit complete and rapid withdrawal of the COVID-19 medical device for which the authorization has been issued.

Retention period

(3) The holder of the authorization must retain the distribution record for the period during which this Interim Order is in force.

Timely retrieval

(4) Distribution records must be maintained in a manner that will allow their timely retrieval.

Complaint handling

17 A holder of a COVID-19 medical device authorization must, in respect of a COVID-19 medical device for which the authorization has been issued, maintain records of the following:

a. any reported problems relating to the performance characteristics or safety of the device that are received by the holder after the device was first sold in Canada; and
b. all actions taken by the holder in response to those problems.

Documented procedures

18 A holder of a COVID-19 medical device authorization must, in respect of a COVID-19 medical device for which the authorization has been issued, establish and implement documented procedures that will enable the holder to carry out:

a. an effective and timely investigation of the problems referred to in paragraph 17(a); and
b. an effective and timely recall of the device.

Information — recall

19 (1) A holder of a COVID-19 medical device authorization must, on or before recalling a COVID-19 medical device for which the authorization has been issued, provide the Minister with the following:

a. the name of the device and its identifier, 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;

b. the name and contact information of the manufacturer and, if applicable, the importer and the name and contact information of the establishment where the device was manufactured, if different from that of the manufacturer;
c. the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
d. an evaluation of the risk associated with the defectiveness or possible defectiveness;
e. the number of affected units of the device that were manufactured or sold in Canada or imported into Canada;
f. the period during which the affected units of the device were sold in Canada;
g. the name of each person to whom the affected device was sold and the number of units sold to each person;
h. a copy of any communication issued with respect to the recall;
i. the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;
j. the proposed action to prevent a recurrence of the problem; and
k. the name, title and telephone number of the representative of the holder of the authorization to contact for any information concerning the recall.

Information — after recall

(2) The holder of the authorization must, as soon as feasible after the completion of the recall, prepare and submit to the Minister:

a. the results of the recall; and
b. the action taken to prevent a recurrence of the problem.

Submission on holder's behalf

(3) Despite subsection (1) and (2), the holder of the authorization may permit the importer of the COVID-19 medical device to prepare and submit, on the holder's behalf, the information and material required under those subsections if the importer has the same information and material.

Notice to Minister

(4) The holder of the authorization must notify the Minister, in writing, if the holder has permitted the importer to prepare and submit the information and material with respect to the recall on the holder's behalf.

Part 2 COVID-19 Drugs

Application

20 (1) An application for a COVID-19 drug authorization must be signed and dated by the applicant's senior medical or scientific officer in Canada and their senior executive officer and must be submitted to the Minister in the form and manner specified by the Minister.

Content

(2) The application must contain sufficient information and material to enable the Minister to determine whether to issue the authorization and must include the following:

a. the protocol of the proposed clinical trial;
b. a copy of the statement, as it will be set out in each informed consent form, that states the risks and anticipated benefits arising to the health

of clinical trial subjects as a result of their participation in the clinical trial;

c. a clinical trial attestation containing:
    i. the title of the protocol and the clinical trial number,
    ii. the brand name, chemical name or code for the drug,
    iii. the therapeutic and pharmacological classifications of the drug,
    iv. the medicinal ingredients of the drug,
    v. the non-medicinal ingredients of the drug,
    vi. the dosage form of the drug,
    vii. the name and contact information of the applicant,
    viii. if the drug is to be imported, the name and contact information of the applicant's representative in Canada who is responsible for the sale of the drug,
    ix. for each clinical trial site, the name and contact information of the qualified investigator, if known at the time of submitting the application,
    x. for each clinical trial site, the name and contact information of the research ethics board that approved the protocol referred to in paragraph (a) and the informed consent form containing the statement referred to in paragraph (b), if known at the time of submitting the application, and
    xi. a statement that:
        A. the clinical trial will be conducted in accordance with good clinical practices and this Interim Order, and
        B. all information and material contained in, or referenced by, the application is complete and accurate and is not false or misleading;
d. the name and contact information of any research ethics board that has previously refused to approve the protocol referred to in

paragraph (a), its reasons for doing so and the date on which the refusal was given, if known at the time of submitting the application;

e. the physical, chemical and pharmaceutical properties of the drug;
f. the pharmacological aspects of the drug, including its metabolites in all animal species tested;
g. the pharmacokinetics of the drug and the drug metabolism, including the biological transformation of the drug in all animal species tested;
h. any toxicological effects of the drug in any animal species tested under a single dose study, a repeated dose study or a special study;
i. any results of carcinogenicity studies in any animal species tested in respect of the drug;
j. any results of clinical pharmacokinetic studies of the drug;
k. any information regarding drug safety, pharmacodynamics, efficacy and dose responses of the drug that were obtained from previous clinical trials in humans;
l. if the drug contains a human-sourced excipient, including any used in the placebo,
    i. a statement indicating that the excipient has been assigned a drug identification number under subsection C.01.014.2(1) of the *Food and Drug Regulations* or, in the case of a new drug, has been issued a notice of compliance under subsection C.08.004(1) of those Regulations, or
    ii. in any other case, sufficient information to support the identity, purity, potency, stability and safety of the excipient;
m. if the drug has not been assigned a drug identification number under subsection C.01.014.2(1) of the *Food and Drug Regulations* or, in the case of a new drug, a notice of compliance has not been issued under section C.08.004 or C.08.004.01 of those Regulations, the chemistry and

manufacturing information in respect of the drug, including its site of manufacture; and

n. the proposed date for the commencement of the clinical trial at each clinical trial site, if known at the time of submitting the application.

Marketed drug

(3) If the application for the authorization is in respect of a COVID-19 drug that meets the requirements of paragraphs 27(a) to (c), the application must also contain:

a. a copy of the label of the drug; and
b. information on how the proposed use of the drug is consistent with the standard of medical practice.

Issuance

21 The Minister must issue a COVID-19 drug authorization if the following requirements are met:

a. the applicant has submitted to the Minister an application that meets the requirements set out in section 20;
b. the applicant has submitted to the Minister any additional information or material requested under subsection 30(1) in the time, form and manner specified under subsection 30(2); and
c. the Minister determines that:
    i. the use of the drug that is to be tested in the clinical trial will not unduly affect the health or safety of clinical trial subjects or other persons,
    ii. the clinical trial is not contrary to the best interests of clinical trial subjects, and
    iii. the objectives of the clinical trial are achievable.

Additional information prior to clinical trial

22 A holder of a COVID-19 drug authorization must not import or sell a COVID-19 drug for which the authorization has been issued or conduct a clinical trial in respect of such a drug unless the holder has:

a. for each clinical trial site, obtained the approval of a research ethics board in respect of the protocol referred to in paragraph 20(2)(a) and the informed consent form that contains the statement referred to in paragraph 20(2)(b); and
b. submitted to the Minister the information and material referred to in subparagraphs 20(2)(c)(ix) and (x) and paragraphs 20(2)(d) and (n), if it was not submitted at the time of submitting the application.

Terms and conditions

23 The Minister may, at any time, impose terms and conditions on a COVID-19 drug authorization or amend those terms and conditions.

Amendment

24 (1) A holder of a COVID-19 drug authorization must not import or sell a COVID-19 drug for which the authorization has been issued or conduct a clinical trial in respect of such a drug if the substance of any of the information or material referred to in paragraph 20(2)(a) or (m) is significantly different from the substance of the information or material contained in the application, unless:

a. the holder has filed with the Minister an application to amend the authorization;
b. for each clinical trial site, the holder has obtained the approval of a research ethics board in respect of the protocol referred to in

paragraph 20(2)(a) and the informed consent form that contains the statement referred to in paragraph 20(2)(b);

c. the holder has submitted to the Minister the information and material referred to in subparagraphs 20(2)(c)(ix) and (x) and paragraphs 20(2)(d) and (n), if it was not submitted at the time of submitting the application;
d. the Minister determines that the requirements set out in subparagraphs 21(c)(i) to (iii) are met;
e. the holder has submitted to the Minister any additional information or material requested under subsection 30(1) in the time, form and manner specified under subsection 30(2); and
f. the Minister amends the authorization.

Immediate change

(2) Despite subsection (1), if the holder of the authorization is required to make an immediate change to the substance of any of the information or material referred to in paragraph 20(2)(a) or (m) because the clinical trial or the use of the COVID-19 drug that is tested in the clinical trial endangers the health of a clinical trial subject or other person, the holder may immediately make the change.

Application to amend

(3) The holder of the authorization must, within 15 days after the day on which the change is made, file an application under subsection (1) to amend the authorization.

Prohibition — import

25 A holder of a COVID-19 drug authorization must not import a COVID-19 drug for which the authorization has been issued if the sale of the drug would constitute a violation of the Act.

Prohibition — import and sale

26 A holder of a COVID-19 drug authorization must not import or sell a COVID-19 drug for which the authorization has been issued unless the holder has a representative in Canada who is responsible for the sale of the drug.

Marketed drugs

27 Paragraphs 20(2)(e) to (l), section 33 and paragraphs 35(2)(a) to (c) do not apply to a COVID-19 drug for which a COVID-19 drug authorization has been issued if:

a. the use of the drug is consistent with the standard of medical practice;
b. the drug has been issued a notice of compliance under subsection C.08.004(1) of the *Food and Drug Regulations* or has been assigned a drug identification number under subsection C.01.014.2(1) of those Regulations; and
c. the clinical trial for which the authorization has been issued is in respect of a purpose or condition of use other than that for which the notice of compliance was issued or drug identification number was assigned.

Good clinical practices

28 A holder of a COVID-19 drug authorization must ensure that the clinical trial for which the authorization has been issued is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, must ensure that:

a. the clinical trial is scientifically sound and clearly described in the protocol;
b. the clinical trial is conducted, and the drug is used, in accordance with the protocol and this Interim Order;
c. systems and procedures that assure the quality of every aspect of the clinical trial are implemented;
d. for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins;
e. at each clinical trial site, there is no more than one qualified investigator;
f. at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of a health care professional who is authorized to provide medical care and make medical decisions;
g. each person who is involved in the conduct of the clinical trial is qualified by education, training and experience to perform their respective tasks;
h. informed consent, given in accordance with section 36 and any other applicable laws governing consent, is obtained from every person before they participate in the clinical trial, but only after that person has been informed of:
    i. the risks and anticipated benefits to their health arising from participation in the clinical trial, and
    ii. all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial; and
i. the drug is manufactured, handled and stored in accordance with the applicable good manufacturing practices referred to in Divisions 2 and 4 of Part C of the *Food and Drug Regulations*, with the exception of sections C.02.019, C.02.025 and C.02.026 of those Regulations.

Suspension

29 (1) The Minister may suspend, in whole or in part, a COVID-19 drug authorization by notice, giving reasons, if:

a. the Minister determines that any of the requirements set out in subparagraphs 21(c)(i) to (iii) is no longer met;
b. the holder of the authorization has not provided to the Minister any additional information or material requested under subsection 30(1) in the time, form and manner specified under subsection 30(2); or
c. the holder of the authorization has contravened this Interim Order or any provisions of the Act relating to the drug.

Reinstatement

(2) The Minister must reinstate a COVID-19 drug authorization if the holder of the authorization 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.

Additional information and material

30 (1) The Minister may request an applicant for a COVID-19 drug authorization or a holder of such an authorization to submit any additional information or material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or suspend the authorization.

Form and manner

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

Discontinuance

31 If a holder of a COVID-19 drug authorization discontinues, in whole or in part, the clinical trial for which the authorization has been issued, the holder must, without delay:

a. notify the Minister, in writing, of the discontinuance and the reasons for it;
b. inform all qualified investigators, in writing, of the discontinuance and the reasons for it and advise them, in writing, of any potential risks to the health of clinical trial subjects or other persons; and
c. in respect of each clinical trial site at which the trial is discontinued, stop the importation or sale of the drug as of the date of the discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the drug that have been sold.

Discretionary revocation

32 (1) The Minister may revoke, in whole or in part, a COVID-19 drug authorization by notice, 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 29(2).

Mandatory revocation

(2) The Minister must revoke, in whole or in part, the authorization if the Minister has received a notice of discontinuance referred to in paragraph 31(a).

Labelling

33 (1) A person must not import or sell a COVID-19 drug for which a COVID-19 drug authorization has been issued or conduct a clinical trial in respect of such a drug unless the drug has a label that sets out the following

information:

a. a statement indicating that the drug is an investigational drug to be used only by a qualified investigator;
b. the name, number or identifying mark of the drug;
c. the expiration date of the drug;
d. the recommended storage conditions for the drug;
e. the lot number of the drug;
f. the name and contact information of the holder of the authorization; and
g. the protocol code or identification.

Presentation of information

(2) The information required by subsection (1) to be set out on the label must be in English and in French.

Serious unexpected adverse drug reaction

34 A holder of a COVID-19 drug authorization must inform the Minister of any serious unexpected adverse drug reaction that has occurred inside or outside Canada, in respect of the COVID-19 drug that is tested in the clinical trial, as follows:

a. within 15 days after becoming aware of the reaction, if it is neither fatal nor life threatening; and
b. within seven days after becoming aware of the reaction, if it is fatal or life threatening.

Records

35 (1) A holder of a COVID-19 drug authorization must record, handle and store all information in respect of the clinical trial for which the authorization has been issued in a manner that allows for the complete and accurate reporting as well as the interpretation and verification of the information.

Content

(2) The holder of the authorization must maintain complete and accurate records in respect of a COVID-19 drug for which the authorization has been issued in order to establish that the clinical trial is conducted in accordance with good clinical practices and this Interim Order, and that include the following:

a. the information and material referred to in paragraphs 20(2)(e) to (k);
b. records respecting each change made to the information and material referred to in paragraph (a), the rationale for each change and documentation that supports each change;
c. records respecting all adverse events in respect of the drug that have occurred inside or outside Canada, including the indication for use and the dosage form of the drug at the time of the adverse event;
d. in respect of a drug that meets the requirements of paragraphs 27(a) to (c), records respecting any serious unexpected adverse drug reaction that has occurred inside or outside Canada;
e. records respecting the enrolment of clinical trial subjects, including information that allows all subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the subjects or other persons;
f. records respecting the shipment, receipt, disposition, return and destruction of the drug;

g. for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by them prior to the commencement of their responsibilities in respect of the clinical trial that states that:
    i. the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and
    ii. the qualified investigator will immediately, on discontinuance of the clinical trial, in whole or in part, by the holder, inform both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them, in writing, of any potential risks to the health of subjects or other persons;
h. for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by a research ethics board for that clinical trial site; and
i. for each clinical trial site, an attestation, signed and dated by a research ethics board, stating that it has reviewed and approved the protocol and informed consent form and that the board carries out its functions in a manner consistent with good clinical practices.

Retention period

(3) The holder of the authorization must retain all records for the period during which this Interim Order is in force.

Part 3 General

Remote written informed consent

36 (1) If a qualified investigator is not able to obtain, in person, the written informed consent of a person to participate in a clinical trial in respect of a COVID-19 medical device for which a COVID-19 medical device authorization has been issued or a COVID-19 drug for which a COVID-19 drug authorization has been issued, the qualified investigator may obtain the written informed consent remotely.

Non-written informed consent

(2) In the case where the person is not able to provide their written informed consent, the qualified investigator may obtain their non-written informed consent if the following conditions are met:

a. the qualified investigator reads the contents of the informed consent form to the person;
b. the person provides their informed consent before a witness; and
c. an attestation by the witness that the person has provided their informed consent is provided to the qualified investigator as soon as feasible.

Part 4 Other clinical trials

Exemption — certain drugs

37 (1) A person that is authorized under Division 5 of Part C of the *Food and Drug Regulations* to sell or import a drug for the purposes of a clinical trial — and any other person that conducts the clinical trial — is, in respect of the clinical trial, exempt from section 3.1 of the Act.

Clarification — suspension and cancellation

(2) For greater certainty, the exemption does not apply:

a. if the authorization to sell or import the drug is suspended in its entirety; or
b. in respect of the conduct of the clinical trial at a clinical trial site, if the authorization to sell or import the drug is suspended or cancelled in respect of that site.

Definition of clinical trial

(3) In this section, **clinical trial** has the same meaning as in section C.05.001 of the *Food and Drug Regulations*.

Exemption — positron-emitting radiopharmaceuticals

38 (1) A person that is authorized under Division 3 of Part C of the *Food and Drug Regulations* to sell or import a positron-emitting radiopharmaceutical for the purposes of a study — and any other person that conducts the study — is, in respect of the study, exempt from section 3.1 of the Act.

Clarification — suspension and cancellation

(2) For greater certainty, the exemption does not apply:

a. if the authorization to sell or import the radiopharmaceutical is suspended in its entirety; or
b. in respect of the conduct of the study at a study site, if the authorization to sell or import the radiopharmaceutical is suspended or cancelled in respect of that site.

Exemption — natural health products

39 (1) A person that is authorized under Part 4 of the *Natural Health Products Regulations* to sell or import a natural health product for the purposes of a clinical trial — and any other person that conducts the

clinical trial — is, in respect of the clinical trial, exempt from section 3.1 of the Act.

Clarification — suspension and cancellation

(2) For greater certainty, the exemption does not apply:

a. if the authorization to sell or import the natural health product is suspended in its entirety; or
b. in respect of the conduct of the clinical trial at a clinical trial site, if the authorization to sell or import the natural health product is suspended or cancelled in respect of that site.

Definitions

(3) The following definitions apply in this section.

clinical trial has the same meaning as in section 63 of the *Natural Health Products Regulations*. *(essai clinique)*

natural health product has the same meaning as in subsection 1(1) of the *Natural Health Products Regulations*. *(produit de santé naturel)*

Exemption — medical devices

40 (1) A person that is authorized under Part 3 of the *Medical Devices Regulations* to sell a medical device for investigational testing — and any person who conducts the testing of the device — is, in respect of the testing, exempt from section 3.1 of the Act.

Exception

(2) The exemption does not apply in respect of any person to whom the medical device can no longer be sold as a result of a measure taken by the Minister under subsection 85(2) of the *Medical Devices Regulations*.

Suspension — deemed holder

41 (1) An authorization to conduct a clinical trial in respect of a drug is suspended if:

a. the holder is deemed to hold the authorization under any of sections 180 to 182 of the *Budget Implementation Act, 2019, No. 1*; and
b. the holder's authorization to sell or import the drug for the purposes of the clinical trial is suspended under:
    i. section C.03.317, C.05.016 or C.05.017 of the *Food and Drug Regulations*, or
    ii. section 80 or 81 of the *Natural Health Products Regulations*.

Reinstatement

(2) An authorization that is suspended under subsection (1) is reinstated if the authorization referred to in paragraph (1)(b) is reinstated.

Revocation — deemed holder

(3) An authorization to conduct a clinical trial in respect of a drug or medical device is revoked if:

a. the holder is deemed to hold the authorization under any of sections 180 to 183 of the *Budget Implementation Act, 2019, No. 1*; and
b. the holder's authorization to sell or import the drug or device for the purposes of the clinical trial is cancelled:
    i. in the case of a drug, under
        a. section C.03.319 or paragraph C.05.016(4)(b) or C.05.017(3)(b) of the *Food and Drug Regulations*, or
        b. paragraph 82(b) of the *Natural Health Products Regulations*, and
    ii. in the case of a device, under paragraph 85(2)(b) of the *Medical Devices Regulations*.

Partial suspensions and cancellations

(4) If the authorization referred to in paragraph (1)(b) or (3)(b) is only partially suspended or cancelled, the authorization to conduct the clinical trial is suspended or revoked to the same extent.

Footnotes

a	S.C. 2004, c. 15, s. 66
b	R.S., c. F-27

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