Health Canada Santé Canada

Guidance on the Food and Drug Regulations for public health emergency drugs

Canada

Foreword

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied by industry. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We must make sure that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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Overview

Background

The COVID-19 pandemic posed an immediate and significant risk to the health and safety of people in Canada. As the pandemic represented a public health emergency, Health Canada introduced interim measures. These included the *Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19* (ISAD IO) and the COVID-19 drugs transition to the *Food and Drug Regulations* (regulations).

Health Canada is now expanding the provisions in Part C, Divisions 1A and 8 of the *Regulations* for activities related to COVID-19 and the authorization of COVID-19 drugs. The expanded provisions will also apply to a public health emergency drug, which is a drug that relates to COVID-19 or a condition referred to on the incorporated by reference (IbR) List of Conditions that Threaten Public Health in Canada (List).

This new authority for **public health emergency drugs** is introduced to:

- enable regulations that are agile in a public health emergency and
- apply modified requirements to address a public health emergency

This guidance document explains the modified requirements prescribed in these amendments to the *regulations*.

For more information on these measures, refer to the following items:

- Regulatory impact analysis statement: Regulations amending certain regulations made under the Food and Drugs Act (agile licensing)
- Canada Gazette, Part I Regulations

For more information about documents incorporated by reference, refer to Health Canada Incorporation by Reference Policy.

Scope and application

This guidance document applies to:

- sponsors planning to file a submission for a notice of compliance (NOC) for a **public health emergency drug** as defined in C.08.001.1 of the regulations, whether or not they are taking advantage of modified requirements
- public health emergency drugs filed and/or authorized under the *Food and Drug Regulations* for COVID-19 or for a condition that is described in the *List of Conditions that Threaten Public Health in Canada (List)*
- establishments seeking a drug establishment licence (DEL) related to public health emergency drugs
- pre-positioning of public health emergency drugs (C.08.009.03)

For guidance on obtaining product authorization for disinfectants, hand sanitizers and veterinary health products, sponsors should refer to the following guidance documents:

- Management of drug submissions and applications
- Management of disinfectant drug applications
- Human-use antiseptic drugs
- Antiseptic skin cleansers (personal domestic use)
- Veterinary health products: About the VHP notification program

The amendments introduced in Part C, Divisions 1, 1A, 2 and 8 of the *regulations* are described in this guidance document.

The amendments expand the application of measures introduced with regard to requirements for drug product authorizations, terms and conditions, DEL applications and pre-positioning of products prior to authorization for COVID-19 to other conditions that threaten public health. The aim is to give people in Canada continued and timely access to safe and effective public health emergency drugs.

Policy objectives

The objective of the amendments to the *regulations* is to allow for a mechanism for continued and timely access to safe and effective public health emergency drugs.

The amendments to the *regulations* offer the following tools to enable:

- access to safe, effective and high-quality public health emergency drugs
- modified requirements (for example, rolling review, labelling and sufficient safety, quality and efficacy evidence) and terms and conditions
- the early importation and placement in Canadian facilities (pre-positioning) of a promising public health emergency drug for which a federal government contract for its procurement is in place, before that drug receives market authorization in Canada
- an agile approach for DELs that authorizes regulated activities for public health emergency drugs
- post-market regulatory obligations placed on authorization holders, manufacturers and importers

Under the amended *regulations*:

- Health Canada only grants an NOC for a public health emergency drug if it's determined that the benefits and risks of the product are supported by evidence of the drug's safety, efficacy and consistent quality.
- When making its decision, Health Canada considers the public health need as well as the uncertainties related to the benefits and risks of the product. Terms and conditions will be used to help manage any uncertainties or risks related to the drug in the context of COVID-19 or the condition on the List.
- As with all drugs, Health Canada assesses and monitors the safety and effectiveness of all public health emergency drugs for which an NOC was issued.
    - If required, Health Canada takes immediate action, including compliance and enforcement measures and the suspension of an NOC or the cancellation of a DIN, to protect the health and safety of people in Canada.

Policy statements

Manufacturers of public health emergency drugs may be able to obtain an NOC under the *regulations* by leveraging certain options and modified requirements.

These amendments to the *regulations* allow for a submission for public health emergency drugs to treat or prevent COVID-19 or a condition on the List to be filed earlier through a "rolling review" process. Manufacturers are responsible for completing the required documentation and providing the necessary evidence to Health Canada. Public health emergency drug submissions will be prioritized based on public health needs.

Licensing decisions are based on the materials submitted in the application. Health Canada will consider the use of the drug in addressing a condition that threatens public health.

Public health emergency drugs are reviewed on an expedited timeline above the usual performance standards. As such, the Priority Review Policy does not apply.

Manufacturers with a proposed public health emergency drug for which the purpose and conditions of use recommended by the manufacturer relate to COVID-19 or a condition on the List can file a new drug submission (NDS) or a supplement to a new drug submission (SNDS) leveraging the modified requirements for public health emergency drugs in the regulations.

Removal of a condition from the List

A drug remains a public health emergency drug for the purposes of Division 8 until the Minister makes a final decision on the submission under C.08.004, if:

- a condition is removed from the List after a sponsor files a new drug submission for a public health emergency drug in accordance with subsections C.08.002(2) to (2.5) and section C.08.005.1 but
- before the Minister makes a final decision on the submission under section C.08.004 (C.08.001.3)
- a record of each version of the List is maintained

Refer to Health Canada Incorporation by Reference Policy for more information.

Explanation of key terms

List of Conditions that Threaten Public Health: The *List of Conditions that Threaten Public Health in Canada* is an IbR List published on the Government of Canada's website and amended from time to time.

The Minister may add a condition to the List if the Minister has reasonable grounds to believe that:

a. the condition presents, or is the result of, a significant risk to public health in Canada and
b. immediate action is required to deal with the risk (C.08.001.2)

Public health emergency drug: As defined in C.08.001.1, this is a "new drug" under C.08.001 for which the purpose and conditions of use recommended by the manufacturer relate to COVID-19 or a condition that is described in the List.

A public health emergency drug is subject to the requirements in Part C, Division 8 of the *Food and Drug Regulations*.

Preparing a submission

Submission process

The amendments to the regulations provide a mechanism for public health emergency drugs (PHED) to be authorized through a notice of compliance (NOC) based on modified requirements.

Table 1 gives an overview of the modified requirements for public health emergency drugs in the regulations.

To make use of any of the alternative requirements, the manufacturer must make the following statements in their NDS:

- that the NDS is for a public health emergency drug (C.08.002(2.4)(a)) and
- that the purpose and conditions of use specified in the NDS relate only to COVID-19 or a condition described in the List (C.08.002(2.4)(b))

To meet the requirements in subsection C.08.002(2.1), the manufacturer must also make the statement required by paragraph C.08.002(2.1)(a) and meet the requirement in C.08.002(2.1)(b). Manufacturers should ensure that all statements required are made in module 1.2.3, "Certification and Attestation Forms."

Table 1: Overview of modified requirements for public health emergency drug submissions

Scenario	Submission code	Available modified requirements	Terms and conditions
New public health emergency drug	NDS	C.08.002(2.1): supportive evidence C.08.002(2.2): draft label C.08.002(2.3): rolling review	Yes
Marketed drug adding additional indication for COVID-19 or a condition described in the List	SNDS	Modified requirements (as above)	Yes
Supplemental new drug submissions (SNDS) following authorization of the NDS for a PHED	SNDS	Modified requirements (as above)	Yes

Manufacturers who intend to file a submission seeking an NOC for a public health emergency drug on the basis of a comparison with another public health emergency drug are encouraged to contact us for a pre-submission meeting. Please refer to the Pre-submission meetings subsection.

Modified requirements

Manufacturers of public health emergency drugs will have the option to follow requirements as set out in subsections C.08.002(2.1) to (2.3). To make use of these alternate requirements, manufacturers must include

a statement identifying that the purpose and conditions of use specified in the NDS address only the public health need related to COVID-19 or the applicable condition described in the List.

Manufacturers should ensure that all statements required are made in the cover letter and "Certification and Attestation Forms."

Modified requirements include:

- ability to provide missing information or material during a rolling review (C.08.002(2.3))
- exemption from submitting detailed reports of tests made to establish the safety and clinical effectiveness of the new drug under paragraphs C.08.002(2)(g) and (h)
    - however, the manufacturer must provide sufficient evidence that the benefits of the drug outweigh the risks, taking into account uncertainties as well as the public health need related to COVID-19 or to the condition on the List (C.08.002(2.1)(b))
- exemption from being required under C.08.002(2)(j.1) to provide final mock-up if the manufacturer provides a draft of the label
    - submission must also include any package insert and document provided upon request that sets out supplementary information on use of the drug (C.08.002(2.2))
- exemption from being required under C.08.002(2)(o) to conduct an assessment as to whether there is a likelihood the new drug will be mistaken for another drug due to a resemblance between the brand names
    - commonly referred to as a brand name assessment

The options available in subsections C.08.002(2.1), C.08.002(2.2) and C.08.002(2.3) only apply if the manufacturer has met the requirements outlined in subsection C.08.002(2.4).

Health Canada intends to assess whether the submission qualifies under subsections C.08.002(2.1), C.08.002(2.2), C.08.002(2.3) and C.08.002(2.4) in screening.

In accordance with subsection C.08.002(2.5), the amended regulations do not apply if the manufacturer is seeking an NOC for a public health emergency drug on the basis of a direct or indirect comparison between the public health emergency drug and another public health emergency drug (for example, a generic or biosimilar submission).

Safety and efficacy: C.08.002(2.1) as an alternative to C.08.002(2)(g) and C.08.002(2)(h)

The *regulations* were amended to allow manufacturers who seek approval for a public health emergency drug to file a submission with an alternative data package for a COVID-19 drug or a condition that is on the List.

As more products emerge to address COVID-19 or a condition on the List, manufacturers should discuss data requirements with Health Canada before filing. A data package based on C.08.002(2.1) may only be appropriate in some circumstances.

Following discussion with Health Canada, a manufacturer may file an NDS for a public health emergency drug without complying with the requirements set out in paragraphs C.08.002(2)(g) and C.08.002(2)(h). To do so:

- the manufacturer must state that the NDS is for a public health emergency drug (C.08.002(2)(2.1)(a))
- the NDS must contain sufficient safety, efficacy and quality evidence such that the benefits of the new drug outweigh the risks (C.08.002(2)(2.1)(b))
- Health Canada also considers in addition to the evidence:
    - the uncertainties relating to the benefits and risks
    - the public health need relating to COVID-19 or the condition on the List

Manufacturers should make the required statement in module 1.2.3, "Certification and Attestation Forms." Manufacturers are encouraged to specify in a cover letter that the NDS relies on subsection C.08.002(2.1) of the *regulations* to facilitate processing.

A manufacturer who relies on C.08.002(2.1) to provide evidence of safety and efficacy will be subject to any terms and conditions that might be imposed on a DIN issued for the public health emergency drug. Refer to section C.01.014.21(1.1). In the context of the public health need related to COVID-19 or a condition on the List, the manufacturer is required to include in the NDS sufficient safety, efficacy and quality evidence showing that the drug's benefits outweigh the risks. Terms and conditions on the DIN may be imposed as needed, including to require the manufacturer to address and/or manage risks and uncertainties after authorization.

A manufacturer that has a substantive data package to support the NDS may choose not to rely on subsection C.08.002(2.1).

For more information, consult the following guidance documents:

- Evidence requirements for COVID-19 vaccines
- Evidence requirements for COVID-19 drugs

Product labels

Subsection C.08.002(2.2) provides for exemption from the requirement in paragraph C.08.002(2)(j.1) to provide a mock-up of labels of the public health emergency drug.

However, the submission must contain a draft of every label to be used with the new drug. This includes any package insert and any document that sets out supplementary information on the use of the new drug.

Health Canada will accept text-only labels and/or mock-up labels (if available). Sponsors should refer to sections 3, 9 and 10 of the *Food and Drugs Act* as well as related provisions of the *regulations* to ensure they are complying with the labelling requirements. You may also refer to the following guidance documents for more information:

- Guidance document: Labelling of pharmaceutical drugs for human use
- Guidance on veterinary drug labelling
- Guidance for market authorization requirements for COVID-19 vaccines: Labelling and post-market requirements

Sponsors are also encouraged to contact us in advance to discuss their labelling proposals. If utilizing the exemption in C.08.002(2.2), sponsors should include a rationale and 'note to reviewer' in the submission outlining the labelling approach.

To facilitate processing, manufacturers are encouraged to specify in a cover letter that the NDS relies on subsection C.08.002(2.2) of the *regulations*.

Rolling review

Health Canada recognizes that the submission may not contain all of the information otherwise required by section C.08.002 at the time it is filed. Health Canada will begin our review using the information submitted by the manufacturer and accept new evidence as it becomes available. When providing the balance of the remaining missing information, the sponsor should confirm that it considers all missing information to have been provided.

A manufacturer may file an NDS for a new public health emergency drug without including some of the data otherwise required under:

- paragraphs C.08.002(2)(e) to C.08.002(2)(k), C.08.002(2)(m), and C.08.002(2)(n)
- paragraph C.08.002(2)(p) (coming into force on one-year anniversary of the date on which the regulations are registered in Canada Gazette, Part II)
- paragraph C.08.002(2.1)(b)
- subsection C.08.002(2.2) or
- section C.08.005.1

Similarly, a sponsor may file an SNDS without some of the information that is required to be included in a supplement under subsection C.08.003(3) and, if applicable, corresponding information that is required to be included in the supplement under section C.08.005.1.

To file an NDS for rolling review, the manufacturer must include all applicable forms and other administrative components. The NDS must also include a plan identifying the missing parts of the submission. This plan must specify how and when the missing information or material will be provided to the Minister during the review period. Refer to C.08.002(2.3).

The plan should be up-to-date and complete. The manufacturer should discuss and agree upon the plan in advance of the submission to Health Canada. Some elements of the plan may be more appropriate to file as an SNDS following approval of the NDS, rather than as part of a rolling review. Health Canada recommends a pre-submission meeting to discuss efficient filing strategies for changes, such as chemistry, manufacturing and control changes. Health Canada expects the missing information to be provided in a small number of regulatory transactions.

Manufacturers are encouraged to specify in a cover letter that the NDS relies on subsection C.08.002(2.3) of the *regulations* to facilitate processing.

As with other NDSs under Division 8, the filing date refers to the date that:

- the NDS is deemed administratively complete by Health Canada
- all the elements and forms required for processing are completed and submitted to Health Canada

This is typically the same day the regulatory activity is received by Health Canada.

The filing date may differ from the date of original receipt if the submission is considered to be administratively incomplete at that time. Any missing data or information that is subsequently provided during a rolling review will be considered solicited information under the NDS and will not change the filing date of the submission.

The process for establishing a filing date has not changed from the standard process outlined in the following guidance documents:

- Guidance document: The management of drug submissions and applications
- Veterinary drugs - Management of regulatory submissions guidance

Sufficient information must be submitted within a reasonable timeframe. The Minister reviews the NDS based on the requirements and makes a decision, as per section C.08.004 of the *regulations*.

The plan should contain:

- a list of the non-clinical, clinical and quality data to be provided (planned and in progress)
- a timeframe for when this clinical and quality data will be available
- a timeframe for when this clinical and quality data will be filed for review

If the missing information outlined in the plan will be submitted through multiple regulatory transactions, the plan must clearly specify what information will be contained in each regulatory transaction. For example:

- regulatory transaction A will be submitted on DD/MM/YYYY and contains results from studies XX, YY and ZZ
- regulatory transaction B will be submitted on DD/MM/YYYY and contains results from studies MM, NN and OO

Pre-submission meetings provide an opportunity to discuss the PHED application plan in detail. These meetings should be used to:

- establish submission content and timelines
- determine the data that will be submitted when the submission is filed
- determine the data that will be provided at a later date

The cover letter should refer to the plan. If changes are required to labelling to reflect the new information, annotated and clean copies of the drug labels should be included.

Health Canada will:

- review the submission to ensure it includes the detailed plan
- assess the information submitted by the manufacturer
- accept new evidence as it becomes available until the review has been completed

Any subsequent data or information sent after the submission has been filed is considered solicited information under the NDS if the data or information is provided according to the plan or in response to Health Canada's request. Information or data provided otherwise may be considered unsolicited information. Refer to section 14 of the *Management of Drug Submissions and Applications Guidance Document*. There may be situations where an update to the plan is appropriate. We will assess these on a case-by-case basis. However, changes in the timing or content should be avoided if possible as they will impact the review timeline and efficiency.

Health Canada will not issue an NOC unless the Minister is satisfied that the NDS complies with the requirements of section C.08.002.

Regulatory activity and transaction details for public health emergency drugs

As noted, modified requirements introduced through amendments to the *regulations* are available for NDS and SNDSs. The "NDS CV" submission code is the code used for current submissions for NDSs that use any of the provisions in subsections C.08.002(2.1), C.08.002(2.2) or C.08.002(2.3) of the regulations. The manufacturer must select the "NDS CV" submission code in the appropriate Regulatory Enrolment Process (REP) regulatory transaction template when submitting their NDS. "NDS CV" submission code is described as "Drug submission with modified requirements for public health emergency drugs."

To file an NDS that does not benefit from any of the modified requirements mentioned in the previous 3 subsections (on safety and efficacy, rolling review, product labels), a manufacturer must select the regular NDS submission code when submitting their NDS.

Pre-submission meetings

Manufacturers are encouraged to communicate regularly with Health Canada. Early and ongoing consultation(s) with us help ensure that regulatory requirements are met.

Before filing an NDS, manufacturers are encouraged to request a pre-submission meeting to discuss all aspects of their submission. At this meeting, we will expect you to describe your submission plan and indicate how and when you will provide the Minister with the missing information or material, if applicable (subsection C.08.002(2.3)).

To request a pre-submission meeting with the appropriate directorate, consult the guidance documents on the:

- Management of drug submissions and applications
- Management of regulatory submissions for veterinary drugs

For relevant contact information, please refer to key contacts.

Format and structure for filing

For general procedures on how to file applications, please also refer to the guidance documents on the:

- Management of drug submissions and applications or
- Management of regulatory submissions for veterinary drugs

Submissions for human drugs should be formatted, structured and filed as outlined in the:

- Guidance document on the preparation of regulatory activities in the eCTD format
- Organization and document placement for Canadian module 1
- Guidance document on the regulatory enrolment process (REP)

Manufacturers who cannot comply with the formatting requirements may contact the Office of Submissions and Intellectual Property for further options and guidance. Please send an email to ereview@hc-sc.gc.ca.

Submissions for veterinary drugs should be formatted, structured and filed as outlined in the following guidance documents on the:

- Preparation of regulatory activities in the non-eCTD format
- Regulatory enrolment process (REP)

Manufacturers who cannot comply with the formatting requirements may contact the Veterinary Drugs Directorate by email at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

Content and requirements for filing

The sponsor must include all the data they rely on to support their submission in the NDS. The sponsor should consult with Health Canada at a pre-submission meeting before filing.

For both the non-clinical and clinical information package, you may not need to include as much information at the time of filing as you do for a data package in a typical drug submission. This is balanced by additional information, which is to be provided as part of the rolling review.

Non-clinical information and requirements

Key non-clinical information may be required to:

- demonstrate the potential for clinical effectiveness under the proposed conditions of use
- support the safety of the public health emergency drug

All key studies should be conducted in accordance with good laboratory practices.

For more information, consult the following guidance document for human drugs:

- Non-clinical laboratory study data supporting drug product applications and submissions: Adherence to good laboratory practice

Clinical information and requirements

A manufacturer may submit an NDS relying on the modified requirements in subsections C.08.002(2.1) to (2.3). Sufficient evidence should be provided to support the safety and efficacy of the public health emergency drug. This includes all available clinical trial data and the safety and efficacy summary documents.

For more information on COVID-19 products, refer to the following guidance documents:

- Evidence requirements for COVID-19 vaccines
- Evidence requirements for COVID-19 drugs

Quality (chemistry and manufacturing) information and requirements

For further guidance on meeting submission and information requirements, consult the list of guidance documents.

Under subsection C.08.002(2.3) in the *regulations,* the manufacturer may provide the information and material normally required under paragraphs (2)(e), (f) and (m) on a rolling basis. The manufacturer must specify in their plan how and when they will provide the missing information to Health Canada.

Manufacturers should make sure that their plan is detailed and accurate, and discuss the plan with us before submitting it.

We will review the timing proposed in the plan as well as the chemistry and manufacturing information.

For more information on COVID-19 products, refer to the following guidance documents:

- Evidence requirements for COVID-19 vaccines
- Evidence requirements for COVID-19 drugs

Comparative submissions for subsequent entry drugs

The *regulations* do not allow comparative submissions to be filed while benefitting from any of the modified requirements, even where consent from the reference product manufacturer is provided.

Subsection C.08.002(2.5) excludes the application of subsections C.08.002(2.1), (2.2) and (2.3). Where subsection C.08.002(2.5) applies, the submission will be assessed against regular criteria in screening.

Information and requirements for veterinary drugs

A new drug submission for a public health emergency drug for veterinary use should include evidence of its efficacy in the target species, animal safety, human safety and quality.

For drugs used in a food-producing animal, information should be provided on the safety of drug residues in meat and other food products from the treated animal intended for human consumption.

Risk management plan

Until such time that the requirement to provide a risk management plan (RMP) for an NDS comes into force (for exmaple, C.08.002(2)(p)), RMPs for public health emergency drugs for human use will be required through the use of terms and conditions. In the case of a rolling review, the sponsor may provide the RMP to Health Canada after the submission has been filed.

The RMP should focus on the product's updated safety risks and uncertainties in the context of public health emergency use to ensure that:

- the benefit-risk profile of the product is managed optimally during its life cycle
- knowledge gaps at the time of authorization are described and risks are further quantified and characterized over time

It should:

- outline the product's safety risks and uncertainties related to the purpose and conditions of use related to COVID-19 or a condition on the List
- outline the pharmacovigilance activities and risk minimization activities used to identify, characterize, prevent or minimize risks
- contain an evaluation of the effectiveness of such risk minimization measures

To ensure the safe and effective use of a product, additional post-market requirements may be imposed as a term or condition on the DIN. For example, elements of an RMP such as additional measures to minimize risk or uncertainty might become terms and conditions if they meet the criteria.
For information on the scope and application of RMPs, please refer to the following guidance document:

- Submission of risk management plans and follow-up commitments

For public health emergency drugs submitted for authorization, the RMP should include the following:

- safety specification section with a detailed description of the risks associated with the drug and the uncertainties relating to those risks (for example on the identified risks, potential risks and missing information for the product) such as, special populations where there is limited information or who were excluded from clinical trials
- pharmacovigilance plan with a detailed description of the measures that the manufacturer intends to take to address and monitor the uncertainties, such as the specific activities to be taken to identify and report safety issues, including expedited adverse reaction reporting, periodic reporting and ongoing/planned studies to quantify and characterize those risks (for example, registries, prospective cohort studies)
- risk minimization plan with a detailed description of the measures that the manufacturer intends to take to prevent or reduce the risks, including routine risk minimization measures (for example, labelling) and additional measures beyond those considered routine (such as educational materials for health care professionals or patients, or a restricted access or distribution program), if needed
- a detailed description of how the manufacturer intends to evaluate the effectiveness of the measures that they intend to take to prevent or reduce the risks
- a summary of the plan's contents, in English and in French

An RMP that has been reviewed and accepted as part of the submission for a public health emergency drug is expected to be implemented. If the manufacturer filed under the requirement in subsection C.08.002(2.1), any elements of an RMP that are essential for the safe and effective use of the product could be identified as terms and conditions and must be implemented.

When section C.08.002(2)(p) of the regulations is in force, sponsors or Market Authorization Holders must submit an RMP summary as part of their submission or RMP updates. The format of the RMP summary will be specified in the Submitting risk management plans guidance document that will support section C.08.002(2)(p).

A Canadian addendum that demonstrates that the RMP meets Canadian regulatory requirements must accompany the core RMP. Information on these requirements is provided in the following guidance documents and recent notice:

- Evidence requirements for COVID-19 vaccines
- Evidence requirements for COVID-19 drugs
- Notice of clarification to drug manufacturers and sponsors on Canadian-specific considerations in risk management plans

If you have a question about the type of quality, safety and effectiveness information required, please contact the appropriate directorate within Health Canada. Please refer to the key contacts for relevant contact information.

Labelling

Manufacturers of a public health emergency drug must comply with all applicable labelling requirements in the *Food and Drugs Act* and parts A and C of the regulations.

Existing regulatory provisions on the labelling of veterinary drugs also apply.

Manufacturers who file an NDS for a public health emergency drug using the modified requirements may be asked to include a warning statement on the inner and outer labels. This statement may be displayed on any panel. The data submitted to support the NDS and any associated terms and conditions that the Minister places on the DIN will dictate this.

Drug products that are packaged in special containers or ones that are too small to accommodate the inner label requirements outlined in the *regulations* may contain abbreviated labelling (subsection C.04.009(6)). But there must be an outer label that meets all regulatory requirements. Sponsors are encouraged to contact Health Canada to discuss their labelling proposals. If using the exemption in C.08.002(2.2), sponsors should include a rationale and 'note to reviewer' in the submission.

The plain language labelling requirements for mock-up labels and a brand name assessment package do not apply (paragraphs C.08.002(2)(j.1) and C.08.002(2)(o)).

While exempt from these requirements, manufacturers are strongly encouraged to complete and submit a brand name assessment package and to provide mock-up labels:

- at the time of NDS filing (if available) or
- at the earliest time after the NDS is filed

Manufacturers may also file these materials after the NOC is granted.

Health Canada may apply labelling terms and conditions as necessary. We will request that the sponsor submit a brand name assessment and final mock-up package labels at an agreed-upon time if the sponsor chooses to use the exemption in C.08.002(2.2).

Manufacturers who are unable to provide a complete brand name assessment package at the time of filing or at the earliest time after the NDS is filed may provide a package where simulation exercises are omitted.

The update to Canadian specific labels (including when final mock-ups are to be provided) will continue to be assessed based on the global supply and public health emergency situation. Health Canada will work with manufacturers to develop an appropriate timeline to:

- submit the labelling materials to support their market authorization
- transition to the Canadian labelling at a point when the global supply and public health situation will make this possible

Plain language labelling and Look-alike Sound-alike components are not needed for the labelling of veterinary drugs.

Consult the list of guidance documents for further guidance on labelling.

Filing a supplement to an NDS for a public health emergency drug

A manufacturer of a public health emergency drug may file an NDS under section C.08.002 of the *regulations*. Once the manufacturer receives an NOC for the public health emergency drug, they may file a supplement to that new drug submission (SNDS) for any changes post-NOC.

Filing a supplement to an NDS for a public health emergency drug depends on the situation. The SNDS relies on the original modified requirements on the NOC. Discuss with Health Canada before filing.

Consult the following guidance documents on post-notice of compliance (NOC) changes:

- Framework document for pharmaceutical, biologic and radiopharmaceutical drugs for human use only
- Safety and efficacy document for pharmaceutical, biologic and radiopharmaceutical drugs for human use only
- Quality document

Notice of compliance for a public health emergency drug

For Health Canada to issue a notice of compliance (NOC) (C.08.004) for the sale of a public health emergency drug, the NDS must meet the requirements of section C.08.002.

For drugs relying on the modified requirements in subsection C.08.002(2.1), the NDS must contain sufficient evidence to support the conclusion that the drug's benefits outweigh the risks when used as indicated. The evidence takes into consideration the uncertainties around the drug in the context of the public health need related to COVID-19 or the condition on the List.

Drug identification number

Once an NOC is issued for a public health emergency drug, Health Canada assigns a drug identification number (DIN).

For more information on DINs, refer to the:

- Guidance document on the regulatory requirements for drug identification numbers (DINs)

Terms and conditions on a DIN pertaining to a public health emergency drug

A term and condition is an obligation that the Minister may impose on the DIN of a drug for an authorized indication, at anytime, in which the holder of a drug authorization is obligated to conduct an activity with respect to that drug. The main purpose of a T&C is to optimize the benefits and manage risks and uncertainties associated with the safety, efficacy and/or quality of a drug. Examples of potential terms and conditions can include:

- specific pharmacovigilance and risk mitigation and management measures
- additional quality information
- confirmation of effectiveness

The Minister may at any time impose or amend terms and conditions on a DIN (C.01.014.21(1.1)) assigned for a public health emergency drug if an NOC was issued under section C.08.004 in respect of:

- a new drug submission that contains the statement referred to in paragraph C.08.002(2.1)(a), or a supplement to such a submission
- an NDS, ANDS or supplement to either submission, that does not rely on the statement referred to in paragraph C.08.002(2.1)(a) but was filed on the basis of a direct or indirect comparison to another public health emergency drug submission that did

Terms and conditions will be determined on a case-by-case basis for drug submissions that have relied on a comparator drug where terms and conditions have been imposed. Any post-market commitments for a reference product may also be imposed on DINs for NOCs issued on the basis of a comparison, if appropriate.

Health Canada will discuss the terms and conditions with the sponsor before imposing or amending them. All terms and conditions are enforceable under section 21.7 of the act.

Note: New authorities respecting terms and conditions that can be placed on any drug that has been assigned a DIN will come into force on the one-year anniversary of the day on which the *Regulations Amending Certain Regulations made under the Food and Drugs Act (Agile Licensing)* are registered.

For more information, refer to the:

- Terms and conditions guidance for human and veterinary drugs

Submitting information to fulfill terms and conditions

Information on the fulfilment of terms and conditions should be submitted in accordance with Health Canada's post-notice of compliance (NOC) changes guidance documents with an accompanying cover letter. These can be filed as an SNDS or as a notifiable change, as appropriate. The subject line of the cover letter should state "Solicited information, fulfilling terms and conditions for public health emergency drug." Supporting documentation is to be provided. In some cases, information may be submitted as solicited information under the corresponding submission file/control number or as a separate pharmacovigilance submission.

Health Canada will review the documentation to determine if the conditions have been met. All terms and conditions will be published and Health Canada will note if they are on-going, pending or completed. Once we are satisfied that the manufacturer has complied with all the terms and conditions, we will indicate this in a letter and reference the original file/control number.

Market notification

The manufacturer of a public health emergency drug authorized under the regulations must notify Health Canada when they first sell the public health emergency drug under an NOC. The manufacturer must complete, sign, date and return the Health Canada-issued drug notification form (DNF) within 30 days of the date of the first sale. All pages of the DNF must be returned to us.

Our drug product database will indicate the DIN as "approved" until the manufacturer submits a completed DNF, at which point the DIN will be "marketed."

If the manufacturer did not file mock-up labels during review, the manufacturer should submit final mock-ups or final printed labels when the public health emergency drug is marketed or launched.

For more information on market notifications or notifications for the 'interruption of sale,' consult the:

- Guidance document on the regulatory requirements for drug identification numbers (DINs)

Changes in product ownership, mergers and buyouts or licensing agreements

Submissions proposing administrative changes should be filed within administrative (abbreviated) new drug submissions ((A)NDS).

If sponsors are proposing labelling changes along with the proposed administrative changes, they must file these changes within an (A)NDS 'labelling only' to obtain Health Canada authorization. They must do so before making any changes to labelling materials on the market.

Refer to the following guidance document for more information:

- Administrative processing of submissions and applications involving human or disinfectant drugs

Notification of discontinuation of sale

The manufacturer of a public health emergency drug must submit the notification of discontinuation of sale to Health Canada within 30 days after the public health emergency drug is permanently discontinued in Canada. The date of discontinuance is when the manufacturer last sells their drug, not when it is last sold at retail.

For information and general procedures on notification of discontinuance, authorization holders should consult the:

- Guidance document on the regulatory requirements for drug identification numbers (DINs)

For more information on additional requirements for reporting a discontinuance of sale, refer to the:

- Guide to reporting drug shortages and discontinuations

Transparency

Health Canada will continue to communicate up-to-date information about public health emergency drugs under the amended *Food and Drug Regulations*.

You can find the following information online:

- COVID-19 product-related information, such as terms and conditions and their status, can be viewed on the COVID-19 vaccines and treatments portal and the drug and health product register
- submissions for public health emergency drugs that have been accepted for review in the lists for drug and health product submissions under review
- regulatory decision summaries (RDS) and summary basis of decision documents (SBDs) for public health emergency drugs for the condition on the List of Conditions that Threaten Public Health in *Canada* (List) are in the drug and health product register
- clinical information used to seek approval of public health emergency drugs for COVID-19 or the condition on the List can be viewed on Health Canada's clinical information portal
- drug inspection outcomes and measures in the drug and health product inspections database
- summaries of risk management plans, providing the sponsor or market authorization holder's specified measures for pharmacovigilance and risk minimization

In addition, Health Canada will continue to provide the most up-to-date approved RMPs for public health emergency drugs in their entirety to external stakeholders upon request. We will consult with sponsors before any risk management plan for a public health emergency drug is made public.

For more information, please consult the:

- Labelling and post-market requirements section of the Guidance for market authorization requirements for COVID-19 vaccines
- Public release of clinical information

Performance standards

Health Canada aims to prioritize submissions for public health emergency drugs. Drug submissions will be prioritized and reviewed to reflect the public health need.

The time required to review a submission will depend on the submission itself, the volume of data to be assessed and the ability of the manufacturer to submit the data as per the plan, where applicable. Published performance standards will apply to submissions related to public health emergency drugs, other than submissions related to COVID-19 undergoing a rolling review.

For more information, refer to the following guidance documents on the:

- Management of drug submissions and applications
- Management of regulatory submissions for veterinary drugs

Fees

Fees for regulatory activities related to human drugs (pharmaceutical and biological) are charged as per the *Fees in Respect of Drugs and Medical Devices Order*.

Submission fees

Once a drug has received an NOC under the *regulations*, the existing Drug Right To Sell (DRTS) fee will apply.

Existing evaluation fees will be charged for public health emergency drug submissions filed under the *regulations*.

Please consult the following guidance documents:

- Fees for the review of human and disinfectant drug submissions and applications
- Guidance document - Fees for the review of veterinary drug submissions and applications

Submissions with fees have associated performance standards. Penalties may apply. Published performance standards will apply, but it's expected that most public health emergency drug submissions will be managed and reviewed before the performance standard deadline.

Drug establishment licences, good manufacturing practices

DELs for public health emergency drugs

Division 1A of Part C of the *Food and Drug Regulations* (regulations) applies to public health emergency drugs. A person must hold a drug establishment licence (DEL) authorizing any activities conducted for public health emergency drugs.

You can find the following information online:

- how to interpret the *regulations* for DEL requirements in the Guidance on drug establishment licences (GUI-0002)
- your responsibilities related to the DEL application process and how Health Canada manages DEL applications in Management of applications and performance for drug establishment licences (GUI-0127)

If you have questions about the DEL requirements or DEL applications for public health emergency drugs, please email us at del.questions-leppp@hc-sc.gc.ca. Include the term "public health emergency drug" in your email subject line for a faster response.

Applying for a new or amended DEL for a public health emergency drug

New DEL applications (C.01A.005(1) and (2)) or amendment applications (C.01A.006(1) and (1.1)) for a public health emergency drug can be submitted under the *regulations*. Follow the standard process and use the most current version of the application form (FRM-0033).

When applying for a new or amended DEL for a public health emergency drug, be sure to include the following information:

- the subject line "public health emergency drug" in the application email, which signals that this is a high-priority application
- a statement in the body of the application email or cover letter that the DEL application is for a public health emergency drug submitted under subsection C.01A.005(2) or C.01A.006(1.1) of the *regulations*
- the name of the drug

Submit your completed application form by email to el.applications-le@hc-sc.gc.ca.

For more information on DEL requirements, please consult the following guidance documents on:

- Drug establishment licences (GUI-0002)
- How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
- Management of applications and performance for drug establishment licences (GUI-0127)

Issuance of a DEL for a public health emergency drug

Health Canada issues or amends DELs in accordance with Part C, Division 1A of the *regulations*.

Public health emergency drug-related DEL applications submitted under the regulations are processed in an expedited manner. Timelines for the expedited review are determined on a case-by-case basis. The materials submitted in the application and the volume of information to be assessed are factors in how quickly we can review the application.

For more information on the issuance of a DEL or DEL amendments, please consult the:

- Guidance on drug establishment licences (GUI-0002)

DEL terms and conditions

At any time, Health Canada may impose or amend terms and conditions on DELs for a public health emergency drug submitted under the *regulations*. Decisions to impose or amend terms and conditions are based on the need to mitigate, prevent, or manage risk to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled, or tested.

Any existing terms and conditions imposed on a DEL for a COVID-19 drug will continue to apply under the Regulations as necessary. The authority to impose and amend terms and conditions at any time on existing COVID-19 DELs will continue to apply.

DEL holders that do not comply with the terms and conditions imposed on their licence will be subject to compliance and enforcement action for contravening section 21.7 of the *Food and Drugs Act*. Such actions will align with the legislative framework and the principles outlined in our compliance and enforcement policy for health products (POL-0001).

DEL suspension and cancellation

To prevent a risk to health and safety in relation to a public health emergency drug, Health Canada can suspend or cancel a DEL in full or in part for any of the reasons set out in sections C.01A.016 to C.01A.017.1. When a DEL is suspended or cancelled, the DEL holder must cease all suspended or cancelled activities.

For more information on DEL suspension and cancellation, consult the:

- Guidance on drug establishment licences (GUI-0002)

DEL performance standards

DEL applications for public health emergency drugs will be prioritized and reviewed based on the:

- public health need
- materials submitted in the application
- volume of information to be assessed

For more information on the performance standard, consult the guidance document on the:

- Management of applications and performance for drug establishment licences (GUI-0127)

Drug establishment licence fees

Drug establishment licence fees apply to the review of DEL applications submitted in relation to a public health emergency drug.

Please consult the guidance document on:

- Fees for the review of human and veterinary drug establishment licence applications

Fees apply for the review of the following types of DEL applications:

- an application for a new or reinstated DEL
- an application for an amendment to add a domestic building to a DEL
- an application for the annual licence review of a DEL

The DEL fee is calculated using the following components:

- Domestic component: the fee charged for each building listed on the licence or application based on the most upstream activity at that building
- Foreign building component: the fee charged for each unique foreign building (or building outside Canada) on the licence or application

Fees can be requested to be waived or reduced for applications filed by:

- a small business
- a publicly funded health care institution
- any branch or agency of the Government of Canada or of a province or territory

Good manufacturing practices

For information on the requirements around good manufacturing practices (GMP), consult the:

- Good manufacturing practices guide for drug products (GUI-0001)

Evidence requirements to support GMP compliance of foreign buildings is included in the following guidance:

- How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)

If you're unable to obtain documents outlined in GUI-0080 because of challenges directly associated with the public health emergency, please email us at foreign.site-etranger@hc-sc.gc.ca. You should contact us before you send in your DEL application. Be sure to include "public health emergency drug" in your subject line.

If you're unable to host a GMP drug inspection at your facility because of challenges directly associated with the public health emergency, please email us at GMP_Questions_BPF@hc-sc.gc.ca. We may consider operational relief and flexibilities to inspection timelines as set under the current fee regime on a case-by-case basis. To monitor compliance, GMP inspections will be conducted using a risk-based approach for licensable activities.

Finished product testing

DEL holders must meet all product release requirements as outlined in the *regulations.*

Finished product testing requirements in section C.02.019 of the regulations do not apply to a distributor or importer of a Schedule D (biologic) COVID-19 drug if the lot of the drug is the subject of a request made under the lot release program (subsection C.04.007(1)).

Licence holders must comply with testing requirements set out in Division 2 of the *regulations*. If you are unable to meet these requirements due to the applicable public health emergency, contact us at GMP_Questions_BPF@hc-sc.gc.ca.

For more information, refer to the:

- Good manufacturing practices guide for drug products (GUI-0001)

Post-market requirements

Pharmacovigilance reporting requirements

Health Canada manages an evidence-based post-market surveillance program to monitor and assess risks after health products have been authorized in Canada, and makes regulatory decisions to manage those risks. Market authorization holders (MAHs) contribute safety information to this evidence base through their reporting obligations under the *Food and Drug Regulations* (regulations).

Adverse reaction reporting

Adverse reactions must be reported to the Canada Vigilance Program.

The MAH must report within 15 days of receiving the following information (C.01.017 of the regulations):

- domestic serious expected and unexpected adverse drug reactions (C.01.017)
- foreign serious unexpected adverse reactions (C.01.017)
- unusual failures in efficacy for new drugs (C.08.007, C.08.008)

However, adverse reactions associated with public health emergency drugs are a priority. MAHs are strongly encouraged to submit reports related to this priority area to Health Canada without delay. MAHs should identify in the report that the drug is a public health emergency drug.

For information and general procedures on how to report serious adverse drug reactions, consult the guidance document on:

- Reporting adverse reactions to marketed health products (human drugs)

You can also obtain more information on submitting reports electronically.

For details on how to report adverse reactions associated with veterinary drugs, MAHs of veterinary drugs are encouraged to contact the Veterinary Drugs Directorate by email at hc.pv-vet.sc@hc-sc.gc.ca.

Annual summary reporting

Once a year and when requested by the Minister of Health, MAHs must conduct a concise, critical analysis of the adverse reactions and serious adverse reactions to a drug. They must also prepare a summary report relating to the reports received during the previous 12 months (C.01.018).

For information on preparing and submitting an annual summary report, consult the guidance document on:

- Preparing and submitting summary reports for marketed drugs and natural health products (human drugs)

Issue-related summary reports

Health Canada may request an issue-related summary report (C.01.019) any time. This report is a concise, critical analysis of a specific safety or effectiveness issue.

For information on preparing and submitting an issue-related summary report, consult the guidance document on:

- Preparing and submitting summary reports for marketed drugs and natural health products (human drugs)

Additional good pharmacovigilance practices

For additional information on good pharmacovigilance requirements, consult the:

- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)

Foreign actions reporting

Under section C.01.050 of the *regulations*, authorization holders must notify Health Canada of foreign regulatory actions. These include serious risk related to recalls, suspension or revocation of manufacturing or market authorizations within one of the specified foreign regulatory jurisdictions.

For information on this reporting requirement, consult the guidance document on:

- Notifying Health Canada of foreign actions

Other post-market requirements

DEL holders that fabricate, package/label, distribute or import a public health emergency drug are subject to several other post-market requirements, including record keeping, reporting shortages and discontinuation of sale.

Record keeping

Under subsection C.01.020(1) of the *regulations,* manufacturers of a public health emergency drug must maintain records and case reports as they relate to sections C.01.017 to C.01.019.

Under section C.02.020, DEL holders must maintain records for each public health emergency drug that they fabricate, package/label, distribute or import.

For more information, consult the:

- Good manufacturing practices guide for drug products (GUI-0001)

Shortages or discontinuation of sale

For drugs for human use, authorization holders should consult sections C.01.014.9 and C.01.014.10 and the guide to reporting drug shortages and discontinuations. The guide contains additional information and general procedures on how to report drug shortages and discontinuations of sale.

For details on shortages, refer to the:

- Drug shortages in Canada: Regulations and guidance

For more information on reporting shortages, authorization holders should contact the Veterinary Drugs Directorate by email at vdd.vetdrugs-medsvet.dmv@hc-sc.gc.ca.

Compliance and enforcement

Health Canada monitors compliance, undertakes enforcement activities and works to prevent non-compliance. When taking compliance and enforcement action, Health Canada considers a number of factors while adhering to the legislative framework and principles of our compliance and enforcement policy for health products (POL-0001).

For further guidance, consult the list of guidance documents.

Pre-positioning a public health emergency drug

A promising public health emergency drug may be imported into Canada before it receives a Canadian market authorization. This early importation and placement in Canadian facilities is referred to as "pre-positioning." It facilitates the immediate distribution of the drug upon authorization, making it available to Canadians as early as possible.

This mechanism may be used to import a promising public health emergency drug into Canada if the Chief Public Health Officer of Canada (CPHO) has notified the Minister of Health identifying the public health emergency drug that is to be pre-positioned.

To be eligible to import a public health emergency drug for pre-positioning, several conditions are required:

- The Government of Canada has entered into a contract for its procurement.
- An authorization for the drug has not been issued.
- The manufacturer has filed a submission for the drug's authorization.
- The DEL holder is authorized to import and the public health emergency drug is within the same category of drugs that is authorized by the licence
- The CPHO has provided the Minister with information required under paragraph C.08.009.03(1)(a).
- The DEL holder has provided the Minister with information required under paragraph C.08.009.03(1)(b).

Pre-positioning a public health emergency drug

Importation and distribution of a pre-positioned drug

After reviewing the information provided by the Chief Public Health Officer (CPHO) and importer, the Minister of Health issues a letter to the CPHO indicating if the requirements of pre-positioning have been met. To facilitate importation of the pre-positioned drug into Canada, a copy of this letter should accompany the product across the border.

The importer of the pre-positioned public health emergency drug is subject to certain sections in Part C, Divisions 2 to 4 of the *Food and Drug Regulations* (regulations) concerning storage, distribution, quality control and rapid recall.

A pre-positioned public health emergency drug cannot be distributed for use until it is authorized in Canada. It can, however, be moved to an alternate storage facility, as long as the Minister of Health is notified by the CPHO of the civic address of that facility.

Once the drug receives market authorization in Canada, all DEL requirements apply to subsequent importation and distribution.

Pre-positioned public health emergency drugs that do not receive market authorization under the *Regulations* must be destroyed or returned to the manufacturer.

For guidance on meeting the regulatory requirements for record keeping, storage and distribution of pre-positioned public health emergency drugs, consult the:

- Good manufacturing practices guide for drug products (GUI-0001)

Evidence requirements to support the GMP compliance is included in the following guidance document:

- How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)

References, key contacts

References

Authorization applications

- Management of drug submissions and applications
- Guidance document: Preparation of regulatory activities in the eCTD format
- Regulatory enrolment process
- Common electronic submissions gateway
- Management of regulatory submissions for veterinary drugs
- Filing submissions electronically

General

- Information and submission requirements for biosimilar biologic drugs
- Drug submissions relying on third-party data (literature and market experience)
- The use of foreign reviews by Health Canada
- Determining prescription status for human and veterinary drugs
- Questions and answers: Prescription drug list
- Regulatory requirements for drug identification numbers (DINs)
- Compliance and enforcement policy for health products (POL-0001)
- Drug and medical device databases
- Regulatory roadmap for biologic (Schedule D) drugs in Canada
- Draft guidance document: Disaggregated data requirements for human drugs (NEW)

Safety and efficacy

- Non-clinical laboratory study data supporting drug product applications and submissions: Adherence to good laboratory practice
- Preparation of comparative bioavailability information for drug submissions in the CTD format
- *Cochrane Handbook for Systematic Reviews of Interventions*
- Preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement

Quality

- Preparation of quality information for drug submissions in the CTD format: Biotechnological/biological (biotech) products
- Preparation of quality information for drug submissions in the CTD format: Conventional biotherapeutic products
- Quality (chemistry and manufacturing) guidance: New drug submissions (NDSs) and abbreviated new drug submissions (ANDSs)

Labelling

- Review of drug brand names: Guidance document for industry
- Frequently asked questions review of drug brand names
- Good label and package practices guide for prescription drugs (GLPPG)
- Questions and answers: Plain language labelling regulations for prescription drugs
- Labelling of special containers policy
- Labelling of pharmaceutical drugs for human use
- Guidance on veterinary drug labelling
- Product monograph guidance documents and notices

COVID-19 drugs

- Guidance for market authorization requirements for COVID-19 drugs

COVID-19 vaccines

- Guidance for market authorization requirements for COVID-19 vaccines: Requirements for vaccines to address SARS-CoV-2 variants
- ACCESS Consortium: Points to consider for strain changes in authorized COVID-19 vaccines in an ongoing SARS-CoV2 pandemic

Establishment licensing

- Guidance on drug establishment licences and drug establishment licensing fees (GUI-0002)
- Management of applications and performance for drug establishment licences (GUI-0127)

Good manufacturing practices

- Good manufacturing practices guide for drug products (GUI-0001)
- Annex 2 to the current edition of the good manufacturing practices guidelines schedule D drugs (biological drugs) (GUI-0027)
- How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
- Good manufacturing practices (GMP) for active pharmaceutical ingredients (APIs) (GUI-0104)

Good laboratory practices

- Good laboratory practices (GLP) guidelines (Dir-9801)

Post-market vigilance

- Reporting adverse reactions to marketed health products (overview)
- Report an adverse reaction to a drug: industry
- Preparing and submitting summary reports for marketed drugs and natural health products
- Good pharmacovigilance practices (GVP) guidelines (GUI-0102)
- Notifying Health Canada of foreign actions: Guidance document for industry
- Amendments to the *Food and Drugs Act*: Guide to new authorities (power to require and disclose information, power to order a label change and power to order a recall)
- Format and content for post-market drug benefit-risk assessment in Canada
- Submission of risk management plans and follow-up commitments
- Guide to reporting drug shortages and discontinuations
- Recall policy for health products (POL-0016)
- Drug and natural health products recall guide (GUI-0039)

Post-notice of compliance (NOC) changes

- Post-notice of compliance (NOC) changes: Framework document (pharmaceutical, biologic and radiopharmaceutical drugs for human use only)
- Quality document
- Safety and efficacy document (for pharmaceutical, biologic and radiopharmaceutical drugs for human use only)

Advertising webpages

- Marketing of drugs and medical devices

Disinfectants guidance documents and monograph

- Management of disinfectant drug applications
- Safety and efficacy requirements for surface disinfectant drugs
- Disinfectant drugs
- Applying for a drug identification number (DIN) for a disinfectant drug during the COVID-19 pandemic
- Hard-surface disinfectants monograph

Non-prescription pharmaceuticals and hand sanitizer (antiseptic skin cleansers)

- Human-use antiseptic drugs
- Management of drug submissions and applications
- Compendium of monographs

Key contacts

To help ensure that we prioritize your inquiry, please include "public health emergency drug" in the subject line of your email.

Biologic and Radiopharmaceutical Drugs Directorate
Office of Regulatory Affairs
Email: brdd.ora@hc-sc.gc.ca

Pharmaceutical Drugs Directorate
Regulatory Project Management Division
Email: rpmd-dgpr@hc-sc.gc.ca

Veterinary Drugs Directorate
Submission and Knowledge Management Division
Email: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca

Natural and Non-prescription Health Products Directorate
General enquiries
Email: nnhpd-dpsnso@hc-sc.gc.ca,

For application format-related inquiries:

Office of Submissions and Intellectual Property
Email: ereview@hc-sc.gc.ca

For adverse reaction reporting-related inquiries:
Canada Vigilance Program (CVP)

For inquiries about good manufacturing practices (GMP) compliance requirements:

Email: GMP_Questions_BPF@hc-sc.gc.ca

For drug establishment licensing (DEL)-related inquiries:

Email: del.questions-leppp@hc-sc.gc.ca