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Guidance on amendments to the Food and Drug Regulations for drugs for use in relation to COVID-19



1 **Forward**

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

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

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

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

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Overview

This guidance applies to sponsors of new COVID-19 drug submissions as well as sponsors seeking a notice of compliance (NOC) for COVID-19 drugs that received temporary authorization under the [Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19](#) (ISAD IO). It also applies to new COVID-19 drug establishment licences under the Food and Drug Regulations.

This document will help manufacturers prepare a submission for a notice of compliance for a COVID-19 drug under the Regulations. It also outlines the process for meeting the post-market regulatory requirements.

Background

The COVID-19 pandemic posed an immediate and significant risk to the health and safety of Canadians. To address the associated public health need in Canada, the Minister of Health made a number of interim orders to expedite and facilitate access to drugs, medical devices and foods for a special dietary purpose. The Minister used the power granted under section 30.1 of the *Food and Drugs Act* to make these interim orders.

The ISAD IO came into effect on September 16, 2020, and provided:

- an optional, expedited authorization pathway for the importation, sale and advertising of drugs to be used in relation to COVID-19
- modified requirements for drug establishment licence (DEL) applications for those drugs
- the introduction of a mechanism for the placement of COVID-19 drugs in Canadian facilities prior to the authorization to sell in Canada (pre-positioning)

The ISAD IO ends 1 year after it came into effect. After this time, drugs authorized through the ISAD IO would no longer have been legally permitted to be sold in Canada, unless transition measures were implemented.

The ISAD IO provided a temporary emergency authorization for COVID-19 drugs to address the pandemic. The authorization was not a notice of compliance. In order for drugs to receive an NOC, a submission needs to be made under Division 8 of the *Food and Drug Regulations*.

The *Food and Drug Regulations* have been amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through a new drug submission (NDS). The amendments maintain some of the mechanisms introduced through the ISAD IO, thus continuing to provide Canadians with quick access to safe and effective COVID-19 drugs. This guidance document explains the modified requirements provided in these amendments to the *Regulations*.

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

- [Explanatory note](#)
- [Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19](#)
- [Information and application requirements for drugs authorized under the interim order: Guidance document](#)
- [Canada Gazette II of amendments to the Food and Drug Regulations](#)

Scope and application

COVID-19 means the coronavirus disease 2019. This guidance document applies to:

- drug products authorized under the interim order
- manufacturers planning to file a submission for a notice of compliance (NOC) for a designated COVID-19 drug as defined in C.08.001.2, whether or not they are taking advantage of modified requirements
- drug products filed and/or authorized for a designated COVID-19 drug under the *Food and Drug Regulations*
- establishments seeking a DEL related to COVID-19 drugs
- pre-positioning mechanism introduced under the ISAD IO

A "designated COVID-19 drug" is a new drug for which the purpose and conditions of use recommended by the manufacturer relate to COVID-19. For the purpose of this document, COVID-19 drugs also include designated COVID-19 drugs.

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

- [Management of drug submissions and applications](#)
- [Management of disinfectant drug applications](#)
- [Human-use antiseptic drugs](#)
- [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 introduce similar provisions found in the ISAD IO with regards to requirements for drug product authorizations, DEL applications and pre-positioning of products prior to authorization. The integration of these measures in the *Regulations* aims to give Canadians continued and timely access to safe and effective COVID-19 drugs.

Policy objectives

The objective of the amended *Regulations* is to allow for a mechanism for continued and timely access to safe and effective COVID-19 drugs. The review, authorization and oversight of these drugs will be conducted under the *Regulations*.

The amendments to the *Regulations* offer the following benefits:

- continues to support access to safe, effective and high-quality COVID-19 drugs
- enables the sale and advertising of COVID-19 drugs that were authorized under the ISAD IO to continue after the IO expires
- enables manufacturers of new COVID-19 drugs for which an authorization was not sought under the ISAD IO to seek authorization under the *Regulations* with similar requirements as those provided under the ISAD IO
- continues the post-market regulatory obligations placed on authorization holders, manufacturers and importers after the ISAD IO expires
- continues to allow the early importation and placement in Canadian facilities (pre-positioning) of a promising COVID-19 drug for which a federal government contract for its procurement is in place, before that drug receives market authorization in Canada
- continues an agile approach for DELs that authorizes regulated activities for COVID-19 drugs

Under the amended *Regulations*:

1. Health Canada only grants an NOC for a COVID-19 drug under the *Regulations* 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.
2. Any uncertainties or risk mitigation measures related to the drug in the context of the public health need due to COVID-19 are managed through the use of terms and conditions.
3. As with all drugs, Health Canada assesses and monitors the safety and effectiveness of all COVID-19 drugs for which an NOC was issued. If required, Health Canada takes immediate action, including compliance and enforcement measures and the suspension or cancellation of an NOC to protect the health and safety of Canadians.

Policy statements

Manufacturers of COVID-19 drugs may be able to obtain an NOC under the *Regulations* by leveraging certain options and modified requirements carried over from the ISAD IO.

These amendments to the *Regulations* allow for a submission for drugs to treat or prevent COVID-19 to be filed earlier through a "rolling submission" process. Manufacturers are responsible for completing the required documentation and providing the necessary evidence to Health Canada. COVID-19 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 necessity of the drug in addressing urgent COVID-19-related public health needs.

Manufacturers who have a valid authorization issued under the ISAD IO can file a new drug submission (NDS) under the *Regulations*. Sale of the drug may continue while the submission is in review, as long as it was filed within the 90-day period.

Where an expanded indication for COVID-19 was authorized under the ISAD IO for a marketed drug, the manufacturer is able to submit an SNDs to add the new COVID-19 indication. Modified requirements, including the ability to file a rolling submission, are available to these SNDs.

An NOC is not needed before September 16 to continue to sell, as long as an authorization was granted under the ISAD IO and a submission was filed within specified timelines. After September 16, if Health Canada has not issued an NOC, the ISAD IO authorization remains in effect until a decision is reached on the submission. (See section on "Timelines within which to file a submission under the *Regulations* to obtain a notice of compliance.")

With this approach, manufacturers who initially obtained an authorization under the ISAD IO may submit an NDS with the same data as was included in their interim order application, along with any necessary updates. Where applicable, newly available data should be included in the NDS. To facilitate an expedited review, the sponsor should provide a summary of the submission package highlighting any changes. COVID-19 drugs are reviewed on an expedited timeline above the usual performance standards. As such, the Priority Review Policy does not apply.

Manufacturers who had their ISAD IO authorization revoked or who have never applied can also file an NDS submission leveraging the modified requirements for COVID-19 drugs in the *Regulations*.

181 Explanation of key terms

182 **Designated COVID-19 drug:** As defined in C.08.001.2, is a "new drug" under C.08.001. As such, it is subject to
183 the requirements in Part C, Division 8 of the *Food and Drug Regulations*, including the:

- 184 • existing NDS and supplemental NDS (SNDs) provisions that require an NOC (see C.08.002(1) and
185 C.08.003(1)) to allow a new drug to be sold
- 186 • submission outcomes under C.08.004
- 187 • suspension provisions under C.08.006

188 For this document, designated COVID-19 drugs will be collectively referred to as COVID-19 drugs.

189 **Drug:** According to the *Food and Drugs Act*, includes any substance or mixture of substances manufactured,
190 sold or represented for use in:

- 191 • the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or
192 its symptoms in human beings or animals
- 193 • restoring, correcting or modifying organic functions in human beings or animals
- 194 • disinfection in premises where food is manufactured, prepared or kept

Preparing a submission or supplement

Submission scenarios

The Governor in Council introduced amendments to the *Regulations* to provide a mechanism for COVID-19 drugs to be authorized through the issuance of an NOC, based on modified requirements that have been transferred from the ISAD IO.

Table 1 provides an overview of the modified requirements for COVID-19 drugs in the Regulations.

The "NDS CV" submission type has been created for NDSs that seek approval on the basis of any of the requirements in subsections C.08.002(2.1), C.08.002(2.2) or C.08.002(2.3) of the *Regulations*. To make use of any of the alternative requirements, the manufacturer must make the statements required by paragraphs C.08.002(2.4)(a) and meet the requirement in 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."

For more details, please refer to submission scenarios. NDS CV submission type means NDS [COVID].

Table 1: Overview of modified requirements for COVID-19 drug submissions

Scenario	Submission type	Available modified requirements	Terms and conditions
New drug with same data as filed under IO (and possible additional data)	NDS	C.08.002(2.1): supportive evidence C.08.002(2.2): draft label C.08.002(2.3): rolling submission	Yes
New designated COVID-19 drug (not previously filed under the ISAD IO)	NDS	C.08.002(2.1): supportive evidence C.08.002(2.2): draft label C.08.002(2.3): rolling submission	Yes
Marketed drug adding additional indication for COVID-19	SNDS	Modified requirements (as above)	Yes

Scenario	Submission type	Available modified requirements	Terms and conditions
Supplemental new drug submissions adding additional indication for COVID-19 following authorization of the NDS for a designated COVID-19 drug	SNDS	Modified requirements (as above)	Yes

210 Timelines within which to file a submission under the *Regulations* to obtain a notice of
211 compliance

212 The amendments to the *Regulations* provide that an ISAD IO authorization will be revoked unless a
213 submission is filed within:

- 214 • 90 days following the coming into force of the amendments, if the drug was authorized under the
- 215 ISAD IO before the amendments came into force or
- 216 • 90 days following the issuance of an authorization under the ISAD IO, if the drug was authorized after
- 217 the amendments came into force

218 Where a submission has been filed within these timelines, the COVID-19 drug may continue to be sold under
219 the ISAD IO authorization until the submission has been approved, rejected or withdrawn. This is the case
220 even after the ISAD IO ceases to have effect.

221 If a manufacturer fails to file a submission under the *Regulations* within the prescribed timelines, the
222 manufacturer will have to wait until the product is authorized under the *Regulations* to resume sale.

223 Manufacturers are encouraged to submit a submission under the *Regulations* before the 90-day deadline to
224 ensure the submission has met the requirements for filing (detailed in the section below).

225 Modified requirements

226 Manufacturers of COVID-19 drugs will have the option to follow similar requirements under
227 the *Regulations* to those under the ISAD IO, as set out in paragraphs C.08.002(2.1) to (2.3). To make use of
228 these alternate requirements, manufacturers must include a statement identifying that the purpose and
229 conditions of use specified in the NDS relate only to COVID-19.

230 Manufacturers should ensure that all statements required are made in module 1.2.3, "Certification and
231 Attestation Forms." Manufacturers are also encouraged to identify in a cover letter the modified
232 requirements they intend to follow.

233 Modified requirements include:

- 234 • ability to file a rolling submission(C.08.002(2.3))
- 235 • exemption from submitting detailed reports of tests made to establish the safety and clinical
- 236 effectiveness of the new drug under C.08.002(2)(g) and (h)
 - 237 ○ however, the manufacturer must provide sufficient evidence that the benefits of the drug
 - 238 outweigh the risks, taking into account uncertainties as well as the public health need due to
 - 239 COVID-19 (C.08.002(2.1)(b))
- 240 • exemption from being required under C.08.002(2)(j.1) to provide a mock-up label if the
- 241 manufacturer provides a draft of the label
 - 242 ○ submission must also include any package insert and document provided upon request that
 - 243 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 the requirements of 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 C.08.002(2.5), the amended regulations do not apply if the manufacturer is seeking a notice of compliance for a COVID-19 drug on the basis of a direct or indirect comparison between the COVID-19 drug and another COVID-19 drug (for example, a generic or biosimilar submission). Submissions will be assessed under C.08.002(2.5) before a submission receives a filing date.

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 COVID-19 drug to file a submission with an alternative data package where justified based on the urgent public health needs resulting from COVID-19. As more products emerge to address the public health needs brought upon by COVID-19, 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 COVID-19 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 COVID-19 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))

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 an NOC issued for the COVID-19 drug. (See paragraph C.01.014.21(1)(b).) In the context of the public health need related to COVID-19, the manufacturer is required to include in the NDS sufficient safety, efficacy and quality evidence showing that the drug's benefits outweigh the risks. Health Canada reviews the NDS and will apply terms and conditions on the authorization to require the manufacturer to address risks and uncertainties after authorization.

If the manufacturer has a full data package to support the NDS, then they may choose not to rely on C.08.002(2.1).

For more information, see the following guidance documents on:

- [Evidence requirements for COVID-19 vaccines](#)
- [Evidence requirements for COVID-19 drugs](#)

Product labels

C.08.002(2.2) provides for exemption from the requirement in C.08.002(2)(j.1) to provide a mock-up of labels of the 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 for more information:

- [Guidance document: Labelling of pharmaceutical drugs for human use](#)
- [Guidance for market authorization requirements for COVID-19 vaccines: Labelling and post-market requirements](#)

Sponsors are also encouraged to contact Health Canada in advance to discuss their labelling proposals. When modified requirements are sought, sponsors should include a rationale and 'note to reviewer' in the submission.

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

Rolling submissions

After September 15, 2021, a sponsor cannot submit anything under the ISAD IO, even if it was in the plan for a rolling submission. No ISAD IO authorization can be granted after September 16, 2021.

C.08.002(2.3) carries over a manufacturer's ability to file a rolling submission, as permitted in the ISAD IO. 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 its 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 COVID-19 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(2.1)(b) or
- subsection C.08.002(2.2)

This rolling review process can reduce the time it takes to authorize these critical new drugs while maintaining appropriate standards of safety, efficacy and quality.

To file a rolling submission, 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. (See 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 with 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 submission. Health Canada recommends a pre-submission meeting to discuss efficient filing strategies for changes, such as chemistry, manufacturing and control changes.

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

The filing date may differ from the date of original receipt if the submission is considered to be administratively incomplete at that time. Data or information that is subsequently provided in a rolling submission 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 [Guidance document: The management of drug submissions and applications](#).

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

- the NDS is deemed administratively complete by Health Canada and
- 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.

For a submission to be considered administratively complete under Division 8 of the *Regulations*, it must meet the requirements of the data protection provisions of the *Food and Drug Regulations* and the *Patented Medicines (Notice of Compliance) Regulations*. It must also contain forms such as the:

- Regulatory Enrolment Process (REP) Regulatory Transaction (RT) File
- REP Product Information (PI) File
- REP RT Form – Fee Section
- Submission Certificate

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 as multiple packages, the plan must clearly specify what information will be contained in each data package. For example:

- data package A will be submitted on DD/MM/YYYY and contains results from studies XX, YY and ZZ
- data package 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 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.

364 Health Canada will:

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

368 Any subsequent data or information sent later is considered solicited information under the NDS if the data
369 or information is provided according to the plan or in response to Health Canada's request. There may be
370 situations where an update to the plan is appropriate. Health Canada will assess these on a case-by-case
371 basis. However, changes in the timing or content should be avoided if possible as they will impact the review
372 timeline and efficiency. Information or data provided otherwise may be considered unsolicited information.

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

375 Regulatory activity and transaction details for designated COVID-19 drugs

376 As noted above, modified requirements introduced through amendments to the *Regulations* are only
377 available for an NDS. The "NDS CV" submission type has been created for NDSs that use any of the provisions
378 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
379 the "NDS CV" submission type in the appropriate Regulatory Enrolment Process (REP) regulatory transaction
380 template when submitting their NDS. "NDS CV" submission types are described as "Drug submission with
381 modified requirements for Designated COVID-19 drugs."

382 To file an NDS that does not benefit from any of the modified requirements mentioned in the 3 subsections
383 above, a manufacturer must select the regular NDS submission type when submitting its NDS.

384 Pre-submission meetings

385 Manufacturers are encouraged to have regular communications with Health Canada. Early and ongoing
386 consultation(s) with Health Canada help ensure that regulatory requirements are met.

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

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

- 393 • [Management of drug submissions and applications](#)
- 394 • [Management of regulatory submissions for veterinary drugs](#)

395 For relevant contact information, please see key contacts.

396 Format and structure for filing

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

- 398 • [Management of drug submissions and applications](#) or
- 399 • [Management of regulatory submissions for veterinary drugs](#)

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

- 401 • [Guidance document on the preparation of regulatory activities in the eCTD format](#)
- 402 • [Organization and document placement for Canadian module 1](#)
- 403 • [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.

Submissions filed under the *Regulations* for which an application was previously filed under the ISAD IO will receive a new dossier ID separate from the ISAD IO application. The new dossier ID must be requested using the dossier ID request forms.

Content and requirements for filing

Submissions made under the *Regulations* must be independent from any ISAD IO application. At a minimum, they must contain all relevant data that was included in the ISAD IO application, along with any required updates. 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 submissions as well as the terms and conditions of authorization.

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 COVID-19 drug

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

For more information, consult the following guidance document:

- [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 C.08.002(2.1) to (2.3). All known information should be provided to support the safety and efficacy of the COVID-19 drug. This includes all available clinical trial data and the safety and efficacy summary documents.

For more information, consult the following guidance document:

- [Evidence requirements for COVID-19 vaccines](#)

Quality (chemistry and manufacturing) information and requirements

For further guidance on meeting application and information requirements, consult the list of guidance documents. Under section 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. They should discuss the plan with Health Canada before submitting it. Health Canada will review the timing proposed in the plan as well as the chemistry and manufacturing information.

For more information, consult the following guidance document:

- [Evidence requirements for COVID-19 vaccines](#)

Comparative submissions for subsequent entry drugs

Under the Abbreviated New Drug Submissions (ANDS) and NDS pathways of the *Food and Drug Regulations*, manufacturers of subsequent entry drugs (generics and biosimilars) can seek an NOC on the basis of a comparison to a drug that has already received an NOC.

Manufacturers must demonstrate similarity to an authorized reference drug (for example, in the case of generics, a Canadian reference product as defined in section C.08.001.1). This is done by filing a comparative submission that relies, in part, on the previously authorized evidence of safety and effectiveness for the previously authorized reference drug. The manufacturer may then submit a reduced data package in the submission.

The amendments do not extend the modified requirements provided under new subsections C.08.002(2.1), (2.2) and (2.3) to cases where manufacturers seek an NOC for a COVID-19 drug on the basis of a direct or indirect comparison between that drug and another COVID-19 drug.

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. Therefore, comparative submissions are expected to be filed as an ANDS or a comparative NDS.

Health Canada will apply subsection C.08.002(2.5) of the *Regulations* in processing and comparative submissions that seek approval on the basis of any of the new subsections C.08.002(2.1), (2.2) and (2.3) will not receive a filing date. When it appears that the filing of a submission is prevented, the manufacturer will be provided with a written preliminary decision and an opportunity to make representations in response. If, following consideration of the representations, Health Canada remains of the view that the submission cannot be filed, the manufacturer will be notified and the submission will not be processed further.

Manufacturers of subsequent entry products are prohibited from filing a submission on the basis of a direct or indirect comparison to a COVID-19 drug for which an authorization was issued under the ISAD IO (C.08.003.01(2)). Note that subsection C.08.003.01(2) is not intended to prevent the filing of a submission that contains new data from clinical trials comparing the efficacy of the new drug to an existing one. Also note that C.08.003.01 does not prevent the filing of a submission or supplement on the basis of a comparison to a COVID-19 drug that has received an NOC (C.08.003.01(3)).

Manufacturers who intend to file a submission seeking an NOC for a COVID-19 drug on the basis of a comparison with another COVID-19 drug are encouraged to contact Health Canada for a pre-submission meeting.

Information and requirements for veterinary drugs

A COVID-19 drug submission should contain all available information to help Health Canada assess the drug's safety, efficacy and quality. Information 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

Manufacturers should submit a Risk Management Plan (RMP) for a COVID-19 drug. If an RMP has been filed as part of the ISAD IO application, an updated RMP with the most recent post marketing data, risk minimization measures and pharmacovigilance activities should be submitted.

The RMP should focus on the product's updated safety risks in the context of COVID-19 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 related to COVID-19 use
- 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

For information on the scope of RMPs, please refer to the following guidance document:

- [Submission of risk management plans and follow-up commitments](#)

For COVID-19 drugs submitted for authorization, the RMP should include the following:

- safety specification section on the identified risks, potential risks and missing information for the product (for example, special populations where there is limited information or who were excluded from clinical trials), with a focus on risks in COVID-19 patients, where appropriate
- pharmacovigilance plan on 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 to manage the safety 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
- plan to measure the effectiveness of additional risk minimization activities

An RMP that has been reviewed and accepted as part of the submission for a COVID-19 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 or conditions and must be implemented.

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

- [Evidence requirements for COVID-19 vaccines](#)
- [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.

524 Labelling

525 Manufacturers of a COVID-19 drug must comply with all applicable labelling requirements in the *Food and*
526 *Drugs Act* and parts A and C of the *Regulations*:

- 527 • A.01.014
- 528 • A.01.015
- 529 • A.01.60.1 to A.01.068
- 530 • A.01.065
- 531 • C.01.004 to C.01.011
- 532 • C.01.401
- 533 • C.03.202
- 534 • C.03.203
- 535 • C.03.206 to C.03.209
- 536 • C.04.019 and C.04.020

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

538 Manufacturers that file an NDS for a COVID-19 drug using the modified requirements may be asked to
539 include a warning statement on the inner and outer labels. This statement may be displayed on any
540 panel. The data submitted to support the NDS and any associated terms and conditions that the Minister
541 places on the DIN will dictate this.

542 Drug products that are packaged in special and/or containers that are too small to accommodate the inner
543 label requirements outlined in the *Regulations* may contain abbreviated labelling. But there must be an outer
544 label that meets all regulatory requirements. Sponsors are encouraged to contact Health Canada to discuss
545 their labelling proposals. When modified requirements are sought, sponsors should include a rationale and
546 'note to reviewer' in the submission.

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

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

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

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

554 Health Canada may apply labelling terms and conditions as necessary. We will request that the sponsor
555 submit a brand name assessment and final mock-up package labels at an agreed-upon time if the sponsor
556 chooses to use the labelling modified requirements provided by the *Regulations*.

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

559 Modified requirements to transition to Canadian specific labelling (including when final mock-ups are to be
560 provided) will continue to be assessed based on the global supply and pandemic situation. Health Canada will
561 work with manufacturers to develop an appropriate timeline to:

- 562 • submit the labelling materials to support their market authorization
- 563 • transition to the Canadian labelling at a point when the global supply and pandemic situation will
- 564 make this possible

565 Plain language labelling and Look-alike Sound-alike components are not needed with respect to the labelling
566 of veterinary drugs.

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

568 Filing a supplement to an NDS for a COVID-19 drug

569 A manufacturer of a COVID-19 drug that holds an authorization for a new drug under the ISAD IO may file an
570 NDS under section C.08.002 of the *Regulations*. Once the manufacturer receives an NOC for the COVID-19
571 drug, they may file a supplement to that new drug submission (SNDS) for any changes post-NOC. Filing a
572 supplement to an NDS for a COVID-19 drug depends on the situation. The SNDS relies on the original
573 modified requirements on the NOC. Discuss with Health Canada before filing. Where applicable, the
574 manufacturer may also be able to incorporate the change as part of its NDS.

575 Consult the following guidance documents on post-NOC:

- 576 • [Framework document for pharmaceutical, biologic and radiopharmaceutical drugs for human use](#)
577 [only](#)
- 578 • [Safety and efficacy document for pharmaceutical, biologic and radiopharmaceutical drugs for human](#)
579 [use only](#)
- 580 • [Post-notice of compliance \(NOC\) changes: Quality document](#)

581 Notice of compliance (NOC) for a COVID-19 drug

582 For Health Canada to issue an NOC (C.08.004) for the sale of a COVID-19 drug, the NDS must meet the
583 requirements of section C.08.002. For drugs relying on the modified requirements in C.08.002 (2.1), the NDS
584 must contain enough evidence to support the conclusion that the drug's benefits outweigh the risks when
585 used as indicated. The evidence takes into consideration the uncertainties around the drug in the context of
586 the public health need related to COVID-19.

587 Drug identification number (DIN)

588 When the manufacturer of a COVID-19 drug that was previously authorized under the ISAD IO submits an
589 NDS to obtain an NOC, the DIN that was assigned under the ISAD IO remains active until the NDS has been
590 approved, rejected or withdrawn. This ensures that all regulatory obligations associated with the DIN
591 continue.

592 Once an NOC is issued for a COVID-19 drug, Health Canada may assign the same digits for the DIN under
593 C.01.014.2 as were issued under section 7 of the ISAD IO.

594 If the submission that was submitted under the *Regulations* is rejected or withdrawn, the DIN will be revoked
595 at that time.

596 For more information on DINs, refer to the:

- 597 • [Guidance document on the regulatory requirements for drug identification numbers \(DINs\)](#)

598 Terms and conditions on a DIN pertaining to a COVID-19 drug relying on modified requirements
599 in C.08.002(2.1)

600 Health Canada may at any time impose or amend terms and conditions on a DIN (C.01.014.21(1)(b)) of a
601 COVID-19 drug where the manufacturer relied on C.08.002(2.1) to obtain an NOC. If the manufacturer only
602 used other provisions, then the terms and conditions power does not apply.

603 This authority allows Health Canada to issue an NOC for a COVID-19 drug while attaching additional
604 conditions that the DIN holder must comply with. These terms or conditions are used to ensure appropriate

oversight, manage uncertainties or mitigate risks. However, the terms and conditions on a DIN for a COVID-19 drug using the submission flexibility in C.08.002(2.1) will be based on what's needed when a submission is not able to meet the usual data requirements. Examples of anticipated terms and conditions include:

- specific pharmacovigilance and risk mitigation and management measures
- additional quality information
- confirmation of effectiveness
- drug shortage measures introduced to prevent or alleviate a shortage

The terms and conditions are on the DIN and remain on the DIN regardless of subsequent SNDSs (supplement to a new drug submission). The exception is if the Minister removes the terms and conditions as part of the (SNDS) process.

The terms and conditions may also apply to drugs authorized on the basis of a comparison to a COVID-19 drug, where the NOC of the comparator product had relied on these submission flexibilities (C.01.014.21(1.1)(b)). This ensures that any post-market commitments for a reference product may also be imposed on NOCs issued on the basis of a comparison.

Terms and conditions can be imposed or amended at any time on a DIN for a COVID-19 drug (C.01.014.21(1.1)(a)) that was filed as:

- an NDS under section C.08.002 relying on the data flexibility referred to in C.08.002(2.1)
- a supplement to an NDS for that new drug

They can also be imposed or amended at any time on a DIN for a COVID-19 drug (C.01.014.21(1.1)(b)) authorized on the basis of a direct or indirect comparison to another COVID-19 drug (see C.01.014.21(1.1)(a)) and filed as:

- an NDS filed under C.08.002
- an abbreviated new drug submission (ANDS) filed under C.08.002.1
- a supplement to a new drug submission or an abbreviated new drug submission that is filed under section C.08.003

Health Canada will discuss the terms and conditions with the sponsor prior to imposing them. All terms and conditions are enforceable under section 21.7 of the Act.

Terms and conditions do not apply to any drugs, including COVID-19 drugs, authorized through the existing NDS and SNDS pathway if the manufacturer:

- is able to satisfy the full data requirements (C.08.002(2)(g) and (h))
- has not relied on C.08.002(2.1)

Submitting information to fulfill terms and conditions

Information on the fulfilment of terms and conditions should be submitted as solicited information with an accompanying cover letter. The subject should state "Solicited information, fulfilling Terms and Conditions for COVID-19 drug." Supporting documentation is to be provided.

Health Canada will review the documentation to determine if the conditions have been met. 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

A market notification for a drug authorized under the ISAD IO does not constitute market notification of a drug under the *Regulations*. This is the case even if the same digits have been issued to the drug as the DIN under both the ISAD IO and the *Regulations*.

The manufacturer of a COVID-19 drug authorized under the *Regulations* must notify Health Canada when they first sell the COVID-19 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 Health Canada.

The DIN assigned under the ISAD IO will be revoked once the same DIN is assigned to the drug under the *Regulations*. 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 COVID-19 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 COVID-19 drug must submit the notification of discontinuation of sale to Health Canada within 30 days after the COVID-19 drug is permanently discontinued in Canada. The date of discontinuance is when the manufacturer last sells its 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 on how to report a discontinuance of sale, see the section on [shortages or discontinuation of sale](#).

Transparency

Health Canada will continue to communicate up-to-date information about COVID-19 drugs under the amended *Food and Drug Regulations*.

You can find the following information online:

- COVID-19 product-related information can be viewed on the [COVID-19 vaccines and treatments portal](#) and the [drug and health product register](#)
- submissions for COVID-19 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 COVID-19 drugs in the [drug and health product register](#)
- clinical information used to seek approval of COVID-19 drugs can be viewed on Health Canada's [clinical information portal](#)
- drug inspection outcomes and measures in the [drug and health product inspections database](#)

In addition, Health Canada will continue to provide the most up-to-date approved Risk Management Plans for COVID vaccines and treatments in their entirety to external stakeholders upon request. Health Canada confirms that sponsors will be consulted before any risk management plan for COVID-19 vaccines and treatments 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 COVID-19 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 COVID-19 drugs, other than rolling submissions, made under the *Regulations*.

Rolling submissions will not be subject to performance standards (in other words, credits to manufacturers due to missed performance standards). This is explained in the Fees section below.

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

Submission fees

Pre-market evaluation fees will be remitted for human drug submissions filed under the *Food and Drug Regulations* seeking approval for a COVID-19 drug, provided that:

- an application was previously filed under the ISAD IO for the same drug and
- no submission was previously filed under the *Food and Drug Regulations* for that drug

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

716 Where an application had not been filed under the ISAD IO, the following fees will apply to COVID-19 drug
717 submissions filed under the *Regulations*:

- 718 • existing evaluation fees will be charged for submissions
- 719 • existing small business mitigation measures are available for COVID-19 drug submissions, and include
- 720 • full waiver of evaluation fee for the company's first drug submission with Health Canada
- 721 • a 50% reduction in all other evaluation fees as well as a 25% reduction in DIN and DEL fees

722 Please consult the following guidance document:

- 723 • [Fees for the review of human and disinfectant drug submissions and applications](#)

724 Submissions with fees have associated performance standards. Penalties may apply:

- 725 • Published performance standards will apply, but it's expected that most COVID-19 drug submissions
- 726 will be managed and reviewed efficiently.
- 727 • Rolling submissions will not be subject to performance standards (in other words, the 25%
- 728 remittance to manufacturers due to missed performance standards will not apply).

Drug establishment licences and good manufacturing practices

Drug establishment licences for COVID-19 drugs

Division 1A of Part C of the *Regulations* applies to COVID-19 drugs. A person must hold a drug establishment licence (DEL) authorizing any activities conducted with respect to COVID-19 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 the document on the [Management of applications and performance for drug establishment licences \(GUI-0127\)](#)

For more information about drug establishment licences and COVID-19, see our page on [drug establishment licences and COVID-19](#).

If you have questions about the DEL requirements or DEL applications for COVID-19 drugs, please email us at del.questions-leppp@hc-sc.gc.ca. Include the term "COVID-19" in your email subject line for a faster response.

Transitioning of DELs issued or amended under the ISAD IO

Stakeholders wishing to apply for a DEL or DEL amendment for a COVID-19 drug may continue to do so under the *Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19 (ISAD IO)* until its expiry on September 16, 2021. For information on how to submit a DEL application under ISAD IO, please refer to the [section on Drug establishment licences of the ISAD IO guidance document](#).

Applications that have been submitted under section 20 of ISAD IO and not issued before its expiry will be automatically transitioned. They will continue to be reviewed as though they were submitted under the *Food and Drug Regulations*. For such applications, DEL fees will not apply.

Notification

DEL holders who wish to maintain their licence, or part of their licence, that was issued under section 20 of the ISAD IO, must notify Health Canada before ISAD IO expires. We recommend doing so at least 30 days before ISAD IO expires.

To maintain a DEL issued under section 20 of ISAD IO, please submit the following information to Health Canada:

- include "Maintain COVID-19 drug IO DEL" in the subject line of the notification email
- include details indicating the notification is being submitted to maintain a DEL or part of a DEL issued for an application submitted under section 20 of the ISAD IO
- include the application number assigned by the Drug Establishment Licensing Unit

Health Canada will review your notification to maintain and will inform you if more information is required. Failure to notify us will result in the DEL being automatically cancelled, in whole or in part, when ISAD IO expires.

765 Applying for a new or amended DEL for a COVID-19 drug



This section is applicable after ISAD IO expires on September 16, 2021. For information on how to submit a DEL application under ISAD IO, please refer to the [Drug Establishment Licences section of the ISAD IO guidance document](#).

766 New drug establishment licence (DEL) applications (C.01A.005(1)) or amendment applications (C.01A.006(1)
767 (1.1)) for a COVID-19 drug can be submitted under the *Regulations*. Follow the [standard process and use the](#)
768 [most current version of the application form \(FRM-0033\)](#).

769 When applying for a new or amended DEL for a COVID-19 drug, be sure to include the following information:

- 770 • the subject line "COVID-19 drug" in the application email, which signals that this is a high-priority
771 application
- 772 • a statement in the body of the application email or cover letter that the DEL application is for a
773 COVID-19 drug submitted under C.01A.005(2) or C.01A.006(1.1) of the *Regulations*
- 774 • the name of the drug

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

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

- 777 • [Drug establishment licences \(GUI-0002\)](#)
- 778 • [How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#)
- 779 • [Management of applications and performance for drug establishment licences \(GUI-0127\)](#)

780 Issuance of a DEL for a COVID-19 drug

781 Health Canada issues or amends DELs in accordance with Part C, Division 1A of the *Regulations*.
782 COVID-19-related DEL applications submitted under the *Regulations* are processed in an expedited manner.
783 Timelines for the expedited review are determined on a case-by-case basis. The materials submitted in the
784 application and the volume of information to be assessed are factors in how quickly we can review the
785 application.

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

- 787 • [Guidance on drug establishment licences \(GUI-0002\)](#)

788 DEL terms and conditions



This section is applicable after ISAD IO expires on September 16, 2021. For information on how to submit a DEL application under the ISAD IO, please refer to the [drug establishment licences section of the ISAD IO guidance document](#).

789 At any time, Health Canada may impose or amend terms and conditions on DELs for a COVID-19 drug
790 submitted under the *Regulations*. Decisions to impose or amend terms and conditions are based on the need
791 to mitigate or manage additional oversight for risk-based reasons. These reasons include matters related to
792 available evidence, medical necessity and activities conducted.

793 The ability to impose or amend terms and conditions gives Health Canada the agility to facilitate rapid access
794 to COVID-19 drugs while mitigating risks.

795 Terms and conditions previously imposed on a DEL issued under the ISAD IO for a COVID-19 drug will
796 continue to apply under the *Regulations* as necessary.

797 Every person who holds a DEL must conduct the licensable activities in accordance with the licence, and any
798 terms and conditions imposed on it.

799 DEL holders that do not comply with the terms and conditions imposed on their licence will be subject to
800 compliance and enforcement action for the contravention of s. 21.7 of the Food and Drugs Act. Such actions
801 will align with the legislative framework and the principles outlined in our [compliance and enforcement](#)
802 [policy for health products](#) (POL-0001).

803 DEL suspension and cancellation



This section is applicable after ISAD IO expires on September 16, 2021. For information on how to submit a DEL application under the ISAD IO, please refer to the [drug establishment licences section of the ISAD IO guidance document](#).

804 Health Canada can suspend or cancel a DEL in full or in part for any of the reasons set out in sections
805 C.01A.016 to C.01A.017.1 in order to prevent a risk to the health and safety of the consumer in relation to a
806 COVID-19 drug. When a DEL is suspended or cancelled, the DEL holder must cease all suspended/cancelled
807 activities.

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

- 809 • [Guidance on drug establishment licences \(GUI-0002\)](#)

810 DEL performance standards



This section is applicable after ISAD IO expires on September 16, 2021. For information on how to submit a DEL application under the ISAD IO, please refer to the [drug establishment licences section of the ISAD IO guidance document](#).

811 DEL applications related to COVID-19 drugs will be prioritized and reviewed based on the:

- 812 • public health need
- 813 • materials submitted in the application
- 814 • volume of information to be assessed

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

- 816 • [Management of applications and performance for drug establishment licences \(GUI-0127\)](#)

817 Drug establishment licence fees

818 DEL fees will be remitted for applications submitted under the ISAD IO until September 16, 2021. After that
819 time, drug establishment licence fees will apply to the review of DEL applications submitted for a COVID-19
820 drug.

821 Please consult the guidance document on:

- 822 • [Fees for the review of human and veterinary drug establishment licence applications](#)

823

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

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

828 The DEL fee is calculated using the following components:

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

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

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

837 Good manufacturing practices



This section is applicable after ISAD IO expires on September 16, 2021. Please refer to the [Good manufacturing practices section of the ISAD IO guidance document](#).

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

- 839 • [Good manufacturing practices guide for drug products \(GUI-0001\)](#)

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

- 841 • [How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#)

842 If you're unable to obtain documents outlined in GUI-0080 due to the pandemic, please email us
843 at foreign.site-etraner@hc-sc.gc.ca. You should contact us before you send in your DEL application. Be sure
844 to include "COVID-19" in your subject line.

845 If you're unable to host a GMP drug inspection at your facility due to the pandemic, please email us
846 at GMP_Questions_BPF@hc-sc.gc.ca. We may consider operational relief and flexibilities to inspection
847 timelines as set under the current fee regime on a case-by-case basis. To monitor compliance, GMP
848 inspections will be conducted using a risk-based approach for licensable activities.

849 Extension of certain flexible measures for DEL and GMP compliance, as communicated in DEL bulletins, will
850 continue until further notice.

851 For more information about good manufacturing practices and COVID-19, see our page on [good
852 manufacturing practices and COVID-19](#).

853 Finished product testing

854 DEL holders must meet all product release requirements as outlined in the *Food and Drug Regulations*.

855 Finished product testing requirements in C.02.019 of the Regulations no longer apply to a distributor or
856 importer of a schedule D (biologic) COVID-19 drug if it's subject to a written request under the lot release
857 program (C.04.015).

858 Licence holders must comply with testing requirements set out in Division 2 of the *Regulations*. If you are
859 unable to meet these requirements due to the pandemic, contact us at GMP_Questions_BPF@hc-sc.gc.ca.
860 For more information on the lot release program requirements, refer to the:
861 • [Guidance for sponsors on the lot release program for schedule D \(biologic\) drugs](#)
862 • [Good manufacturing practices guide for drug products \(GUI-0001\)](#)

Intellectual property

Intellectual property

As a consequence of the review, authorization and oversight of COVID-19 drugs under the *Regulations*, manufacturers may benefit from intellectual property protections that are available in respect of a submission that results in an NOC. These protections include:

- data protection under section C.08.004.1 of the *Food and Drug Regulations*
- protection under the *Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations)*
- protection under the *Certificate of Supplementary Protection* regime

Data protection

The amendments contain one interpretive provision clarifying the impact of an authorization under the ISAD IO on data protection eligibility, but do not alter these protections.

Subsection C.08.004.1(1) of the *Food and Drug Regulations* provides that an “innovative drug” is one that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient. The amendments introduce language to explain that, for the purpose of the definition of “innovative drug” in subsection C.08.004.1(1) of the *Regulations*, a medicinal ingredient is not considered to be approved in a drug by reason of an authorization under the ISAD IO. This provision is not intended to change the scope or current interpretation of “approved” under the existing definition. Rather, it explains the intended application of that definition where a medicinal ingredient was used in a drug authorized under the ISAD IO.

The interpretation of “innovative drug” ensures that an authorization granted under the ISAD IO does not preclude data protection eligibility under the *Regulations*.

Data protection will be assessed in accordance with the existing process, as described in the [Guidance document on data protection under C.08.004.1 of the Food and Drug Regulations](#).

Patented Medicines (Notice of Compliance) Regulations

The amendments to the *Food and Drug Regulations* do not disturb the operation of the *Patent Act* or the *Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations)*. Patent lists may be added to the Patent Register at the time the submission or supplement is approved under the *Regulations*, provided the requirements of the *PM(NOC) Regulations* are met, including that a patent list be submitted in accordance with subsections 4(5) and 4(6), as applicable.

For a rolling submission, data or information provided after the filing date will not change the filing date of the submission. As with other submissions, patent lists provided after the filing date of the submission must meet the timing requirements of subsection 4(6) of the *PM(NOC) Regulations* to be considered for inclusion on the Patent Register.

The *PM(NOC) Regulations* will continue to be administered in accordance with existing processes. These are described in the:

- [Guidance document on Patented Medicines \(Notice of Compliance\) Regulations](#)

Certificate of supplementary protection

The amendments to the *Food and Drug Regulations* do not disturb the operation of the *Patent Act* or the *Certificate of Supplementary Protection Regulations (CSP Regulations)*. Therefore, a certificate of

902 supplementary protection may be issued in respect of a patent to a drug approved under the *Regulations*,
903 provided the requirements of the *CSP Regulations* and *Patent Act* have been met.

904 Though not introduced for this purpose, the provisions contained in these amendments allow an earlier filing
905 of an NDS, making it easier for manufacturers to file their NDS within the time period specified in paragraph
906 106(1)(f) under the *Patent Act* and 6(1)(b) established under the *CSP Regulations* to be eligible to obtain a
907 certificate of supplementary protection.

908 The certificate of supplementary protection scheme will continue to be administered in accordance with
909 existing laws and the process described in the [Guidance document on certificates of supplementary](#)
910 [protection](#). Section 2.2.2 of this document outlines Health Canada’s continued interpretation of an
911 “application for a marketing approval equivalent to an authorization for sale” for the purpose of the timely
912 submission requirements in paragraph 106(1)(f) of the *Patent Act* and paragraph 6(1)(b) of the *CSP*
913 *Regulations*. Such an application is considered equivalent to an NDS rather than equivalent to an ISAD IO
914 application. Similarly, the definition of “authorization for sale” explicitly excludes an authorization issued
915 pursuant to an interim order made under section 30.1 of the *Food and Drugs Act*. Therefore, if a
916 manufacturer submits an application in a prescribed foreign country that’s equivalent to an NDS, in order to
917 meet the timely submission requirements, the manufacturer must file an application for the authorization for
918 sale of the same drug with the Minister before the end of 1 year from the date of the foreign application.

Post-market requirements

The only amendment related to post-market regulation is the Minister's new (continued) authority to impose terms and conditions for a designated COVID-19 drug (C.01.014.21).

To ensure the safe and effective use of a product, additional post-market requirements may be imposed as a term or condition on the authorization. An example of a post-market term or condition on the authorization is the submission and implementation of a risk management plan ((RMP) and/or elements thereof). Otherwise, existing post-market regulations remain the same.

For more information on the scope of RMPs, consult the:

- [Guidance document on the submission of risk management plans and follow-up commitments](#)

Pharmacovigilance reporting requirements

Adverse reaction reporting

Adverse reactions must be reported to the [Canada Vigilance Program](#).

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

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

However, adverse reactions associated with COVID-19 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 COVID-19 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](#)

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](#)

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.

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

- 956 • [Preparing and submitting summary reports for marketed drugs and natural health products](#)

957 Additional good pharmacovigilance practices

958 For additional information on good pharmacovigilance requirements, consult the:

- 959 • [Good pharmacovigilance practices \(GVP\) guidelines \(GUI-0102\)](#)

960 Foreign actions reporting

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

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

- 965 • [Notifying Health Canada of foreign actions](#)

966 Other post-market requirements

967 Record keeping

968 Under sections C.01.020(1) of the *Regulations*, manufacturers of a COVID-19 drug must maintain records and
969 case reports as they relate to sections C.01.017 to C.01.019.

970 Under section C.02.020, DEL holders must maintain records for each COVID-19 drug that they fabricate,
971 package/label, distribute or import.

972 For more information, consult the:

- 973 • [Good manufacturing practices guide for drug products \(GUI-0001\)](#)

974 Shortages or discontinuation of sale

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

978 For details on shortages, see the [Interim order respecting the prevention and alleviation of shortages of
979 drugs in relation to COVID-19](#).

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

982 Compliance and enforcement

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

987 For further guidance, see the [list of guidance documents](#).

988

Pre-positioning of COVID-19 drugs

A promising COVID-19 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 COVID-19 drug into Canada if the Chief Public Health Officer (CPHO) of the Public Health Agency of Canada has notified the Minister identifying the COVID-19 drug that is to be pre-positioned.

To be eligible to import a COVID-19 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 importer of the drug to be pre-positioned has a valid Canadian drug establishment licence.
- The CPHO has provided the Minister with information required under C.08.009.03.
- The DEL holding importer has provided the Minister with information required under C.08.009.03(2), including
- Evidence demonstrating the foreign building(s) for which the COVID-19 drug is fabricated, packaged, labelled or tested meets the applicable requirements of the provisions of Divisions 2 to 4 of Part C of the *Regulations*.

Importation and distribution of a pre-positioned drug

Following the review of the information provided by the CPHO and importer, the Minister of Health issues a letter to the CPHO indicating whether 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 person importing a COVID-19 drug for pre-positioning must have a drug establishment licence (DEL), but does not require the activity of importation to be licensed on the DEL. However, the DEL holder responsible for importing the pre-positioned COVID-19 drug will be subject to certain sections in Part C, Divisions 2 to 4 of the *Regulations* concerning storage, distribution, quality control and rapid recall.

A pre-positioned COVID-19 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 has been 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 COVID-19 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 COVID-19 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 \(GUI-0080\)](#)

- 1028 For more information about good manufacturing practices and COVID-19, visit [Good manufacturing practices](#)
1029 [and COVID-19](#).
- 1030 Transition of pre-positioned drugs from the ISAD IO to the *Regulations*
- 1031 After ISAD IO expires, COVID-19 drugs that met the requirements under sections 27 to 30 of the ISAD IO are
1032 deemed to have been pre-positioned under the *Regulations*.
- 1033 Any information provided under sections 27 to 30 of the ISAD IO before it expires but has not been deemed
1034 to have met all requirements to pre-position will continue to be reviewed under the *Regulations*.

Submission scenarios, reference documents and key contacts

Submission scenarios

Please refer to Table 1 in this guidance document for a summary of submission scenarios.

Scenario 1

COVID-19 drug is authorized under ISAD IO (authorization was not suspended or revoked) and a submission is subsequently filed under the *Food and Drug Regulations* for that drug

Manufacturers would file an NDS under Division 8 of the *Regulations*. The submission must include the same data as was included in the ISAD IO application, along with any necessary updates. This can include new evidence that was not available when the application was filed under the ISAD IO. Manufacturers would outline in a summary the changes to the application compared to the ISAD IO filing.

To maintain the ability to sell the COVID-19 drug authorized under ISAD IO, the NDS must be filed:

- within 90 days following coming into force of the amendments, if the drug was authorized under the ISAD IO before the amendments came into force or
- 90 days following issuance of an authorization under the ISAD IO, if the drug was authorized after the amendments came into force

Manufacturers can continue selling the COVID-19 drug under the ISAD IO authorization until the NDS is approved, rejected or withdrawn. This is the case even after the ISAD IO expires.

Many of the regulatory provisions found in the ISAD IO are available when filing a submission under the *Regulations*. These are further described in:

- [Rolling submissions](#)
- [Clinical information and requirements](#)
- [Non-clinical information and requirements](#)
- [Quality \(chemistry and manufacturing\) information and requirements](#)
- [Product labels](#)
- [Labelling](#)

An NDS filed under the amended *Regulations* would support the issuance of the notice of compliance (NOC), along with any applicable terms and conditions. Further details are provided in the:

- [Issuance of a notice of compliance for a COVID-19 drug](#)
- [Terms and conditions on a drug identification number relying on modified requirements in C.08.002\(2.1\)](#)

While the NDS is under review, the DIN that was assigned under ISAD IO remains assigned to the drug authorized under ISAD IO. This continues to ensure the operation of all regulatory obligations associated with the drug. Sponsors are invited to discuss with Health Canada their plans for packaging and labelling and reuse of a DIN.

1069 Scenario 2

1070 An NDS is filed for a COVID-19 drug for which an application was never filed under ISAD IO

1071 Manufacturers of new COVID-19 drugs who did not file an application under ISAD IO may file an NDS seeking
 1072 approval of the drug on the basis of the modified requirements under the amended NDS pathway in the
 1073 Regulations.

1074 Many of the regulatory provisions found in ISAD IO are available when filing a submission under
 1075 the *Regulations*. These are further described in:

1076 • [Rolling submissions](#)
 1077 • [Clinical information and requirements](#)
 1078 • [Non-clinical information and requirements](#)
 1079 • [Quality \(chemistry and manufacturing\) information and requirements](#)
 1080 • [Product labels](#)
 1081 • [Labelling](#)

1082 An NDS filed under the amended *Regulations* would support the issuance of the NOC, along with any
 1083 applicable terms and conditions. Further details are provided in the:

1084 • [Issuance of a notice of compliance for a COVID-19 drug](#)
 1085 • [Terms and conditions on a drug identification number relying on modified requirements in C.08.002\(2.1\)](#)
 1086 [C.08.002\(2.1\)](#)

1087 The manufacturer will have to wait to receive an NOC before marketing its drug.

1088 Scenario 3

1089 A submission seeking approval for a subsequent entry drug on the basis of a direct or indirect
 1090 comparison to a COVID-19 drug (that is, a comparative submission)

1091 Subsequent entry submissions seeking approval for a COVID-19 drug on the basis of a direct or indirect
 1092 comparison to another COVID-19 drug are not eligible to benefit from the amended *Regulations*. These
 1093 submissions will be filed as an ANDS or a comparative NDS.

1094 Scenario 4

1095 Submitting an amendment to an ISAD IO authorization while an NDS has been filed under
 1096 the *Regulations* and is under review

1097 Manufacturers can file an amendment to their ISAD IO authorization while an NDS is under review during the
 1098 period of June 16 to September 16, 2021.

1099 Manufacturers are encouraged to file relevant information under the ISAD IO and under the *Food and Drug*
 1100 *Regulations*. During the June to September transition period, sponsors should discuss their application plan
 1101 with Health Canada to determine if a concurrent amendment filing under ISAD IO is merited. In this case,
 1102 both submissions must be filed separately to Health Canada. Health Canada will process amendments to the
 1103 ISAD IO authorization in parallel to an NDS.

1104 Review decisions for ISAD IO amendments that are not completed by September 16, 2021, will require
 1105 manufacturers to re-file under the *Regulations* for further consideration.

1106

1107 Many of the regulatory provisions found in ISAD IO are available when filing a submission under
 1108 the *Regulations*. These are further described in:

- 1109 • [Rolling submissions](#)
- 1110 • [Clinical information and requirements](#)
- 1111 • [Non-clinical information and requirements](#)
- 1112 • [Quality \(chemistry and manufacturing\) information and requirements](#)
- 1113 • [Product labels](#)
- 1114 • [Labelling](#)

1115 An NDS filed under the amended *Regulations* would support the issuance of the notice of compliance (NOC),
 1116 along with any applicable terms and conditions. Further details are provided in the:

- 1117 • [Issuance of a notice of compliance for a COVID-19 drug](#)
- 1118 • [Terms and conditions on a drug identification number relying on modified requirements in](#)
 1119 [C.08.002\(2.1\)](#)

1120 While the NDS is under review, the DIN that was assigned under the ISAD IO remains assigned to the drug
 1121 authorized under the ISAD IO. This continues to ensure the operation of all regulatory obligations associated
 1122 with the drug. Sponsors are invited to discuss with Health Canada their plans for packaging and labelling and
 1123 reuse of a DIN.

1124 Upon issuance of an NOC, the ISAD IO authorization will no longer be valid. Any post-NOC changes would be
 1125 filed as an SNDS. Please refer to the:

- 1126 • [Guidance document: Post-notice of compliance \(NOC\) changes: Framework document](#)
 1127 [\(pharmaceutical, biologic and radiopharmaceutical drugs for human use only\)](#)

1128 **Scenario 5**

1129 **Submissions for COVID-19 vaccines against variants**

1130 Sponsors are encouraged to meet with Health Canada to discuss their development and regulatory filing
 1131 plans for variant COVID-19 vaccines. This includes sponsors who are:

- 1132 • modifying authorized COVID-19 vaccines to respond to variants
- 1133 • developing new vaccine platforms against COVID-19 variants

1134 The submission type for a variant COVID-19 vaccine will depend on the specific vaccine, taking into account:

- 1135 • the platform used
- 1136 • whether the proposed variant vaccine is a version of an already authorized COVID-19 vaccine
- 1137 • the extent of change from the previously authorized version

1138 The emergence of SARS-CoV-2 variants is an evolving field. Please refer to the:

- 1139 • [Guidance for market authorization requirements for COVID-19 vaccines: Requirements for vaccines](#)
 1140 [to address SARS-CoV-2 variants](#)

1141 This guidance will be updated as we gain experience with variant COVID-19 vaccines.

1142

1143 Reference documents

1144 Authorization application guidance documents and webpages:

- 1145 • [Management of drug submissions and applications](#)
- 1146 • [Regulatory enrolment process](#)
- 1147 • [Common electronic submissions gateway](#)
- 1148 • [Management of regulatory submissions for veterinary drugs](#)
- 1149 • [Filing submissions electronically](#)

1150 General guidance documents:

- 1151 • [Information and submission requirements for biosimilar biologic drugs](#)
- 1152 • [Drug submissions relying on third-party data \(literature and market experience\)](#)
- 1153 • [The use of foreign reviews by Health Canada](#)
- 1154 • [Determining prescription status for human and veterinary drugs](#)
- 1155 • [Questions and answers: Prescription drug list](#)
- 1156 • [Regulatory requirements for drug identification numbers \(DINs\)](#)
- 1157 • [Drug establishment licences and COVID-19](#)
- 1158 • [Good manufacturing practices and COVID-19](#)
- 1159 • [Compliance and enforcement policy for health products \(POL-0001\)](#)
- 1160 • [Drug and medical device databases](#)
- 1161 • [Regulatory roadmap for biologic \(Schedule D\) drugs in Canada](#)

1162 Safety and efficacy guidance documents:

- 1163 • [Non-clinical laboratory study data supporting drug product applications and submissions: Adherence to good laboratory practice](#)
- 1164 • [Preparation of comparative bioavailability information for drug submissions in the CTD format](#)
- 1165 • [Cochrane Handbook for Systematic Reviews of Interventions](#)
- 1166 • [Preferred reporting items for systematic reviews and meta-analyses \(PRISMA\) statement](#)

1168 Quality guidance documents:

- 1169 • [Preparation of quality information for drug submissions in the CTD format: Biotechnological/biological \(biotech\) products](#)
- 1170 • [Preparation of quality information for drug submissions in the CTD format: Conventional biotherapeutic products](#)
- 1171 • [Preparation of quality information for drug submissions in the CTD format: Conventional biotherapeutic products](#)
- 1172 • [Preparation of quality information for drug submissions in the CTD format: Conventional biotherapeutic products](#)
- 1173 • [Quality \(chemistry and manufacturing\) guidance: New drug submissions \(NDSs\) and abbreviated new drug submissions \(ANDSs\)](#)
- 1174 • [Quality \(chemistry and manufacturing\) guidance: New drug submissions \(NDSs\) and abbreviated new drug submissions \(ANDSs\)](#)

1175 Labelling guidance documents:

- 1176 • [Review of drug brand names: Guidance document for industry](#)
- 1177 • [Frequently asked questions review of drug brand names](#)
- 1178 • [Good label and package practices guide for prescription drugs \(GLPPG\)](#)
- 1179 • [Questions and answers: Plain language labelling regulations for prescription drugs](#)
- 1180 • [Labelling of special containers policy](#)
- 1181 • [Labelling of pharmaceutical drugs for human use](#)
- 1182 • [Product monograph guidance documents and notices](#)

1183

- 1184 COVID-19 vaccines guidance documents:
- 1185 • [Guidance for market authorization requirements for COVID-19 vaccines: Requirements for vaccines](#)
 - 1186 [to address SARS-CoV-2 variants](#)
 - 1187 • [ACCESS Consortium: Points to consider for strain changes in authorized COVID-19 vaccines in an](#)
 - 1188 [ongoing SARS-CoV2 pandemic](#)
- 1189 Establishment licensing guidance documents:
- 1190 • [Guidance on drug establishment licences and drug establishment licensing fees \(GUI-0002\)](#)
 - 1191 • [Management of applications and performance for drug establishment licences \(GUI-0127\)](#)
- 1192 Good manufacturing practices (GMP) guidance documents:
- 1193 • [Good manufacturing practices guide for drug products \(GUI-0001\)](#)
 - 1194 • [Annex 2 to the current edition of the good manufacturing practices guidelines schedule D drugs](#)
 - 1195 [\(biological drugs\) \(GUI-0027\)](#)
 - 1196 • [How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#)
 - 1197 • [Good manufacturing practices \(GMP\) for Active Pharmaceutical Ingredients \(APIs\) \(GUI-0104\)](#)
- 1198 Good laboratory practices (GLP) guidance document:
- 1199 • [Good laboratory practices \(GLP\) guidelines \(Dir-9801\)](#)
- 1200 Post-market vigilance guidance documents:
- 1201 • [Reporting adverse reactions to marketed health products](#) (overview)
 - 1202 • [Report an adverse reaction to a drug: industry](#)
 - 1203 • [Preparing and submitting summary reports for marketed drugs and natural health products](#)
 - 1204 • [Good pharmacovigilance practices \(GVP\) guidelines \(GUI-0102\)](#)
 - 1205 • [Notifying Health Canada of foreign actions: Guidance document for industry](#)
 - 1206 • [Amendments to the *Food and Drugs Act*: Guide to new authorities \(power to require and disclose](#)
 - 1207 [information, power to order a label change and power to order a recall\)](#)
 - 1208 • [Format and content for post-market drug benefit-risk assessment in Canada](#)
 - 1209 • [Submission of risk management plans and follow-up commitments](#)
 - 1210 • [Guide to reporting drug shortages and discontinuations](#)
 - 1211 • [Recall policy for health products \(POL-0016\)](#)
 - 1212 • [Drug and natural health products recall guide \(GUI-0039\)](#)
- 1213 Post-notice of compliance (NOC) changes guidance documents:
- 1214 • [Framework document \(pharmaceutical, biologic and radiopharmaceutical drugs for human use only\)](#)
 - 1215 • [Quality document](#)
 - 1216 • [Safety and efficacy document \(for pharmaceutical, biologic and radiopharmaceutical drugs for](#)
 - 1217 [human use only\)](#)
- 1218 Advertising guidance documents:
- 1219 • [Marketing of drugs and medical devices](#)
- 1220

- 1221 Disinfectants guidance documents and monograph:
- 1222 • [Management of disinfectant drug applications](#)
 - 1223 • [Safety and efficacy requirements for surface disinfectant drugs](#)
 - 1224 • [Disinfectant drugs](#)
 - 1225 • [Applying for a drug identification number \(DIN\) for a disinfectant drug during the COVID-19](#)
 - 1226 [pandemic](#)
 - 1227 • [Hard-surface disinfectants monograph](#)
- 1228 Non-prescription pharmaceuticals and hand sanitizer (antiseptic skin cleansers) guidance documents and
- 1229 monographs:
- 1230 • [Human-use antiseptic drugs](#)
 - 1231 • [Management of drug submissions and applications](#)
 - 1232 • [Compendium of monographs](#)
- 1233 Intellectual property guidance documents:
- 1234 • [Patented Medicines \(Notice of Compliance\) Regulations](#)
 - 1235 • [Data protection under C.08.004.1 of the Food and Drug Regulations](#)
 - 1236 • [Certificates of supplementary protection](#)
- 1237

1238 Key contacts

1239 To help ensure that we prioritize your inquiry, please include "COVID-19 drug" in the subject line of your
1240 email.

1241 Biologic and Radiopharmaceutical Drugs Directorate

1242 Office of Regulatory Affairs

1243 Email: brdd.ora@hc-sc.gc.ca

1244 Pharmaceutical Drugs Directorate

1245 Regulatory Project Management Division

1246 Email: rpmd-dgpr@hc-sc.gc.ca

1247 Veterinary Drugs Directorate

1248 Submission and Knowledge Management Division

1249 Email: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca

1250 Natural and Non-prescription Health Products Directorate

1251 General Enquiries

1252 Email: nnhpd-dpsnso@hc-sc.gc.ca

1253 For intellectual property-related inquiries:

1254 Office of Patented Medicines and Liaison

1255 Email: opml-bmbl@hc-sc.gc.ca

1256 For application format-related inquiries:

1257 Office of Submissions and Intellectual Property

1258 Email: ereview@hc-sc.gc.ca

1259 For adverse reaction reporting-related inquiries:

1260 [Canada Vigilance Program \(CVP\)](#)

1261 For inquiries about good manufacturing practices (GMP) compliance requirements:

1262 Email: GMP_Questions_BPF@hc-sc.gc.ca

1263 For drug establishment licensing (DEL)-related inquiries:

1264 Email: del.questions-leppp@hc-sc.gc.ca