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# Guidance for market authorization requirements for COVID-19 vaccines



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## Foreword

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

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

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

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

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# Overview

## Background

COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2. This new virus and disease were unknown before the outbreak began in December 2019 and have since spread around the world.

COVID-19 has been known to cause respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, COVID-19 infection can cause pneumonia, severe acute respiratory distress, kidney failure and death. Older people and those with underlying medical problems, such as high blood pressure, obesity, heart problems or diabetes, are more likely to develop serious illness.

The availability of safe, effective and high-quality vaccines will offer a potential means to reduce the spread and severity of disease and address its social and economic consequences.

## About this guidance document

This document provides guidance on developing the evidence and documentation needed to obtain an authorization and licensing for importing or selling a COVID-19 vaccine in Canada. This guidance should be read along with the guidance document concerning [amendments to the Food and Drug Regulations for drugs for use in relation to COVID-19](#), which explains recent changes to the regulatory process for new COVID-19 drugs.

## About market authorizations for a COVID-19 vaccine

Health Canada is committed to helping Canadians protect and improve their health by facilitating access to COVID-19 vaccines that are safe, effective and of high quality. We have introduced amendments to the *Food and Drug Regulations* to expedite the authorization of COVID-19 drugs, including vaccines, while protecting the health and safety of Canadians.

Vaccine manufacturers seeking to obtain market authorization should consult with us early on and throughout the development process. We are committed to prioritizing the review of any submission seeking authorization of a COVID-19 vaccine.

Health Canada will grant authorizations only if we determine that the benefits of the vaccine outweigh its potential risks. We will base our decision on the evidence provided on the vaccine's safety, quality and efficacy. For vaccines relying on the modified requirements in C.08.002 (2.1) of the *Food and Drug Regulations*, the risk-benefit analysis weighs the uncertainties about a potential vaccine against the public health need for a vaccine at the time of the decision.

Modified requirements for COVID-19 drugs make it possible for initial authorization, based on early data, while the manufacturer continues working on developing a vaccine. We will use terms and conditions to manage uncertainties or risk mitigation measures related to the vaccine in the context of the public health.

The requirements described in this guidance are a minimum acceptable standard. Health Canada will consider alternate proposals for evidence standards and a rationale for using these standards. As we learn more about the virus and the effectiveness of new vaccines and treatments, we will adjust the evidence requirements as required.

As with all drugs, Health Canada will assess and monitor the quality, safety and effectiveness of all authorized COVID-19 vaccines. We will impose terms and conditions when necessary and take immediate action, if required, to protect the health and safety of Canadians. This action may include suspending or cancelling authorizations or establishment licences.

## Guidance for implementation

Industry sponsors have been seeking guidance from regulatory authorities on the requirements for developing a COVID-19 vaccine. Guidance has been discussed in pre-submission meetings with Health Canada and other regulators, and through publications following workshops under the International Coalition of Medicines Regulatory Authorities (ICMRA).

Guidance documents have also been published by:

- the Access Consortium
- the World Health Organization (WHO)
- the European Medicines Agency (EMA)
- the US Food and Drug Administration (US FDA)
- Japan's Pharmaceuticals and Medical Devices Agency (PMDA)

We continue to work with international regulatory authorities to align requirements for COVID-19 vaccines, where appropriate.

Health Canada's guidance is aligned with these international regulators.

## Rolling submissions, non-clinical and clinical requirements

### Standard for accepting a rolling submission

Modified requirements for COVID-19 drugs allow for the filing of rolling submissions (section C.08.002(2.3) of Canada's *Food and Drug Regulations*). The ability to review data from early development while later-stage clinical trials are taking place helps to expedite the regulatory review process.

Before filing a submission for a rolling review, sponsors of clinical trials are expected to have gathered a certain level of evidence on the safety, quality and efficacy of their vaccine. We advise sponsors to consult with us before filing an application.

To file an application for a rolling review, sponsors should have, at a minimum:

- non-clinical and clinical phase 2 data that demonstrate promising evidence of safety and efficacy
- confirmation that phase 3 trials have started and there are enough people enrolled to provide evidence of safety and efficacy within a reasonable amount of time (expected to be within 6 months from initial filing)
- evidence that manufacturing is in compliance with good manufacturing practices (GMP) and that product quality and consistency are well controlled

Sponsors must also file a plan giving the anticipated timelines for submitting the various components of the application. A plan must be included in the initial filing.

For details on plan requirements, see our guidance document on [amendments to the Food and Drug Regulations for drugs for use in relation to COVID-19](#).

### Non-clinical requirements for authorization

Some non-clinical data requirements and the methods used for non-clinical testing may be specific to the type of vaccine being developed. However, certain non-clinical data will be required for all vaccines.

For the development of a COVID-19 vaccine, the non-clinical data package must include:

- studies that assess the toxicology of the vaccine
- proof of concept, including antibody and cell mediated immune responses and protection
- assessment of the theoretical risk of vaccine-associated enhanced respiratory disease (VAERD)

### Assessment of toxicity

The development and authorization of COVID-19 vaccines must be supported by toxicology studies in relevant animal models. Key animal studies need to be conducted in compliance with the international standards of good laboratory practices. These studies look at the general toxicity, local tolerance and other relevant toxicity endpoints.

If the vaccine is to be used in pregnant women, developmental and reproductive toxicity studies must be conducted to better understand the risks.

### Proof of concept assessment

We require non-clinical tests or studies that characterize the ability of the vaccine to elicit a neutralizing immune response against the SARS-CoV-2 virus. These studies should be performed before proceeding to first-in-human clinical trials. In vivo studies in relevant animal models should evaluate the vaccine's ability to elicit neutralizing immune responses using the same dosing regimen and formulation intended for humans (for instance, single-dose or repeat-dose, adjuvanted).

When demonstrating immune responsiveness, consideration should be given to the humoral and cellular immune responses. Non-clinical data should also demonstrate the capacity of the vaccine to protect from SARS-CoV-2 using an appropriate animal challenge model.

### Vaccine-associated enhanced respiratory disease (VAERD)

Vaccines developed against some respiratory viruses, including other corona viruses, have been associated with VAERD. This occurs when people who are vaccinated and then exposed to the virus develop a worse form of the disease.

At the time of this guidance, the potential for vaccines against SARS-CoV-2 to induce VAERD is theoretical. However, it will be important for the non-clinical vaccine development program to address this theoretical risk. Viral challenge studies intended to demonstrate the capacity of the vaccine to protect against SARS-CoV-2 can provide a suitable model for assessing VAERD. This is the case if studies also include assessments that address enhanced disease such as T-helper cell type 1 and T-helper cell type 2 responsiveness, lung histopathology and immune cell infiltrates.

## Clinical testing requirements for authorization

### Assessing safety

To assess the safety of a vaccine, Health Canada requires:

- an adequate number of vaccine recipients
- monitoring for a sufficiently long time

This requirement is needed to detect common and expected adverse reactions, as well as events that are less common but potentially more severe.

In line with the pre-authorization safety data requirements for preventive vaccines for infectious diseases, the safety database for a COVID-19 vaccine should have at least 3,000 study participants. They should be vaccinated with the dosing regimen intended for authorization.

The data should come from phase 3 randomized placebo-controlled trials that allow for the collection of adverse events in the vaccinated (>3,000 participants) vs. the placebo (>3,000 participants) group. This enables the detection of more common adverse events, which are in the range of at least 1 in 1,000 doses given.

Common adverse reactions include:

- redness and pain at the injection site
- sore arm
- fever
- headaches
- malaise

These should be monitored closely for at least 7 days to adequately characterize the frequency of those events.

Uncommon, rare or adverse events that may take longer to manifest should also be monitored closely. The median duration of safety follow-up to support authorization should be at least 2 to 3 months after all doses in the schedule have been given. Most adverse events are expected to occur within 2 months of vaccination.

Given the previous history with vaccines for other respiratory viruses, which have resulted in enhanced disease in people who were vaccinated and subsequently exposed to the virus (VAERD), this risk should be closely monitored for SARS-CoV-2 vaccines. The stability of the immune response following vaccination should be monitored. A period of 6 months may be required to assess for the potential for VAERD, if data from earlier phase clinical trials suggest that longer-term follow up is needed prior to authorization.

Following authorization, clinical trial participants should be monitored for as long as feasible. The ideal time is at least 1 to 2 years. This length of time is needed to assess the duration of protection and the potential for enhanced disease.

Health Canada may issue terms and conditions requiring the sponsor to provide longer-term clinical follow-up and post-market safety data on adverse events of special interest, such as VAERD, following authorization.

Internationally, regulators are in agreement on the safety assessment criteria. These criteria include defining:

- adverse events of special interest for close monitoring during clinical trials
- the size of the safety databases required

We will use these criteria when reviewing data submitted during the review.

### Assessing efficacy

Health Canada requires robust evidence of the vaccine's ability to prevent COVID-19 infection from well-conducted phase 3 clinical trials in humans. Ideally, we would like to see as high an efficacy as possible. However, as the virus that causes COVID-19 is new, we don't yet know how effective vaccines will be. We consider a target threshold of at least 50% efficacy to be reasonable for COVID-19 vaccines.

Clinical trials should demonstrate that the vaccine reduces the incidence of a symptomatic SARS-CoV-2 infection by at least 50% in people who are vaccinated, compared to a control group of people who don't receive the vaccine. Enough people should be enrolled so that the trial is sufficiently powered to exclude an efficacy result below 30%. The trial must have a sufficient number of participants with severe COVID-19 infection in the control group to show that the vaccine is effective.

This efficacy estimate is expected regardless of when the data are analyzed, including any pre-specified early looks at the data while the clinical trial is under way. Health Canada may issue terms and conditions requiring the sponsor to provide additional data confirming the duration of protection or other pertinent efficacy endpoints.

Although 50% efficacy is the target threshold, vaccines that don't reach this threshold may still be considered for authorization. We will review the safety and efficacy of each vaccine on a case-by-case basis. We will also consider the availability of other vaccines and treatments, public health needs, the status of the pandemic and the epidemiology of the disease in Canada.

When comparing a potential vaccine with a COVID-19 vaccine that has already met the efficacy criteria outlined above and been approved by a stringent regulatory authority, a non-inferiority trial design may be used with a non-inferiority margin of less than 10%. This means that the vaccine may show no more than 10% lower efficacy compared to the approved vaccine (lower bound of the confidence interval around the primary relative efficacy point estimate is  $>-10\%$ ).

Critical efficacy results will be summarized in the labelling for the vaccine along with the dosing regimen and the patient populations used to demonstrate efficacy. Efficacy should be shown using the dosing regimen intended for authorization. The National Advisory Committee on Immunization (NACI) and public health officials use this information to develop vaccination programs.

# Quality, manufacturing and lot release requirements

## Product quality

COVID-19 vaccines must be manufactured under good manufacturing practices (GMP) conditions. These conditions must be in line with international requirements, which are outlined in the International Council for Harmonization [Q7A guideline](#) and applicable [Health Canada guidance](#).

We require sufficient data to demonstrate that the manufacturing process is well controlled and consistent. This involves details on the manufacturing process for both the drug substance and drug product, including information on:

- assay validation
- source materials
- virus and cell banks
- drug substance and drug product stability
- in-process control testing based on specifications developed to evaluate critical process parameters

Data should be collected in a sufficient number of batches to demonstrate process consistency.

Authorization will also require establishment of stability parameters and expiry date on the drug product in its final container and formulation.

## Establishment licensing and good manufacturing practices

To bring a COVID-19 vaccine to market in Canada, a company must have a Drug Establishment Licence (DEL) to fabricate, package/label, test, import, distribute or wholesale a health product. A DEL is issued under the *Food and Drug Regulations*.

A company without such a licence must apply for one.

During the DEL application review process, a company must demonstrate compliance with GMP. Depending on several criteria, including where the building is located, a company can demonstrate GMP compliance through:

- a Health Canada on-site inspection
- a certificate of GMP compliance issued by a partner with whom Health Canada has a mutual recognition agreement
- an inspection report from a regulatory authority, qualified authority, the WHO or, in some cases, a corporate/consultant auditor

Evidence requirements to support GMP compliance of foreign buildings is included in the guidance [how to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#).

If you're unable to obtain documents outlined in GUI-0080 due to the pandemic, please email us at [hc.foreign.site-etranger.sc@canada.ca](mailto:hc.foreign.site-etranger.sc@canada.ca). You should contact us before you send in your DEL application. Be sure to include "COVID-19" in your subject line.

Licensing decisions are based on the materials submitted in the application. Timelines for the expedited review are determined on a case-by-case basis and will consider the necessity of the drug in addressing urgent COVID-19-related health needs.

To reduce burden and duplication, finished product testing requirements in section C.02.019 do not apply to importers and distributors of a COVID-19 drug that is subject to the lot release program requirements.

## Lot release

Biologic drugs in Canada are subject to lot release program requirements as outlined in section C.04.015 of Canada's *Food and Drug Regulations*. Vaccines are considered biologic drugs and are generally subject to the highest level of regulatory oversight since they're administered to healthy children and adults.

Health Canada's lot release program allows the application of a flexible, risk-based approach. This approach considers the evidence on manufacturing quality and controls as a whole, as well as testing from other international regulatory authorities. For example, Health Canada is an associate member of the European Official Medicines Control Laboratory network, which supports the sharing of testing data among its members.

Health Canada's lot release program covers both the pre- and post-market stages for biologic drugs. Each lot of a biologic drug is subject to the lot release program before sale. We base the level of regulatory oversight (testing and/or protocol review) on the degree of risk linked to the product.

# Labelling and post-market requirements

## Brand name assessment

The guidance document concerning amendments to the Food and Drug Regulations for drugs for use in relation to COVID-19 indicates that the plain language labelling requirements for mock-up labels and a brand name assessment package do not apply (C.08.002(2)(j.1) and C.08.002(2)(o)). Although not required, sponsors are invited to provide a brand name assessment should one be available.

Health Canada will assess proposed brand names for COVID-19 vaccines to determine whether a vaccine's brand name could:

- mislead, such as:
  - imply it alone is effective but fails to provide evidence to support the claim
  - exaggerate the vaccine's effectiveness
  - minimize risk
  - make a claim of superiority
- be confused with another product authorized for use in Canada (with the aim of preventing medication errors)

Sponsors should refer to the criteria outlined in section 2.2 of our [guidance document on the review of drug brand names](#) before proposing a brand name for their vaccine.

## Inner and outer product labels

Sponsors of a COVID-19 vaccine are to comply with applicable labelling requirements outlined in the *Food and Drugs Act* and parts A and C of the Regulations. For vaccines, the requirements are found in A.01.014, A.01.015, C.01.004.1(2), C.01.005 to C.01.011 and C.04.019.

Although the plain language labelling requirements for mock-up labels and a brand name assessment package don't apply to drugs (including vaccines) that are filed under the modified requirements for COVID-19 drugs, we recommend that sponsors consider applying plain language principles in their submissions, as a best practice.

Health Canada believes that labelling in both official languages is critical to the safe and effective administration of vaccines. Bilingual text should be present within the labelling information, where feasible.

For inquiries about the labelling requirements for proposed vaccines, sponsors are asked to contact the Office of Regulatory Affairs, Biologic and Radiopharmaceutical Drugs Directorate (BRDD), at [hc.brdd.ora.sc@canada.ca](mailto:hc.brdd.ora.sc@canada.ca). We will consider all concerns, proposals and/or other suggestions for meeting the labelling requirements.

## Risk management plan

Companies should submit a risk management plan (RMP) that focuses on the safety risks for a COVID-19 vaccine. For more information on RMPs, please see our [guidance document for submitting RMPs and follow-up commitments](#).

In addition, the Canadian addendum must demonstrate compatibility with Canadian regulatory requirements.

The addendum should contain the following sections:

### Safety specifications

- include special events of interest, known and potential safety risks and special populations with limited information from (or that were excluded from) clinical trials
- address monitoring strategies in marginalized, remote and indigenous communities where data is available
- include timely updates of the list of safety concerns if a safety signal is observed from post-authorization surveillance

### Pharmacovigilance plan

- consider activities in Canada during a pandemic related to collecting, collating, assessing and reporting spontaneous adverse events
- confirm expedited spontaneous reporting of adverse events (spontaneous reporting in Canada is different from other jurisdictions)
- discuss additional measures related to the detection of cases, such as:
  - fatal/life-threatening, serious unexpected, special events of interest
  - vaccination failure and errors
  - special populations
  - patients with comorbidities
  - potential interaction with other vaccines
  - concomitant treatments
- include additional post-market activities as required, such as:
  - registries
  - questionnaires
  - safety/effectiveness studies
  - timely and effective monitoring of the safety profile
- include monthly safety summary reports
- include rapid signal detection and communication of signals leading to a change in the balance of risks and benefits

### Risk minimization plan

- include the following information:
  - robust labelling with warnings and precautions
  - educational materials
  - a plan for communicating and sharing safety information internationally in a timely and effective manner

To support the Government of Canada's commitment to transparency and openness, Health Canada will provide the most up-to-date approved Canadian-specific Addendum RMPs for COVID vaccines in their entirety, in conjunction with the core RMPs, to external stakeholders upon request. As part of the authorization process, and before the information becomes available, the sponsor will have the opportunity to make representations about this transparency measure, including with respect to confidential business information and/or confidential information as covered by the vaccine purchase agreements.

# Requirements for vaccines to address SARS-CoV-2 variants

## Introduction

Variant strains of SARS-CoV-2 are emerging that may affect the level of protection provided by currently authorized COVID-19 vaccines. As a result, manufacturers are adapting authorized COVID-19 vaccines to provide protection against infection and disease caused by virus variants.

We encourage sponsors to meet with us to discuss their development and regulatory filing plans for variant COVID-19 vaccines. This includes sponsors who are adapting authorized COVID-19 vaccines against variants as well as sponsors who are developing new vaccine platforms against variants.

The emergence of SARS-CoV-2 variants is an evolving field. We will update our guidance as we gain experience with variant COVID-19 vaccines.

## Submission type

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

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

Vaccine manufacturers seeking to obtain market authorization for a variant COVID-19 vaccine should consult with us to discuss their regulatory filing plans.

## Quality, non-clinical, clinical and post-market requirements

We are collaborating with other international regulatory authorities to align the requirements for evaluating, authorizing and post-market surveillance of variant COVID-19 vaccines as much as possible.

In the pandemic context where clinically proven vaccines are broadly available, large safety and efficacy studies, similar to those required for the initial approval of a COVID-19 vaccine, may not be feasible for a variant COVID-19 vaccine.

We have collaborated with the [Access Consortium](#) to develop a guidance document to support regulatory alignment on the minimal requirements for variant COVID-19 vaccine authorization. This guidance is for variant COVID-19 vaccines that are made using the same process and by the same manufacturer as an authorized COVID-19 vaccine (the prototype vaccine).

Sponsors should refer to the [Access Consortium points to consider for strain changes in authorized COVID-19 vaccines in an ongoing SARS-CoV-2 pandemic](#) for specific guidance on the quality, non-clinical, clinical and post-market information required to support authorization of a variant COVID-19 vaccine. The Access Consortium guidance is closely aligned with international regulators, including guidance released by the European Medicines Agency (EMA) and US FDA.

An updated Risk Management Plan (RMP), including a Canadian-specific addendum, should be submitted to ensure that adverse events can be appropriately captured for both the variant and prototype vaccine versions. The safety specification, pharmacovigilance plan and risk minimization plan should be updated for both variant and prototype vaccine versions. Traceability of the brand and batch, and distinguishing suspected AEFIs with new and old formulations should be a key focus of the updated RMP.

## Labelling requirements

Sponsors should follow guidance in the relevant sections of this document on labelling. They should also indicate how the variant vaccine will be clearly distinguishable from the previously authorized vaccine.

## Review process, communications and transparency

### Review process

Decisions made about COVID-19 vaccines will follow processes established for reviews under the modified requirements for COVID-19 drugs. Health Canada will start rolling reviews to build towards a complete dossier for each vaccine. The dossier will include data to support the safety, efficacy and quality of the proposed vaccine.

In accordance with section 21.1 (3) of the *Food and Drugs Act*, we will share information on the safety and efficacy of a vaccine with the Public Health Agency of Canada and the National Advisory Committee on Immunization (NACI). This collaboration will begin as early as possible to assist public health recommendations, as described in NACI's published [guidance](#).

With the sponsor's agreement, we may also collaborate with international regulatory partners to share analyses and perspectives and supplement the Health Canada review process.

Teams of medical and scientific experts at Health Canada will carry out the vaccine reviews. These people have experience in reviewing complex data and study results on the safety, efficacy and quality of a variety of vaccines. Review activities include developing strategies for the continued accumulation of data on vaccine quality, safety and effectiveness following authorization through terms and conditions and/or pharmacovigilance activities, including post-market studies.

Collaborative review with international regulatory partners may be possible in cases where manufacturers file a rolling submission simultaneously with Health Canada and another jurisdiction with which there is a mutual collaborative agreement. While recommendations may be informed by discussions between regulatory partners during a collaborative review, authorization decisions will be based on a thorough assessment of the evidence by Health Canada. These decisions are independent of those made by international partners.

Authorization decisions will be based on the overall benefits and risks. We will also consider all of the data available, including the results that have been provided in the rolling submission and the current knowledge about the virus and disease, which will need to be continually monitored following authorization. Sources of knowledge include the scientific literature, public health and surveillance data, and collaborations with our international regulatory partners.

Vaccines are given to healthy individuals, so the tolerance for risk is much lower than that of other health products. The bar for safety is understandably higher.

### Communications and transparency

Information about vaccines under review and those that are authorized is posted on our website or provided upon request.

Our [lists for drug and health product submissions under review](#) include COVID-19 vaccines under review. Once authorized, COVID-19 vaccines will be included on our [list of authorized drugs](#) and [vaccines for COVID-19](#). We will publish a [regulatory decision summary](#) at the time of authorization. A [summary basis of decision](#) follows, giving health care system partners and the public access to data and information supporting the authorization. We will include information on drug inspection outcomes and measures in the [drug and health product inspections database](#). Detailed clinical data will be published under the Public Release of Clinical Information initiative, in accordance with Health Canada's guidance on the [public release of clinical information](#). We publish [reported side effects following COVID-19 vaccination in Canada](#) on a weekly basis. We provide the most up-to-date approved Canadian-specific Addendum RMPs for COVID-19 vaccines in their entirety, in conjunction with the core RMPs, to external stakeholders upon request.

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13. [Guidance on amendments to the Food and Drug Regulations for drugs for use in relation to COVID-19](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html) <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html>