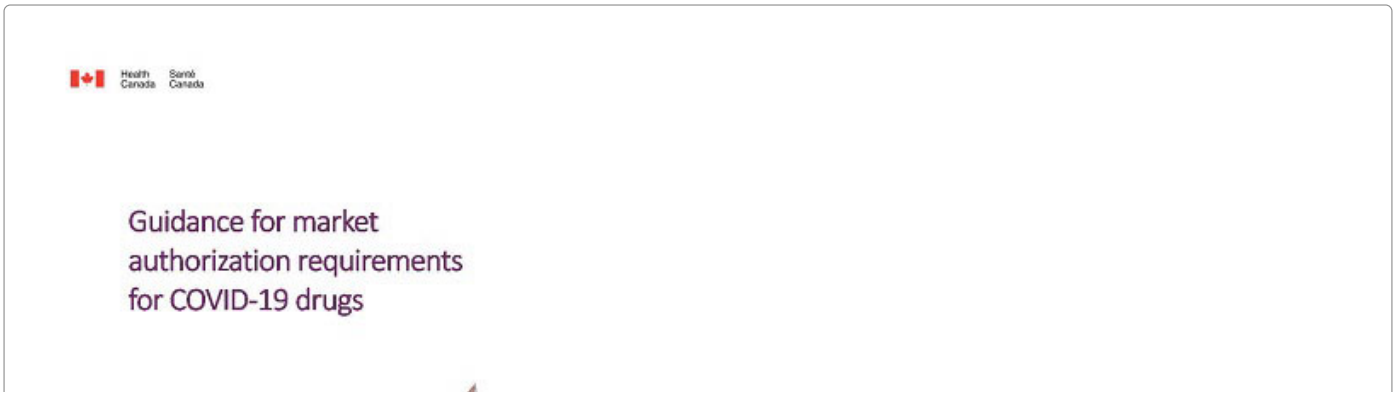
Exhibit R25-7

Guidance for market authorization requirements for COVID-19 drugs: Overview



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(PDF format, 1,418 Kb, 20 pages)

Organization: Health Canada

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On this page

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. COVID-19 can range from mild to severe disease. In more severe cases, this can include pneumonia, severe acute respiratory syndrome, multi-organ 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 drugs is a key public health measure of the COVID-19 response, providing a potential means to reduce the spread and the

severity of disease and address its social and economic consequences.

About this guidance document

This document provides guidance to drug manufacturers seeking authorization for their drug manufactured, sold, or represented for use in relation to COVID-19. 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. The guidance explains recent changes to the regulatory process for new COVID-19 drugs.

This guidance document does not apply to COVID-19 vaccines. Manufacturers seeking authorization for COVID-19 vaccines should instead refer to the guidance for market authorization requirements for COVID-19 vaccines.

For guidance on applications for the import or sale of non-prescription pharmaceuticals available over-the-counter, 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

About market authorizations for COVID-19 drugs

Health Canada is committed to helping Canadians protect and improve their health by facilitating access to COVID-19 drugs 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, while protecting the health and safety of Canadians.

Drug 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 application seeking authorization of a COVID-19 drug that shows promising evidence of efficacy and an acceptable safety profile.

Health Canada will grant authorizations only if we determine that the potential benefits of the drug outweigh its potential risks. We will base our decision on the evidence provided on the drug's safety, efficacy and quality. Benefit-risk analysis weighs the uncertainties

about a potential drug against the urgent public health need related to COVID-19 at the time of the decision.

Modified requirements for COVID-19 drugs make it possible for authorization, based on early data, while the manufacturer continues studying and gathering data on its drug. We will use terms and conditions to manage uncertainties or risk mitigation measures related to the drug in the context of 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 treatments, we will adjust the evidence requirements as required.

As with all drugs, Health Canada will assess and monitor the safety and effectiveness of all COVID-19 drugs. We will impose terms and conditions when necessary and take 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

This guidance focuses on the development of drugs with direct antiviral activity or immunomodulatory activity. However, the recommendations in this guidance may apply to development plans for drugs for COVID-19 with other mechanisms of action. The mechanism of action of the drug may affect key study design elements (for example, population, efficacy endpoints, safety assessments, duration of follow-up).

Industry sponsors have been seeking guidance from regulatory authorities on the requirements for developing COVID-19 drugs. Guidance has been discussed in pre-submission meetings with Health Canada and other regulators. We continue to work with international regulatory authorities to align requirements for COVID-19 drugs, where appropriate.

Note about guidance documents in general

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 do not replace the regulations. 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.

Related links

- Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
- ICH Q7: Good manufacturing practice guide for active pharmaceutical ingredients (PDF version)
- Good manufacturing practices guide for drug products (GUI-0001): Summary
- Product monograph guidance documents and notices
- Guidance document for industry – Review of drug brand names
- Frequently asked questions – Guidance document for industry – Review of drug brand names
- Guidance document: Labelling of pharmaceutical drugs for human use
- Good label and package practices guide for prescription drugs
- Questions and answers: Plain language labelling regulations for prescription drugs

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