Rx IP - Feature Article | Rx IP - Regulatory

New Interim Order for COVID-19 drugs has wide-reaching impact, allowing Minister to unilaterally expand indication for non-COVID-19 drugs.

September 29, 2020

Nancy Pei and Alice Tseng

On September 16, 2020, Canada's Minister of Health approved an *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the Interim Order), which introduces a new pathway to expedite the authorization for importing, selling and advertising of COVID-19 drugs. Accompanying the Interim Order are a Notice, a Guidance document for Information and application requirements for drugs authorized under the Interim Order (Guidance Document) and an FAQ.

The Interim Order covers various types of drugs, including vaccines and veterinary drugs, but excludes over-the-counter drug identification number (DIN) products, Natural Health Products, veterinary health products and disinfectants/hand sanitizers. The Guidance Document says, "Although COVID-19 is understood to be primarily a human disease and the SARS-CoV-2 virus is thought to spread mainly from person-to-person, COVID-19 is a new disease and its impacts on animal health may not be fully known at this time….It is therefore important for Health Canada to be able to issue expedited authorization for the import or sale of veterinary drugs should a need for them arise as a result of COVID-19."

The Interim Order pathway introduces three mechanisms for Health Canada to expedite the availability of COVID-19 drugs in Canada. These are:

1. Authorizing a drug, including those not yet licensed in Canada or other jurisdictions, based on a modified set of application requirements (with the potential for a "rolling" submission of information as it becomes available).
2. Authorizing a drug based on certain elements being approved by a trusted foreign regulatory authority (namely, Europe's European Medicines Agency and the regulators in the U.S., Australia, Switzerland, Japan, the U.K. and Singapore). Only drugs included in *The List of Foreign Drugs* are eligible. A drug may be included on this list if it has been shown to provide benefit in the context of the COVID-19 pandemic and has received an authorization for sale in a foreign jurisdiction.
3. Expanding the indication for an already approved drug to include a COVID-19 indication based on known evidence, with or without an application from the market authorization holder. Expanded indication includes an expanded age group or population compared to the indication in the notice of compliance or Interim Order, or it can be broader. The expanded indication will be published on the List of New Drugs for Expanded Indication in Relation to the COVID-19 Pandemic. Although Health Canada intends on notifying sponsors that their indication has been expanded, Health Canada is not obligated under the Interim Order to do so.

Compared to the regular process of obtaining market authorization for new drugs pursuant to Division 8 of the *Food and Drug Regulations*, the Interim Order is more flexible regarding the information required for authorization and also permits

greater reliance on post-market surveillance to manage safety and effectiveness through terms and conditions that can be imposed on an authorization.

Details on how to submit an application for authorization are outlined in the Guidance Document. Health Canada is requesting comments on the Guidance Document by October 8, 2020.

The Interim Order is generally limited to applications from manufacturers of innovator COVID-19 drugs. However, a manufacturer of a generic or biosimilar drug may submit an application for authorization for a COVID-19 drug on the basis of a direct or indirect comparison to another drug if the manufacturer first notifies the Minister of the manufacturer's intention to submit such an application and provides information to the Minister which establishes the following:

- a notice of compliance or authorization is issued in respect of the other drug, and
- the other drug is not offered for sale in Canada or else is offered for sale in Canada but not in sufficient quantities to address the urgent public health need related to COVID-19.

Upon receipt of such information, the Minister must notify the innovator, who can make representations respecting its ability to supply the Canadian market. The Minister then makes a determination regarding the insufficient quantities issue and whether the generic or biosimilar submission shall be accepted. If the requirement for "sufficient quantities" is not met and a generic or biosimilar submission is therefore accepted, innovators should note that once an authorization for a generic or biosimilar under the Interim Order is issued, even if insufficient supply ceases to be an issue, authorization will not be revoked. The potential need to issue authorizations for generic and biosimilar products will be limited to products used to *treat* COVID-19 and not vaccines, which are considered to be unique and can only be provided by innovators.

The Interim Order also introduces a mechanism to import into Canada drugs that show promise for treating or preventing COVID-19. This mechanism (known as "pre-positioning") allows promising treatments to be placed in Canadian facilities before their authorization to allow for quicker distribution after authorization. The use of pre-positioning is restricted to promising COVID-19 drugs for which the Government of Canada has entered into a procurement contract with the manufacturer. Use of the drug cannot occur until after market authorization from Health Canada is obtained.

One advantage of proceeding under the Interim Order instead of the regular *Food and Drug Regulations* pathway is that applications are not subject to the fees that apply when an applicant seeks market authorization for a drug under the regular regime.

As for intellectual property, according to the Guidance Document, products authorized under the Interim Order will not be eligible for data protection, to list patents under the *Patented Medicines (Notice of Compliance) Regulations*(*PMNOC Regulations*), or to support an application for a Certificate of Supplementary Protection. However, such authorizations will not preclude data protection or the ability to list patents on the Patent Register for that product if approved after the Interim Order expires. Further, the *PMNOC Regulations* will not apply to generic or biosimilar applications under the Interim Order. The Interim Order has no impact on the rights under the *Patent Act*.

See our Patented Medicine Prices Review Board (PMPRB) Update here for how COVID-19 drugs authorized under the Interim Order will be treated by the PMPRB under the amended *Patented Medicines Regulations*. From a labelling perspective, depending on the data submitted to support an authorization under the Interim Order and any associated terms and conditions, applicants may be asked to include a "warning statement" such as the following:

> "HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION."

No Look-alike Sound-alike (LASA) assessment will be required.

The Interim Order, once approved by the Governor-in-Council, is only valid for a one-year term from the day it was signed by the Minister, and product authorizations issued under the Interim Order are only valid while the Interim Order is in effect. However, Health Canada is developing transition measures to avoid disruptions when the Interim Order ends.

Health Canada will maintain the following four lists on the Government of Canada website in relation to this Interim Order:

- List of Applications Received for Drugs for Use in COVID-19
- List of Drugs Authorized for Use in COVID-19
- List of New Drugs for Expanded Indication in Relation to the COVID-19 Pandemic
- List of Foreign Drugs in Relation to the COVID-19 Pandemic

In addition, Health Canada will publish summaries of the rationales for various decisions related to the Interim Order, including the decision to authorize a product and to add a product to one of the above lists. Health Canada will also make publicly available, on Health Canada's Clinical Information portal (see article here), the safety and efficacy evidence relied upon to issue a market authorization under the Interim Order.

Should you have any questions, please do not hesitate to contact a member Life Sciences Regulatory & Compliance of the group.

RELATED PEOPLE

Nancy Pei

E nppei@smartbiggar.ca
T: 416.595.2761

Alice Tseng

E atseng@smartbiggar.ca
T: 647.798.0025

RELATED SERVICES

- Life Sciences Regulatory & Compliance

RELATED INDUSTRIES

- Pharmaceutical & Biologics
- Chemical & Biotechnology