Rx IP - Regulatory

U.S. rule permitting import of drugs from Canada prompts Health Canada to release Interim Order prohibiting exports that may risk drug shortages.

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On November 27, 2020, the Minister of Health (the Minister) signed the *Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply)* (the Interim Order), which introduces measures to help alleviate/prevent shortages in Canada's drug supply additional to those introduced by two previous COVID-19-related Interim Orders: (i) *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* (March 30, 2020, which permits exceptional importation, see article here) and (ii) *Interim Order respecting the prevention and alleviation of shortages of drugs in relation to COVID-19* (October 16, 2020, see article here). Accompanying the newest Interim Order are a News Release, Explanatory Note, Backgrounder, Notice and Guidance Document.

Background

As stated in the Explanatory Note, "Drug shortages are a growing global problem with particular implications for vulnerable markets like Canada. Since 2017, approximately 10-15% of drugs have been in shortage at any given time. Canada is a small market representing 2% of global drug sales that sources 68% of its drugs internationally."

The U.S. final rule on the *Importation of Prescription Drugs*, which came into effect on November 30, 2020, creates a pathway to allow U.S. pharmacists and wholesalers to import in bulk certain prescription drugs from Canada. The Interim Order is intended to help prevent bulk importation frameworks, such as the U.S. rule, from causing or worsening a drug shortage in Canada, which would put the health of Canadians at risk. As noted in the Explanatory Note, "Comments received from industry and health interest groups to date are supportive of the government of Canada taking immediate action to address the risk of drug shortages presented by the U.S. rule."

Interim Order

Under the Interim Order, a drug establishment licence (DEL) holder is prohibited from distributing certain drugs for consumption or use outside Canada unless the DEL holder has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug. The Guidance Document provides a non-exhaustive list of factors a DEL holder is to consider in making this assessment. If a DEL holder does distribute a drug for consumption or use outside Canada, the DEL holder must create and retain a detailed record of the information that they relied on to determine that such distribution is not prohibited by the Interim Order.

The Interim Order applies to the following drugs for which a drug identification number has been assigned under the *Food and Drug Regulations* or the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*:

(a) drugs listed in Schedules I, II, III, IV or V of the *Controlled Drugs and Substances Act*;

(b) prescription drugs;

(c) drugs listed in Schedules C and D of the *Food and Drugs Act*; and

(d) drugs that may be sold without a prescription, but that are administered only under the supervision of a practitioner.

This list is not limited to drugs affected by the COVID-19 pandemic and encompasses all drugs that are eligible for U.S. bulk importation. The scope of the Interim Order does not extend to over-the-counter drugs, natural health products or drugs for veterinary use, or to drugs manufactured in Canada intended for export that meet the conditions set out in subsection 37(1) of the *Food and Drugs Act*.

Health Canada may request that a manufacturer or DEL holder provide certain information on a voluntary basis to help assess existing and potential drug shortages. If a response is not received, the Interim Order authorizes the Minister to require a manufacturer or DEL holder to provide information within their control, if the Minister has reasonable grounds to believe the conditions in subsection 4(1) of the Interim Order are met.

Pharmaceutical companies who market drugs in Canada, as well as pharmaceutical companies who license others to market their drugs in Canada, may wish to review their relevant contracts (*e.g.* with customers, other pharmaceutical companies they collaborate with) to ensure the potential export of their products is sufficiently addressed in light of this development.

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

The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.

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