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Health Canada issues Interim Order respecting drug shortages related to COVID-19.

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On October 16, 2020, the Minister of Health (the Minister) approved the *Interim Order respecting the prevention and alleviation of shortages of drugs in relation to COVID-19* (the Interim Order), which introduces new tools to address drug shortages, or the risk of drug shortages, that may be caused or exacerbated by the COVID-19 pandemic. Health Canada has also published a Notice, Explanatory Note and Guidance Document relating to the Interim Order.

Information request

The Interim Order authorizes the Minister to request information from a person that sells a drug, except for personal information in respect of a consumer of the drug, where there are reasonable grounds to believe that:

- a. there is a shortage or risk of shortage of the drug;
- b. the shortage is caused or exacerbated, directly or indirectly, by COVID-19;
- c. the shortage poses a risk of injury to human health;
- d. the information is necessary to assess the existence of a shortage or risk of shortage, the reasons for the shortage, the effects on human health of the shortage, or measures that could be taken to prevent or alleviate the shortage; and
- e. the person will not provide the information without a legal obligation to do so.

The person selling the drug can be an individual or a company and the drug can be any drug that is not a veterinary or natural health product. Requests for information will be accompanied by the reason for the request, which will be based on evidence available to the Minister. Evidence may, for example, be in the form of complaints, media reports, notifications of shortages, a quality issue requiring Health Canada to take action, a discontinuation of a product or broader supply chain issues. The Minister can only request information that is in the control of the person and cannot require a person to create new information in response to the request.

The requested information must be provided within the time limit specified by the Minister, which can be as soon as 24 hours after the request or even sooner if the Minister believes there to be a serious and imminent risk of injury to human health.

Terms and conditions

If the Minister has reasonable grounds to believe that the conditions set out in a. - c. above are met, terms and conditions may be imposed on the market authorization holder (MAH) for the drug for the purpose of preventing or alleviating a drug shortage. Examples of possible terms and conditions include identifying alternative sources for raw materials and supplies and reporting on inventory levels on a regular basis. Health Canada will notify MAHs before a term or condition is applied and will work with MAHs to develop the appropriate measures to be applied. Terms and conditions may change as the drug shortage changes and will expire at Health Canada's discretion.

This is Health Canada's fifth Interim Order relating to COVID-19. The prior Interim Orders are:

1. *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* (March 18, 2020, see article here);
2. *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* (March 30, 2020, see article here);
3. *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19* (May 23, 2020, see article here); and
4. *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (September 16, 2020, see article here).

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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