
Cynthia L. Tape
416-865-6769
ctape@litigate.com


Jordana Sanft
416-596-1083
jsanft@litigate.com

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Health Canadaâ€™s Proposed Regulations Addressing Drug and Medical Device Shortages Now Open for Public Comment

Following on Health Canada's plan to introduce new regulations aimed at addressing therapeutic product shortages as discussed previously in our Fall Regulatory Roundup, proposed amendments to the *Food and Drug Regulations* and *Medical Device Regulations* were published for public comment on December 28, 2024. The comment period closes on March 8, 2025.

The proposed amendments set out in the *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Shortages and Discontinuation of Sale of Drugs and Medical Devices)* will provide the Minister of Health with new tools and impose new obligations on market authorization holders (MAHs) and drug establishment license holders (DELHs), all intended to improve the existing framework for avoiding and managing shortages that could present a risk, or cause serious or imminent risk of injury, to public health. The proposed new obligations include maintaining mandatory shortage prevention and mitigation plans for certain drugs, holding minimum stocks of certain drugs within Canada, and reporting surges in the demand for certain drugs.

A key feature of the proposed amendments is the creation of new lists of drugs. Some of these will be incorporated by reference into the *Food and Drug Regulations*, to allow the scope of shortage regulations to be readily adapted to address changing circumstances. The proposed lists to be incorporated by reference are as follows:

- *List of Drugs for the Purpose of the Definition of "Drug" in Section C.01.014.8* (Expanded Scope List);
- *List of Drugs for the Purposes of Section C.01.014.84* (Safety Stock List);
- *List of Drugs with Extended Expiration Dates* (Extended Expiration Date List); and
- *List of Drugs for Exceptional Importation and Sale*.

The Critical and Vulnerable Drugs List is another new list that

will be maintained by Health Canada. Consultation on a draft list is underway (see Consultation on the Draft Critical and Vulnerable Drugs List). This list is intended to provide guidance to

(i) MAHs in determining whether a shortage prevention and mitigation plan will be required for a given drug; and

(ii) DELHs in determining whether demand surge reporting is mandatory.

The threshold for amending a list will depend on the list in question. Amendments would be preceded by consultations with stakeholders or affected MAHs.

For medical devices, the proposed amendments will clarify aspects of the existing device-shortage framework, including the management of current medical device lists and shortage reporting. Manufacturers and importers of certain classes of devices will also be required to maintain documented procedures for monitoring the risk of, and identifying, shortages.

For additional information about the proposed amendments, see Health Canada’s Consultation on Proposed Amendments to Regulations to Address Health Product Shortages in Canada or contact us.