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Potential changes to medical device establishment licensing under Canada's *Medical Devices Regulations*

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Health Canada is currently soliciting feedback on their proposal to amend the *Medical Devices Regulations* (Regulations), with the intention of modernizing the import and sale of medical devices. The consultation period will close on December 9, 2024.

What you need to know

- Health Canada has published a notice to inform stakeholders of its intent to amend the Regulations to:
  - remove the requirement for foreign distributors to have a medical device establishment license (MDEL) if they are selling their medical devices through Canadian distributors that already have an MDEL;
  - require all MDEL applicants and licence holders to provide a supplier list to Health Canada, identifying all persons selling into and within Canada; and
  - include explicit requirements for MDEL holders to establish, implement, and maintain standard operating procedures relating to the importation and distribution of medical devices.
- Businesses that have MDELs and/or medical device licenses (MDLs) should assess how these changes will affect their operations.
- Health Canada is soliciting feedback from industry stakeholders on their views of the regulatory proposal until December 9, 2024. Comments can be submitted by mail, or by email to prsd-questionsdspr@hc-sc.gc.ca.

Details on the proposal to amend the Regulations

On November 9, 2024, Health Canada published a notice of intent to amend the Regulations. The proposed changes aim to (1) clarify uncertainties around the importation of medical devices and (2) improve regulatory oversight of the import and sale of medical devices in the Canadian supply chain.

There are three main targeted amendments to the Regulations, discussed below.

Adopting a risk-based approach to licensing distributors outside Canada

Currently, the Regulations require any person who imports a medical device to ensure that the person from whom they import holds an MDEL. Health Canada is proposing to remove this requirement, meaning that a distributor outside of Canada will not need to have an MDEL if they are selling solely to Canadian importers that already have an MDEL.

If the proposed amendment proceeds, Canadian importers with an MDEL would no longer need to verify that their foreign distributors have their own MDEL. The amendment would not, however, alleviate the MDEL requirement for foreign distributors whose Canadian importer does not have an MDEL (for example, foreign distributors selling directly to a hospital that does not have an MDEL).

Enabling more targeted compliance and enforcement action with a requirement for supplier lists

Currently, MDEL applicants and holders are requested to voluntarily provide a list of suppliers to Health Canada. Suppliers include any person other than a manufacturer of a medical device (i.e., the entity that holds an MDL for the device) who sells the medical device to the MDEL holder for the purpose of import or sale in Canada.

Health Canada is proposing to make the submission of a supplier list mandatory, meaning that MDEL applicants and holders must identify suppliers during their initial application and annual license review. Health Canada is seeking to better identify persons selling into Canada so that it can be more targeted and efficient in approaching compliance and enforcement actions.

Closing enforcement gaps for standard operating procedures

Currently, MDEL applicants must attest to having procedures in place to manage health and safety risks related to the import and distribution of medical devices in Canada. Health Canada inspections have shown these procedures to be lacking and to contain gaps in documentation and implementation.

To address this, Health Canada is proposing to establish explicit requirements for MDEL holders to establish, implement, and maintain standard operating procedures. These proposed changes aim to improve management of health and safety risks related to medical devices sold in Canada.

Stakeholders' feedback and next steps

Health Canada is soliciting feedback from stakeholders on their regulatory proposal.

This consultation period ends on December 9, 2024. Interested parties may submit written comments, in English or in French, by email to prsd-questionsdspr@hc-sc.gc.ca or by mail to Jillian Andrews, Acting Associate Director, Compliance Policy and Regulatory Affairs, Policy and Regulatory Strategies Directorate, 200 Eglantine Driveway, Ottawa, Ontario, K1A 0K9.

Health Canada will use this feedback to support a prepublication in the *Canada Gazette, Part I* (draft regulation published for comment). This will then be followed by another period for stakeholders to provide comments (expected to take place in 2025). An additional step (publication in *Canada Gazette, Part II*) would be required for the proposed regulation to become law.

To discuss these issues, please contact the author(s).