Notice: New regulations strengthening the post-market surveillance and risk management of medical devices in Canada

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Changes to the regulations

Health Canada is making regulatory changes to the *Medical Devices Regulations* to strengthen the lifecycle approach to the regulation of medical devices by increasing post-market surveillance authorities. With these amendments, we have implemented certain powers included in Vanessa's Law and additional measures to improve post-market surveillance of medical devices. Together these will help to reduce the risk of medical devices and improve their safety, quality and effectiveness.

The post-market surveillance regulations amending the *Medical Devices Regulations* will improve our ability to identify, assess and manage new risks for medical devices used in Canada.

Consultations and publication

In the spring of 2018, Health Canada published a notice on our intent to strengthen the post-market surveillance and risk management of medical devices in Canada. We consulted with manufacturers and importers of medical devices on the proposed regulatory changes and related guidance documents.

The proposed regulations were published in *Canada Gazette, Part I*, on June 15, 2019. Stakeholders had 70 days within which to comment. We also made available guidance documents for comment.

In June 2020, Health Canada advised that this regulatory initiative had been delayed due to the COVID-19 pandemic. However, it has now been published.

Coming into force

The post-market surveillance regulations amending the Medical Devices Regulations were published in the *Canada Gazette, Part II* (CGII) on December 23, 2020. The various provisions under the regulations are coming into force as follows:

Amending Regulations	Coming into Force	Date	Note

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Summary Reports (*Medical Device Regulations*)	First anniversary after publication in CGII	December 23, 2021	Relates to Summary Report provisions under sections 61.4, 61.5 and 61.6
Other amendments to the *Medical Devices Regulations*	Six months after publication in CGII	June 23, 2021	Excludes sections related to Summary Report provisions under sections 61.4, 61.5 and 61.6

Guidance documents

We have prepared and updated 4 guidance documents. We'll be releasing and publishing these guidance documents in the weeks following publication of the amending regulations in *Canada Gazette, Part II*. The guidance documents are for:

1. incident reporting for medical devices
2. foreign risk notification for medical devices
3. summary reports and issue-related analyses of safety and effectiveness for medical devices
4. guide to new authorities on the amendments to include power to require assessments and power to require tests and studies

Note: To inform us of notifiable actions under foreign risk notification requirements for medical devices, industry will be using an electronic form. We will make this form available on Canada.ca in the coming months. You

can find information on what's required in the form in the Guidance Document for Foreign Risk Notification for Medical Devices.

Contact us

If you have questions about this notice, please contact:

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