

# Health Canada releases draft pre-market guidance for machine learning medical devices

September 01, 2023

On Aug. 30, 2023, Health Canada released its anticipated [draft guidance document on obtaining authorization for machine learning-enabled medical devices](#) (machine learning medical devices). This publication seeks to assist manufacturers of class II, III, and IV machine learning medical devices who are submitting applications for, or amendments to, a Medical Device License. The guidance document outlines Health Canada's expectations for demonstrating the machine learning medical devices' safety and effectiveness requirements required under s. 10 of the [Medical Device Regulations](#) (MDR), and introduces a proposed mechanism for manufacturers to obtain pre-authorization for planned changes to one of its existing machine learning medical devices.

## Safety and effectiveness requirements

Medical devices that use machine learning technology to accomplish their intended medical purpose are called machine learning medical devices. Machine learning medical devices present challenges to regulators seeking to evaluate the device's safety and effectiveness because, by their very nature, machine learning medical devices are continually evolving.

The current regulatory scheme addresses safety and effectiveness requirements. Under section 10 of the MDR, the manufacturer of a medical device is required to "take reasonable measures" to identify the risks inherent in the device, reduce or eliminate risks where possible, and provide protection and information appropriate to those risks during the projected useful life of the device.

Key takeaways from the draft guidance:

- Manufacturers should clearly state in a cover letter for all Class II, III, and IV applications that their device uses machine learning. Manufacturers will also want to ensure that there is objective evidence that supports the safety and effectiveness of their machine learning medical device relevant to its intended use. The evidence should also include a description of how the manufacturer has implemented good machine learning practices that remain implemented throughout the machine learning medical device's product lifecycle. For a

summary of these GMLP, please our article on Health Canada's [Guiding Principles on Artificial intelligence and Machine Learning for Medical Devices](#).

- Manufacturers are encouraged to provide detailed description of the kinds of information Health Canada is seeking in machine learning medical device **applications relating to the device's intended use, indications for use, contraindications, clinical validation, device description, product labelling, risk management strategies, and data selection and management.**
- The guidance encourages manufactures to consider providing descriptions of the machine learning development, training, and tuning approaches, system performance testing, and post-market performance monitoring.
- **Health Canada's guidance has also introduced the concept of a Pre-determined Change Control Plan (PCCP) that manufacturers would submit as a standalone section in their MDL application. Through the PCCP, a manufacturer can seek pre-approval for otherwise significant changes in its machine learning medical device's design and performance that would otherwise require an MDL amendment application.**
- The PCCP is proposed to consist of three sections: change description, change protocol, and impact assessment. **The PCCP's change description section invites manufacturers to characterize the machine learning medical device's baseline design and performance and list anticipated or planned changes across the product's life cycle (whether by the manufacturer, a user, a patient, or by the device itself).** The change protocol section would require manufacturers to describe the set of policies and procedures that control how the planned or anticipated changes will be implemented and managed in a manner that ensures **the machine learning medical device's safety and effectiveness. Depending on the nature of the machine learning medical device and the planned/anticipated changes, the change protocol may need to include the manufacturer's plans for ongoing data/risk management, modification/update procedures, monitoring, and corrective actions.** Finally, the impact assessment section would require manufacturers to outline the potential influence and implications of the changes listed in its PCCP.

## Finalization of the draft guidance and opportunity for industry feedback

Health Canada is soliciting feedback on its draft guidance from Class II to IV medical device manufacturers, regulatory representatives, and machine learning experts. For example, Health Canada has requested feedback whether it should add or remove any information that manufacturers would be required to provide in PCCP sections. The window to provide Health Canada with input closes Oct. 29, 2023, after which the guidance document will be finalized.

For any assistance with product regulatory related inquiries, please feel free to get in touch with the key contacts below.

By

[Edona C. Vila](#), [Benjamin Fuhrmann](#)

Expertise

[Health Law](#), [Products Law](#), [Health Care & Life Sciences](#)

---

## **BLG | Canada's Law Firm**

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 725 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

[blg.com](http://blg.com)

### **BLG Offices**

#### **Calgary**

Centennial Place, East Tower  
520 3rd Avenue S.W.  
Calgary, AB, Canada  
T2P 0R3

T 403.232.9500  
F 403.266.1395

#### **Ottawa**

World Exchange Plaza  
100 Queen Street  
Ottawa, ON, Canada  
K1P 1J9

T 613.237.5160  
F 613.230.8842

#### **Vancouver**

1200 Waterfront Centre  
200 Burrard Street  
Vancouver, BC, Canada  
V7X 1T2

T 604.687.5744  
F 604.687.1415

#### **Montréal**

1000 De La Gauchetière Street West  
Suite 900  
Montréal, QC, Canada  
H3B 5H4

T 514.954.2555  
F 514.879.9015

#### **Toronto**

Bay Adelaide Centre, East Tower  
22 Adelaide Street West  
Toronto, ON, Canada  
M5H 4E3

T 416.367.6000  
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing [unsubscribe@blg.com](mailto:unsubscribe@blg.com) or manage your subscription preferences at [blg.com/MyPreferences](http://blg.com/MyPreferences). If you feel you have received this message in error please contact [communications@blg.com](mailto:communications@blg.com). BLG's privacy policy for publications may be found at [blg.com/en/privacy](http://blg.com/en/privacy).

© 2024 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.