Health Canada releases guiding principles on artificial intelligence and machine learning for medical devices

November 11, 2021

Medical devices that harness the power of artificial intelligence and machine learning (AI/ML) have the potential to revolutionize the field of healthcare.

Jointly with the U.S. Food and Drug Administration (FDA) and the U.K's Medicines and Healthcare Products Regulatory Agency (MHPA), Health Canada identified **ten guiding principles** to inform the development of Good Machine Learning Practices (GMLP) in medical devices.[1]

What you need to know

- The information extracted with the assistance of AI/ML is expected to continue to lead to a number of high value and life-saving applications, including the improvement of medical diagnosis accuracy, earlier disease detection, and the development of personalized medicines and diagnostics.[2]
- In recent years, AI/ML applications in healthcare have attracted some regulatory attention by Health Canada and other regulators across the globe. For example, in 2019, Health Canada identified the need to develop a policy with respect to the regulation of AI/ML medical devices to ensure timely and safe access.[3]
- On October 27, 2021, the FDA, MHPA and Health Canada each released an identical bulletin on the GMLP guiding principles with the intent to promote "safe, effective, and high-quality" medical devices that use AI/ML.[4]

The guiding principles

The 10 guiding principles are an important starting point for the development of GMLP that addresses the complexity of AI/ML in the medical technology and health care sector and provides a foundation for best practices to progress.

The guiding principles are summarized as: [5]

- Leveraging multi-disciplinary expertise throughout the product's total life cycle.

- Implementing good software engineering and security practices.
- Ensuring that clinical study participants and data sets are representative of the intended patient population.
- Ensuring training datasets are independent of test sets.
- Basing reference datasets on best available methods.
- Tailoring the model design to the available data and ensuring the model design is reflective of the intended use of the device.
- Focusing on the performance of the human-AI team where the model has a "human in the loop".
- Ensuring that testing demonstrates device performance during clinically relevant conditions.
- Ensuring that users are provided with clear and contextually relevant information.
- Monitoring deployed models for performance and managing re-training risks.

Takeaways

In light of the international regulatory alignment on these key principles, developers, suppliers, manufacturers and importers of AI/ML powered medical devices operating or desiring to enter the Canadian market, would benefit from adopting these guiding principles in their product life cycle.

If you have any questions about medical devices, including AI/ML powered medical devices, please reach out to your BLG lawyer or any of the key contacts listed below.

[1]See Health Canada's "Good Machine Learning Practice for Medical Device Development – Guiding Principles," October 27, 2021, online. See the U.K. bulletin here and the U.S. bulletin here.

[2] The U.S. FDA's "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) Based Software as a Medical Device – Discussion Paper and Request for Feedback," April 2, 2019.

[3] The Canadian Institutes of Health Research in Collaboration with Health Canada "Introduction of Artificial Intelligence and Machine Learning in Medical Devices," May 10, 2019.

[4] *Ibid*.

[5] *Ibid*.

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