LAW360™ Canada

Law360 Canada | 111 Gordon Baker Road, Suite 900 | Toronto, ON M2H 3R1 | www.law360.ca

In-House Counsel

Health Canada revising medical device premarket guidance framework in response to evolving AI

By **Jean-Raphaël Champagne, Dara Jospé and Justine Letellier**

Jean-Raphaël Champagne

Dara Jospé

(November 24, 2023, 11:41 AM EST) -- Health Canada recently issued a *Draft guidance: Pre-market guidance for machine learning-enabled medical devices*.

Machine learning (ML) is a subdivision of artificial intelligence (AI) that involves training algorithms to create ML models based on data rather than relying on explicitly programmed models. Approaches using ML are increasingly prevalent in various fields, including the automotive industry, robotics, finance, and, notably, medicine.

In the healthcare sector, the utilization of ML models can significantly expedite illness detection and diagnosis by identifying novel observations and patterns in humans. Medical devices (including software) that use ML, either partially or entirely, to fulfill their intended medical purpose are referred to as machine learning-enabled medical devices (MLMDs). The most striking advantage of MLMDs lies in their ability to continue learning as additional data becomes available (including real-world-evidence), to improve the quality of healthcare.

A pivotal element in Health Canada's updated guidance framework is its emphasis on transparency and the communication of information to caregivers. This includes details about security hazards and device effectiveness, empowering caregivers to make well-informed decisions for their patients.

The draft guidance presents the concept of a predetermined change control plan (PCCP) that provides a mechanism enabling Health Canada to address cases where the regulatory pre-authorization of planned changes to ML systems is needed to address known risks. For machine learning-enabled medical devices, the PCCP is a crucial component of device design. The PCCP should be risk-based and supported by evidence, take a total product lifecycle perspective and provide a high degree of transparency.

Good machine learning practice for medical device development (guiding principles)

To uphold the highest standards and consensus norms, the U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have collaboratively outlined key factors to be considered from the initial development stage. These guiding principles hold significance for businesses involved in the design or collaboration with emerging companies developing MLMDs.

Justine Letellier

The regulatory agencies hope that these general principles will empower stakeholders in advancing responsible innovations. In practice, we expect that complying with these key principles should help industry participants with the regulatory approval process in Canada and abroad.

The Good Machine Learning Practice for Medical Device Development: Guiding Principles (GMLP) include these 10 guiding principles:

1. Multi-disciplinary expertise is leveraged throughout the total product life cycle.
2. Good software engineering and security practices are implemented.
3. Clinical study participants and data sets are representative of the intended patient population.
4. Training data sets are independent of test sets.
5. Selected reference datasets are based upon best available methods.
6. Model design is tailored to the available data and reflects the intended use of the device.
7. Focus is placed on the performance of the human-AI team.
8. Testing demonstrates device performance during clinically relevant conditions.
9. Users are provided clear, essential information.
10. Deployed models are monitored for performance and re-training risks are managed.

The GMLP are designed as adaptable best practices that can evolve alongside advancements in the field of machine learning. Stakeholders are encouraged to share their feedback for continuous improvement.

The Fasken team is actively monitoring regulatory developments in the Canadian medical device sector. Please don't hesitate to get in touch with any of our team members for additional information on the recent guidance provided by Health Canada.

Jean-Raphaël Champagne is a partner with Fasken who works with a wide variety of players in the technology and life sciences sectors on issues related to commercial, regulatory and competition law. He provides advice on drug and medical device market access, pricing and reimbursement questions, and regularly advises on complex licensing agreements, including distribution, co-promotion and outsourcing agreements. Dara Jospé is a partner with Fasken who practises law in the area of life sciences, health and food regulation. She advises manufacturers on all stages of the lifecycle of a pharmaceutical product, from conception until it reaches the consumer. In all cases, Dara develops low-risk and creative ways to adjust to the legal prohibitions and policy restrictions while keeping business interests and the safety of patients in mind. Justine Letellier is a student at the Université de Sherbrooke in the Law and Life Sciences program. As part of her studies, she is completing a master's degree in biology. Her main fields of interest are technology and life sciences, with a particular focus on artificial intelligence and its interaction with the drug and medical device market.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the author's firm, its clients, LexisNexis Canada, Law360 Canada, or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

Photo credit / metamorworks ISTOCKPHOTO.COM

Interested in writing for us? To learn more about how you can add your voice to Law360 Canada, contact Analysis Editor Richard Skinulis at Richard.Skinulis@lexisnexis.ca or call 437-828-6772.