The Canadian legal landscape on AI enabled medical devices

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Medical devices that harness the power of artificial intelligence (AI) have the potential to revolutionize the field of healthcare. While the Government of Canada's July 2022 Pan-Canadian Artificial Intelligence Strategy highlights Canada's efforts to support AI research, develop AI standards, and commercialize AI-enabled technologies, the regulatory framework in respect of AI powered medical devices in Canada continues to evolve.

Evolving AI regulatory frameworks and regulation of medical devices

Businesses working to design, create, and deploy new AI-enabled medical devices in Canada must be cognizant of the changing regulatory landscape they face. Canada's efforts to develop and deploy powerful AI-enabled technologies have been accompanied by a corresponding push to implement new AI-specific regulatory frameworks. In the past two years, Health Canada (the department of the Canadian Government responsible for regulating medical devices) has signaled its desire to create a regulatory landscape that balances the promotion of AI-enabled medical devices with the safety of Canadians. To that effect, Health Canada has published guidance identifying ten guiding principles for developing good machine learning practice. Health Canada is also considering developing a pathway for regulation of machine learning-enabled medical devices under Canada's *Food and Drugs Act*, RSC, 1985, c F-27 (FDA).

Businesses that design, create, and deploy new AI-enabled medical devices should also be aware that the Government of Canada is currently considering a new national AI regulatory framework. The proposed *Artificial Intelligence and Data Act* (AIDA)[1] addresses the design, development, and use of AI. AIDA is before Canadian Parliament and there is some suggestion that it may move swiftly through the Canadian legislative system to become law in the next few months.

In its current form, AIDA's regulatory scheme is primarily aimed at preventing "high impact AI systems" from 1) causing harm (both individual and collective); and 2) generating biased outputs based on prohibited grounds under the *Canadian Human*

Rights Act. There are presently no clear accountabilities in Canada for what businesses should do to ensure that high-impact AI systems are safe and non-discriminatory.

Under AIDA, persons who are responsible for any AI system would be responsible for assessing whether their system is "high impact" and for keeping records describing the reasons supporting their conclusion. While the Canadian Government has yet to define what a "high impact" AI system is, Innovation, Science and Economic Development Canada has recently published an AIDA Companion Document to provide businesses with guidance regarding the proposed incoming legislation.

At this time, AIDA does not purport to modify the regulation of medical devices under the FDA. The Government of Canada has also yet to propose a legislative framework specifically for regulating AI-enabled medical devices, as has been done in the United Kingdom. Without a specific regulatory framework (although arguably AIDA may well provide for a parallel regulatory framework to the FDA), AI-enabled medical devices remain subject to the classification system detailed in Health Canada's general guidance on Software as a Medical Device released in 2019.

The current classification system is largely based on whether software is intended for one or more "medical purposes" as defined in the FDA. On its face, many AI-based software programs designed for assisting healthcare professionals may arguably fit within the scope of this broad definition. Manufacturers, importers, and distributors looking to import or sell AI-enabled software intended for a medical purpose may be subject to obligations under the FDA and its *Medical Devices Regulations*, SOR/98-282. That said, Health Canada does not consider all software that is tangentially involved in healthcare to be medical devices, and has provided a set of exclusionary criteria in its guidance.

Takeaways

Manufacturers, distributors, and importers of AI-powered medical devices must remain vigilant of the changing regulatory landscape in Canada. A careful consideration of the classification of the specific product should be undertaken to avoid enforcement action by the regulator and mitigate risk.

For more information on the evolution of AI medical devices and the Canadian legal landscape, please reach out to any of the key contacts listed below.

[1] See the current text of the proposed legislation online.

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