Bill C-244 and Right-to-Repair

Position Paper

March 2024

The Issue

Medical devices are rigorously regulated throughout their lifecycle by Health Canada, except in cases where a device is being repaired by an independent[1] third-party servicing organization. **Health Canada DOES NOT regulate independent third-party medical device service providers.** This is a significant regulatory gap within the medical device ecosystem.

1. **"Independent":** third-party service providers whose main scope is to service medical equipment, but do not purchase, sell, or distribute medical devices.
2. **"Regulated":** companies holding a Medical Device Licence or Medical Device Establishment Licence with Health Canada or biomedical engineering technologists operating within a Canadian hospital.

Our Position

Due to considerable increased safety risks to patients and health care providers, until a federally regulated certification system for the third-party servicing of medical devices is implemented, Medtech Canada is unable to support the inclusion of medical devices within a right-to-repair framework. Furthermore, to protect patient and health care provider safety, Medtech Canada is opposed to the current Bill C-244 (An Act to amend the Copyright Act), unless it is further amended to ensure its application is restricted to regulated[2] service providers only and is not applied to unregulated independent third-party medical device service providers.

Medtech Canada

Medtech Canada supports:

1. The maintenance, repair, and servicing of medical devices by qualified, formally trained, hospital-based biomedical engineering technologists. While Health Canada does not oversee hospital-employed biomedical engineering technologists, these professionals operate within provincially regulated hospital environments. As such, these hospital settings have implemented and enforce quality assurance and transparency controls such as mandatory reporting for all adverse outcomes.

2. The federal government's development of a "right to repair" policy framework that would ensure an appropriate level of oversight is established for both currently regulated service providers and independent third-party service providers. Currently, there is an existing **unsafe** framework for unregulated independent third-party medical device service providers, as they are not captured within the scope of either Health Canada's federal regulatory framework or the hospital's provincial oversight. As such, unregulated independent third-party medical device service providers are **NOT** held to the same safety and efficacy standards (set out by Health Canada) that regulated organizations, such as OEMs, must adhere to. Furthermore, this lack of transparency, accountability and oversight of independent third-party medical device service providers within the medical device sector has already created instances of negative patient impact, health care provider incidents, and recalls. This has increased the ongoing risks to the safety of patients and health care workers.

Recommendations

1. As it is currently written, Bill C-244 directly undermines Bill C-17, also known as Vanessa's Law (Protecting Canadians from Unsafe Drugs Act). To protect patient and health care provider safety, it is Medtech Canada's recommendation that Bill C-244 be amended to ensure that its application for the servicing of medical devices is restricted to those entities that are currently licenced by Health Canada, or biomedical engineering technologists who operate within a Canadian hospital.

2. Medtech Canada further strongly recommends that Health Canada broaden the scope of their existing regulatory framework to include oversight over all independent third-party medical device service providers. This will guarantee that all parties within the medical device ecosystem are held to the same level of transparency and accountability. This will ensure the safety of patients and health care workers is not compromised. Their safety is of paramount importance.

3. To bridge the gap, we recommend that Health Canada develop a Medical Device Establishment Licence – Service (MDEL-S) which can be customized according to the medical device category (Class I, II, III and IV), for which the provider is authorized to perform service.

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ABOUT MEDTECH CANADA

Medtech Canada is the national association representing Canada's medical technology companies. Our association advocates for achieving patient access to leading edge, innovative technology solutions that provide valuable outcomes. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our health care systems.