December 2, 2022

Mr. Francis Scarpaleggia, M.P.
Chair, Standing Committee on Environment and Sustainable Development
Sixth Floor, 131 Queen Street
House of Commons
Ottawa, ON, K1A 0A6
Sent by email: envi@parl.gc.ca

RE: Medtech Canada Comments - Bill S-5, *Strengthening Environmental Protection for a Healthier Canada Act*

Dear Mr. Chairman,

Medtech Canada, the national association representing the Medical Technology (Medtech) industry in Canada, appreciates the opportunity to provide comments on *Bill S-5, Strengthening Environmental Protection for a Healthier Canada Act.*

Medtech Canada and our members are committed to minimizing environmental impact on the planet as well as to researching and developing new medical devices that manage and mitigate health risks from environmental challenges. Medtech Canada members have developed environmental and social initiatives focused on sustainability and participate in multiple stewardship programs. It should be noted, then, that Medtech Canada welcomed the introduction of Bill S-5 earlier this year and found the associated amendments to the *Canadian Environmental Protection Act, 1999* (*CEPA*) to be well-balanced, pragmatic, and generally consistent with the risk-based approach at the heart of the Act. In this spirit of ensuring a Healthier Canada, our members recognize the need to do more to protect the environment, while also recognizing the need to safeguard Canadians by ensuring that they have timely access to both existing, as well as new innovative medical devices.

Access to new and innovative medical devices remains a critical focus for our Canadian population and as we have witnessed throughout the COVID-19 pandemic, supply chain disruptions negatively impacted the timely access to medical devices both for diagnosis and

treatment. The sensitivity of our delicate healthcare system to such disruptions, therefore, must be a critical consideration when evaluating changes to *CEPA* and the *Food and Drugs Act* to ensure that negative impacts to the healthcare system are minimized or removed.

About Medtech Canada

Medtech Canada is the national association representing the medical technology industry in Canada. 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 healthcare system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities across the country.

Overall Regulatory Impact

The strict interpretation and application of the proposed language of the statute to our sector is a possible concern in the future. While we have confidence that the changes proposed in Bill S-5 are limited to the pharmaceutical industry (as noted in the Senate's summary document and as communicated by Health Canada to our association), the strict application of the language in the Act does not guarantee that limited interpretation or application. The proposed broad regulatory controls on medical devices have the potential to negatively impact the medtech sector for both existing and new medical devices by adding uncertainty to access the Canadian market, which would counter both the critical positive benefits Canadians gain from medical technologies, as well as Canada's competitiveness in this sector.

The proposed amendments to both *CEPA* and the *Food and Drugs Act* could potentially limit access to medical devices by our healthcare system and Canadian patients. The amendments would also run contrary to the intentions of Canada's strategy to reduce regulatory delays and backlogs for the approval of necessary and critical medical devices. There is a strong possibility that the proposed amendments in Bill S-5 could create further regulatory uncertainty under both the *Food and Drugs Act* and *CEPA* *if applied to medical devices*.

Post-Market Impact

By virtue of the proposed amendments to the Food and Drugs Act, Bill S-5 imposes additional post-market actions such as potentially imposing recalls and post-market approval changes on licensed medical devices, as well as additional testing and study burdens that do not exist today in Canada and in other regions around the world; this effectively diminishes the attractiveness of Canada as a potential first-to-market country for innovative medical devices and impacts Canada's competitiveness. Medtech Canada has reviewed the indicated changes to the *Food and Drugs Act* and would be pleased to share our verbiage for the proposed amendments to ensure that the changes are limited to drug products, as intended and indicated in the Summary of the Bill.

Toxic Substances

In addition, Bill S-5 proposes to extend a number of the regulatory controls under *CEPA* that previously applied only to toxic substances, to also now apply to products that *contain or that may release a toxic substance into the environment*. These regulatory controls include the potential for restrictions over the design, sale, and use of such products in Canada. This expanded scope of *CEPA* as proposed by Bill S-5, therefore, has the potential to impact medical devices that do not themselves contain a toxic substance, but which interact with, or can be considered as having the effect of releasing, toxic substances into the environment, notwithstanding such products do not, in and of themselves, generate or omit such toxic substances.

Confidential Business Information (CBI)

Canada has an approach to CBI that is government-wide, and the committee should be mindful of this as it considers changes to any CBI provisions in this bill. To the best of our knowledge, no one in industry has any issue with demonstrating that CBI is, in fact, CBI. Mandatory public disclosures of any kind could have a chilling effect. Any mandatory disclosure of information, akin to those proposed in the Senate's amendments on living organisms, has the potential to prevent innovation in Canada as well as prevent the deployment of otherwise approved technologies in Canada.

Our industry has no issue providing information confidentially to the government. The government will use that information to make risk-based decisions on behalf of Canadians. We

are very confident that the government will hold that information, and use that information, to protect the health and safety of Canadians. Changes in this space may not obviously benefit the public, but they could alter the competitive landscape.

The Committee has recently heard of the need to provide an audit of CBI requests. This request seems to be at odds with the established role of the Office of the Information Commissioner. In her 2015 annual report, the Commissioner noted that:

> The Act says that the general right of access may be restricted when necessary by limited and specific exceptions. There is also a presumption in favour of disclosure imposed on institutions.[1] Balancing the right of access against claims to protect certain information is at the core of the access to information regime.
> The Act also requires that decisions on disclosure should be reviewed independently of government. **The Commissioner and the courts provide this independent oversight.**

It is our considered view that any changes to the management of Confidential Business Information must apply across the entire government.

Recommendation and Conclusion

Our industry was able to be extremely responsive during the COVID-19 pandemic because of the certainty afforded us under current regulations. Based on the Senate's summary document for Bill S-5, which expressly contemplates potential exemptions for critical or essential uses for which there are no feasible alternatives (e.g., medical or therapeutic uses), we would recommend that the Committee consider and include **explicit public interest exemptions** under *CEPA* to limit the inclusion of medical devices within this new regulatory regime. Since medical devices are subject to robust regulatory oversight under the Food and Drugs Act/Medical Devices Regulations, we would propose the explicit exclusion of medical devices from the relevant Bill S-5 amendments including from the proposed group of regulated products that *contain or that may release a toxic substance into the environment*. This would align with the general framework of other federal legislation (for example, the *Pest Control Products Act*) where products that are subject to pre-marketing approval under a federal Act are excluded from the application of another set of regulations to avoid duplicative and unnecessary regulatory burden on manufacturers.

[1] 2015 Chapter 4: Maximizing disclosure (oic-ci.gc.ca)