February 12th, 2024

*Sent by electronic email to: plastiques-plastics@ec.gc.ca*

**Subject: Notice of intent to issue a notice under section 46 of the Act with respect to reporting of certain plastic products for 2024, 2025 and 2026**

To whom It May Concern,

Medtech Canada, the national association representing the Medical Device Technology Industry in Canada, appreciates the opportunity to provide comments on the "Notice of intent to issue a notice under section 46 of the Act with respect to reporting of certain plastic products for 2024, 2025 and 2026" which was published on December 30th, 2023.

**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 success of Canada's healthcare system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities across the country.

**Our Environmental Commitment**

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,

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 and 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 such as the plastics Registry to ensure that negative impacts to the healthcare system are minimized or removed.

**Summary of our request**

While we acknowledge and support the government's commitment to reducing plastic pollution and waste, we believe that the Federal Plastics Registry as currently written not only lacks realistic timelines but that it will also place an undue regulatory burden on the healthcare ecosystem.

***We therefore request that Medical Devices and their packaging, which are already highly regulated by the Canadian Food and Drug Act, be considered for exemption from the requirements of the plastics registry. If exemption is not possible, it is requested that the plastics division of Environment Canada meaningfully engage with Medtech Canada and its industry members to develop a solution and timeline that the industry can reasonably achieve along with guidance documents for the sector.***Below are a few of our concerns as well as detailed comments in the regulation change.

**Increased Regulatory Burden on Businesses:**

Medical Devices in Canada are currently regulated by Health Canada. They undergo extensive regulatory assessment and oversight both from a manufacturer as well as product specific regulatory oversight. This includes both requirements in the premarket (before sale) and postmarked (after sale) requirements. The need to comply with additional and multiple reporting requirements requires considerable resources, both in terms of time, manpower and finances.

A more streamlined regulatory environment better enables companies to focus on innovation, sustainability, and strategic planning, which is crucial to ensure for the health of our Canadian patients and healthcare providers.

**Limited data availability**

As of February 2024, EPR data collection covers only packaging from consumer-marketed packaging and medical sharps used by individuals outside clinical care. Electronic medical devices are only covered by existing provincial EPR programs in British Columbia. Electronic medical devices are exempt in Ontario's electronics EPR regulation, O. Reg. 522/20 *Electronic and Electrical Equipment*. The majority of activity in the healthcare sector is in clinical and institutional healthcare applications, which existing EPR regulation does not cover. The scope of the current Notice of Intent requires data collection and provision across all institutional, commercial, and industrial applications, and points to existing PROs as a centralized point of data provision, however, no PROs currently capture the clinical (institutional and commercial) supply-to-market data required of the Notice of Intent and this is a significant gap to address in a very short time period. Collecting this data would disrupt healthcare providers and supply chain partners from focusing on their primary

objective: delivering life-saving equipment to patients in need. Further, there is no centralized, coordinated PRO to address Section 7 (e) through (o) for down-stream plastics treatment in the healthcare sector. There are three main issues that will prevent the industry from successfully complying with the Federal Plastics Registry:

1- Supply-to-market data for plastics marketed to clinical applications (commercial and institutional) is not readily available and would place a burden on Canadian healthcare participants.
2- Treatment of waste plastics from healthcare is complex and varied in approach, overall, it is not currently measured per the requirements of Section 7 (e) through (o) at an aggregate level.
3- The proposed producer hierarchy could implicate hospitals as reporting parties should those hospitals directly procure life-saving products from distributors outside of Canada, placing an undue burden on already highly constrained Canadian healthcare system. Canada exports approximately $3.1 billion of medical technology and imports $8.6-billion. The importers would have a considerable challenge responding to the registry.

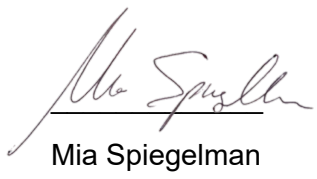
**Duplication and Lack of Coordination:**

At the same time, the proposed Federal Plastics Registry, overlaps with existing provincial and territorial reporting requirements covering consumer product packaging. This introduces redundancy and a lack of coordination. Streamlining reporting processes and ensuring better coordination between federal and provincial initiatives would enhance efficiency. A unified and well-coordinated regulatory framework would provide businesses with clarity and consistency, facilitating compliance and contributing to more effective environmental outcomes.

In Summary, Medtech Canada strongly encourage the Government of Canada to reassess this initiative and **exempt** Medical Devices before committing to what would in all certainty impact our patients and healthcare workers while yielding minimal environmental benefits. Furthermore, the expedited implementation timelines noted within the consultation overlooks the significant time needed to implement such initiatives by numerous international, national and provincial stakeholders.

Please reach out to me directly if you have any questions on the included comments.

Sincerely,



Mia Spiegelman

Vice President Regulatory Affairs

**Medtech Canada members feedback on Notice of intent to issue a notice under section 46 of the Act with respect to reporting of certain plastic products for 2024, 2025 and 2026**

| Section / line # | Current Verbiage | Comments | Recommended Changes |
|---|---|---|---|
| **33-35** | "...or who may reasonably be expected to have access to information described in..." | What is the reasonable expectation? I.e., if you are only an importer/distributor of products, you would not have access to this information. It would take years to collect this level of detail from suppliers. | |
| **37** | 2024 calendar year would be required to be provided no later than September 29, 2025. | A general comment on the short timeframe; unachievable to identify impacted products, reach out to suppliers and their resin manufacturers to collect the relevant information for reporting. | |
| **41 -42** | Persons subject to the notice would be required to submit the information required by the notice 42 using the online portal. | Is the online portal available yet? If not will it be available and accessible to all users on time? | |
| **51** | copies of the information required by the notice, together with any calculations, measurements, | Standardised methods and/or guidance on how to calculate/measure reportable data will be required. | |
| **57-64** | Request for confidentiality under Sections 51 and 52 of CEPA | Medical device product components are subject to strict confidentiality and IP requirements by manufacturers. Would these sections of CEPA be sufficient to protect confidential business information in this sector? | |
| **582 - 583** | • (b) contains a plastic product that is integrated into it; or<br>• (c) has at least one component. | A single-use device will always have at least one-component therefore this statement can be removed. | ~~• (c) has at least one component.~~ |
| **678** | (1) A person who is a producer of a plastic product; and | Add the exemption for medical devices | (1) A person who is a producer of a plastic product other than Medical Devices; and |
| **693-698** | (1) A person subject to this notice under Schedule 3 shall provide a Statement of Certification or electronic certification certifying that the information is true, accurate and complete or shall authorize another person to act on their behalf and so certify using the Statement of Certification or electronic certification<br>(2) A person subject to this notice under Schedule 3 shall provide the information required in this schedule, for each calendar year, using the online reporting system. | Need clarification if electronic certification performed as part of online reporting system. Suggest change to item (2) of Schedule 4 | A person subject to this notice under Schedule 3 shall provide all information required in Schedule 4, for each calendar year, using the online reporting system. |
| **699-705** | A person subject to this notice under Schedule 3 may designate by name, with proof of designation,<br>• (a) a producer responsibility organization (PRO), engaged to fulfil the person's extended producer responsibility (EPR) or stewardship obligations, to make a report to the registry on the person's behalf; or<br>• (b) another person, in cases where no EPR or stewardship obligations exist, to make a report to the registry on the person's behalf | Medical Devices do not have PROs in most of Canada (except BC for electronic medical devices) and any sharps data is only captured for residential use. The vast majority of plastic use in the industry is in clinics and hospitals, that are not currently supported by any PROs that would capture the requested data. There is a lack of centralized data collection for the industry overall and the proposed timelines are not achievable. | |
| **777 - 793** | • (e) the total quantity in tonnes of plastic collected at end of life and sent for diversion;<br>• (f) the total quantity in tonnes of diverted plastics that are recycled;<br>• (g) the total quantity in tonnes of diverted plastics that are processed into chemicals, including fuels;<br>• (h) the total quantity in tonnes of diverted plastics that are sent to final disposal at a landfill;<br>• (i) the total quantity in tonnes of diverted plastics that are sent to final disposal and incinerated without energy recovery;<br>• (j) the total quantity in tonnes of diverted plastics that are sent to final disposal and composted;<br>• (k) the total quantity in tonnes of diverted plastics that are recovered for energy recovery;<br>• (l) the total quantity in tonnes of diverted plastic in products that is collected with direct reuse arranged;<br>• (m) the total quantity in tonnes of diverted plastic in products that are refurbished;<br>• (n) the total quantity in tonnes of diverted plastic in products that is remanufactured;<br>• (o) the total quantity in tonnes of diverted plastic in products that are repaired; and | Apart from consumer Medical Sharps and regulated electronic medical devices in BC, there is no EPR for medical device products that would manage central data for end-of-life material flows for this industry in Canada. Therefore this requirement is not attainable for this industry within the timelines proposed. | ~~• (e) the total quantity in tonnes of plastic collected at end of life and sent for diversion;~~<br>~~• (f) the total quantity in tonnes of diverted plastics that are recycled;~~<br>~~• (g) the total quantity in tonnes of diverted plastics that are processed into chemicals, including fuels;~~<br>~~• (h) the total quantity in tonnes of diverted plastics that are sent to final disposal at a landfill;~~<br>~~• (i) the total quantity in tonnes of diverted plastics that are sent to final disposal and incinerated without energy recovery;~~<br>~~• (j) the total quantity in tonnes of diverted plastics that are sent to final disposal and composted;~~<br>~~• (k) the total quantity in tonnes of diverted plastics that are recovered for energy recovery;~~<br>~~• (l) the total quantity in tonnes of diverted plastic in products that is collected with direct reuse arranged;~~<br>~~• (m) the total quantity in tonnes of diverted plastic in products that are refurbished;~~<br>~~• (n) the total quantity in tonnes of diverted plastic in products that is remanufactured;~~<br>~~• (o) the total quantity in tonnes of diverted plastic in products that are repaired; and~~ |