

**Bill C-17: Improving Patient Safety by
Regulating Reprocessed Single-Use Medical
Devices**

Submission to the House of Commons
Standing Committee on Health



MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

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MEDEC – Reuse of Single-Use Devices Task Force

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MEDEC is the national association representing the medical technology industry in Canada.

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 publically funded health care system.

The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities, and has sales of over \$7 billion per annum. We are committed to supporting the growth of a strong and vibrant medical technology industry that contributes to Canada's innovation economy.



MEDEC is pleased to present this brief to the House of Commons Standing Committee on Health for consideration as part of its review for Bill C-17 – *An Act to amend the Food and Drugs Act*.

MEDEC member companies are fully supportive of Bill C-17 to amend the *Food and Drugs Act* in order to improve patient safety by introducing measures that will strengthen safety oversight and improve reporting of serious adverse events.

It is important to MEDEC members that patients and health care providers have confidence in the safety of our health care system. We all benefit when public trust is at its highest. This is a crucial component to the ability of innovators to bring better, new medical innovations into the system – which ultimately enable better health outcomes and health care system sustainability. Something we all work together to strive for every day. Bill C-17 helps to build that public trust and grow Canadians' confidence in our health care system.

We have an opportunity to work together to further strengthen this legislation. A full list of MEDEC recommendations for Bill C-17 is available in Appendix 1.

We recognize that Bill C-17 is intended to address a number of concerns specific to drugs, however there is a long-standing medical device issue that warrants particular attention by the Committee for amendments and forms the basis for this submission.

This issue is regarding the reuse and reprocessing of single-use medical devices and the fact that there is not any federal regulatory oversight regarding this practice raises concerns for patient safety and questions regarding legal liability.

Reuse of Single-Use Medical Devices - Concern for Patient Safety

In an effort to save money and reduce medical waste, hospitals in Canada are reusing medical devices that are licensed by Health Canada to be used only once or on a single patient during a single procedure and then be discarded.

This practice is widespread. The Canadian Agency for Drugs and Technologies in Health (CADTH) reported in 2008 that 28% of hospitals in Canada and 42% of hospitals with over 250 beds were reprocessing single-use devices (SUDs) either in-house or by a third-party reprocessor.ⁱ

Among the devices being reused are electrophysiology catheters used to diagnose heart arrhythmias, harmonic scalpels used during surgery to cut and seal tissue, and burrs and blades used during an orthopedic procedure.

Single-use devices are not designed or licensed to be disassembled, cleaned, reassembled and reused, and doing so can jeopardize their performance, safety, and effectiveness.ⁱⁱ

Advisory letters sent from Health Canada in 2005 and 2007 to hospital administrators and other stakeholders expressed concern that the reuse of single-use devices may be hazardous to patients.

Federal Situation – No Regulations Despite Repeated Calls for Action

It has been over ten years since the Auditor General of Canada recommended in March 2004 that Health Canada take action, such as regulating the reprocessing of single-use devices, to manage the health and safety risks related to the reuse of single-use medical devices.ⁱⁱⁱ

There have been repeated calls from the Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices^{iv} and the Canadian Orthopaedic Association^v for Health Canada to regulate the reuse and reprocessing of single-use devices.

Health Canada has concluded that the *Food and Drugs Act*, from which the *Medical Device Regulations* derive their authority, is not intended to apply to the use of a device after its sale therefore Health Canada doesn't have the authority to regulate the reprocessing of single-use devices by hospitals or third-party reprocessing companies^{vi}

At the time that Health Canada reviewed their regulatory authority, the vast majority of reprocessing was being done by in-house hospital staff. The situation has evolved now with most hospitals outsourcing this activity and signing contracts with third-party reprocessing companies. There are no third-party reprocessing companies for single-use devices based in Canada.

Health Canada has publicly acknowledged that business models for reprocessing have changed over time^{vii} and that at least one reprocessor is selling reprocessed single-use devices to Canadian hospitals.^{viii}

Health Canada has been unable to take action given the current *Food and Drugs Act* and *Medical Device Regulations*.

Hospitals across the country are shipping used devices licensed for single-use to U.S. based companies for reprocessing without any federal regulatory oversight for the devices that are then being shipped back for use in Canadian hospitals.

Patient Safety – Why Amendments are Important

In Canada, original equipment manufacturers must present substantive scientific evidence of a device's safety, effectiveness and quality as required by the *Food and*

Drugs Act and *Medical Device Regulations*, prior to being given authorization to sell and market a device in Canada. There are also specific requirements for documenting and reporting adverse events with clear guidance on how to issue a recall should the situation warrant such action.

Currently, third-party reprocessing companies are not required to comply with Canada's *Medical Device Regulations*, raising important concerns regarding Health Canada's role in ensuring patient safety.

1. **Device Licensing:** Health Canada does not require third-party reprocessing companies to submit safety, effectiveness or quality data for the devices they are selling and/or shipping back for use in Canadian hospitals.
2. **Adverse Event Reporting:** The *Medical Device Regulations*, specific to adverse event reporting, currently do not apply to third-party reprocessors. For instance, third-party reprocessing companies are not required to maintain records of reported problems related to a device nor are they required to report adverse events to Health Canada.
3. **Device Recalls:** Unlike original equipment manufacturers regulated by Health Canada, third-party reprocessing companies are not required to provide a proposed strategy to the Health Minister as to how a device recall would be conducted and a proposed plan to prevent a recurrence of the problem.

Bill C-17 Amendments - To Regulate Reprocessed Single-Use Devices

Amendments to Bill C-17 provide an opportunity for Health Canada to be granted the authority to regulate reprocessed single-use devices.

It is our recommendation that Health Canada regulate third-party reprocessing companies as manufacturers in the context of Canada's *Medical Device Regulations* as has been the case in other countries including the United States.

The definition of a manufacturer according to Canada's *Medical Device Regulations* is the following:

A person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or assigning it a purpose, whether those tasks are performed by that person or on their behalf.

We are recommending amendments be made to Section 30 of the Act, as this is the section addressing regulation-making authority for therapeutic products (including medical devices).

Recommendation #1

Modify the regulation-making power in section 30 (1.2)(a) to include reprocessing as a listed activity in respect of which authorizations may be issued, as follows:

Respecting the issuance of authorizations - including licenses - that authorize, as the case may be, the import, sale, advertisement, manufacture, reprocessing, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product, and the amendment, suspension and revocation of such authorizations

Recommendation #2

Add a sub-section to section 30 (1.2) providing for the authority to make regulations requiring that reprocessors of devices licensed for single-use obtain therapeutic product authorizations in respect of those reprocessed devices.

Strengthening Bill C-17 – Benefits from Amendments

The benefit of making these amendments to *Bill C-17* to strengthen patient safety would be:

- **Clarity regarding evidence** – clear, appropriate requirements for evidence to demonstrate that devices will perform as intended and are safe for patients when used by a trained healthcare professional.
- **Greater transparency and traceability** - to ensure that patients, doctors, industry and other stakeholders have access to clear information about the medical devices they use.
- **Enhanced vigilance and market surveillance** – to allow for a rapid identification of adverse events and to ensure coherent and timely action.

In conclusion, MEDEC wants to reiterate its support for Bill C-17. We believe that these amendments can address a long-standing issue and enhance this important piece of legislation to improve patient safety.

ⁱ Hailey D, Jacobs P, Ries N, Polisen J, Normandin S, Noorani H, Lafferty S, Gardam M. *Reprocessing of single-use medical devices: National survey of Canadian acute-care hospitals*. (Technology report number 104). Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008

ⁱⁱ Morrison, A and Dowler, J. *Reprocessing of Single-Use Medical Devices: A 2011 Update* (Environmental Scan issue 28). Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011.

ⁱⁱⁱ Report of the Auditor General of Canada. *Chapter 2: Health Canada-Regulation of Medical Devices*. 2.105. March 2004.

^{iv} Health Canada SAP-RMD Meeting. Panel Recommendations. Feb 2005

^v Canadian Orthopedic Association. *Reuse of Single-Use Devices Position Paper*. Sept 2011. Available from <http://www.coa-aco.org>.

^{vi} Health Canada. Letter to Hospital Administrators. *Update on Reprocessing and Reuse of Single-Use Medical Devices*. October 17, 2007

^{vii} D. Boyer, Medical Devices Bureau. *Future Direction of Reprocessing Single-Use Medical Devices*. May 2012.

^{viii} P. Neufeld, Medical Devices Bureau. *Regulatory Status of Reprocessing Single-Use Devices*. Nov 2010

Appendix 1

MEDEC Recommendations Bill C-17 – An Act to amend the Food and Drugs Act June 4, 2014

Suggested amendments to regulate reprocessed single-use devices

1. Section 30 (1.2) (a) should be modified to include reprocessing as a listed activity in respect of which authorizations may be issued, as follows:

Respecting the issuance of authorizations - including licenses - that authorize, as the case may be, the import, sale, advertisement, manufacture, reprocessing, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product, and the amendment, suspension and revocation of such authorizations

2. Add a sub-section to section 30 (1.2) providing for the authority to make regulations requiring that reprocessors of devices licensed for single-use obtain therapeutic product authorizations in respect of those reprocessed devices.

Suggested amendments to further strength Bill C-17

3. *Bill C-17* lacks a definition for the term ‘medical device incident’ – used for example in section 5, 21.8. We suggest either using the term ‘prescribed medical device incident’, which would leave to a later regulation amendment which incidents are to be reported, or to add a definition that ensures that the *Bill* and its future regulations would follow the language or terminology currently used in the *Canadian Guidance Document for Mandatory Problem Reporting for Medical Devices, January 14, 2011*, which is internationally aligned based on work of the GHTF (now IMDRF).

Other Health Canada documents (e.g. Medical Device Problem Reporting by Health Care Facilities, Medical Professionals and other device users) define ‘incident’ broadly as ‘any concerns that relate to the safety, effectiveness or quality of a medical device that have been detected during use or identified during device examination and testing prior to use. The problems include deficiencies in the design of the device, defects arising from the manufacturing and inadequacy or errors in labeling such as directions for use.’

The industry would need clarity regarding the applicable definition also under the aspect that section 5, 21.8 is about ‘serious adverse drug reactions’ and ‘a medical device incident’, which does not sound balanced and could lead to the impression that the term ‘medical device incident’ is used in the broader sense. If it were the case, this would not find agreement by the industry.

4. The powers of the Minister in section 3, 21.1, 21.2, 21.3 (1), and 21.3 (2) should enable action that is evidence based and be in line with other relevant Canadian legislation. In order to clarify this MEDEC requests that these clauses open with '*If the Minister believes on reasonable grounds ...*', language which is consistent with current CMDRs and also used in the *Canada Consumer Products Safety Act*.
5. The powers of the Minister in section 3, 21.2, 21.3, 21.31, and 21.32 (b) will limit the authority given to the licence holder in the licensing process during application review. MEDEC requests that these clauses be amended by 'Prior to issuing such order the Minister shall provide the holder of a therapeutic product authorization the opportunity to be heard'.

In case the request relates to regulations related to these powers it should be considered in the drafting process in order to provide a balanced framework that contains a reasonable approach towards dispute resolution.

6. Section 3, 21.3 (1)(b) should be modified to 'hold the product in quarantine, or send the product or cause it to be sent, to a place specified in the order'.

The nature of certain medical devices may require to rather holding them in quarantine at their current location as shipment and detention could compromise the quality and integrity of the device.

7. Section 3, 21.3 (3) should be modified to '... orders them, or another person, to withdraw from the market'.

The definition of a 'recall' in Canada for medical devices is very broad and includes a variety of corrective actions – depending on the incidence, situation, and type of device – and a stop sale would probably not be appropriate for all these 'recall' situations. It also needs to be clear that a 'corrective action' – provided it mitigates the risk – removes the reason for the order to stop selling.