



**MEDEC**

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**Re: MEDEC Comments on Draft Regulations – Regulations Amending the Medical Devices Regulations (Public Release of Clinical Information)**

Dear Mr. Rodrigue,

MEDEC, the national association representing the Medical Device Technology Industry in Canada, appreciates the opportunity to provide comments on Health Canada's proposed Regulations amending the Canadian Medical Devices Regulations (herein referred to as 'Device Regulations') in relation to the Public Release of Clinical Information.

Global policies around data transparency and access to data are evolving, and it is evident that Health Canada is looking at clinical data transparency initiatives in other key jurisdictions, such as the EMA Policy 70 framework. That being said, Health Canada continues to base overarching Therapeutic Products Directorate policy decisions primarily on the pharmaceutical global landscape. As representatives of the medical device industry, we believe that there needs to be more recognition on the significant differences of the current global transparency landscape for devices included in the RIAs. The Regulatory Impact Analysis Statement (RIAS) states "...It is also out of step with Health Canada's key regulatory partners, including the European medicines Agency (EMA) and the U.S. Food and Drug Administration, which have increased clinical data transparency over the past 10 years." This statement does not reflect medical devices as EMA does not review device submissions and we are unaware of any efforts by U.S. FDA with respect to devices to disclose clinical trial data from 510k or PMA submissions. There are some data transparency initiatives globally related to devices (Appendix 1 provides a comparison of Health Canada's proposal to the US and EU clinical data transparency initiatives for devices), but there is no clinical data transparency program implemented in any other global jurisdiction that requires device data transparency to the level proposed in the Health Canada White Paper and Draft Regulations. MEDEC has already heard from various manufacturers that if Health Canada imposes this level of clinical data

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transparency out of step with other global jurisdictions, device applications to Canada will likely be delayed, hampering Canadians' access to new, innovative devices.

Any changes to Medical Device regulations that can have broad global impact, such as currently being proposed regarding CBI, should be harmonized and aligned with key country government agencies. Canada should not be acting unilaterally and creating an inconsistent global landscape. Furthermore, MEDEC believes that moving forward with the current transparency proposals is premature given the recent communications from the Treasury Board seeking input from stakeholders on potential areas for regulatory cooperation with the E.U., including proposals to align or streamline existing regulatory systems. Article 21.3 b(vi) of the Comprehensive Economic and Trade Agreement (CETA) states that one of the objectives is to avoid unnecessary regulatory differences. Having misalignment in regulations between the European Union and Canada is inconsistent with the Regulatory Cooperation Forum (RCF) stated objectives "to contribute to the protection of human life, health or safety, animal or plant life or health and the environment; avoid and reduce unnecessary regulatory differences; or reduce administrative burden and unnecessary duplication".

MEDEC members have reviewed and assessed the impact of the draft regulations for public release of clinical information (in the context of the implementation proposed outlined in the White Paper), and we believe the financial impact on industry will be substantial. The increase in costs to perform data analysis to de-identify personal information and redact CBI will significantly shift a manufacturer's return on investment (ROI) calculations when making a decision to submit a Canadian licence application. We have identified several options below to help minimize this untoward impact while meeting Health Canada's data transparency objectives.

MEDEC's Recommendations regarding the proposed additions to the Device Regulations, explained in further detail below, are as follows:

#### **MEDEC RECOMMENDATIONS**

- 1. Exemptions to the release of CBI: A third exemption should be added to the regulations (section 43.12(2)) to ensure intellectual property in the clinical submission sections that is not directly related to the clinical data continues to be treated as CBI.**
- 2. Retrospective application of the data transparency requirements should be reconsidered as it has 1) no global precedent 2) past submissions were made with the understanding that the information would remain confidential, and 3) clinical trial consent forms may have not included the appropriate clauses to allow for public disclosure.**
- 3. Phased implementation: Public release of CBI for medical devices and IVDDs should be delayed to harmonize with implementation of the EU MDR & EU IVDR timelines, respectively.**
- 4. Health Canada's first version of the Implementation Guidance should focus exclusively on implementation for drugs, with device implementation details being incorporated subsequent to further detailed discussions on harmonization and addressing the unique nature of device submissions.**

## **1. Exemptions to the Release of Confidential Business Information**

While the overall scope of the proposed policy includes clinical information available for use to assess the safety and efficacy of medical devices in humans, in some cases supporting data not relating to an assessment of safety and efficacy can be included in clinical sections of the Table of Contents (ToC) or other submission formats. This information should not be automatically considered for public release, such as detailed device design information or user questionnaires not related to the clinical study primary endpoints.

There are inherent differences between devices and drugs such as the submission clinical sections scope, study design, molecules vs. hardware/software devices, and Intellectual Property (IP) protection ability that call for differences in the CBI provisions for devices. The exclusions in the draft regulations (section 43.12(2)) are very narrow. While we appreciate Health Canada's recognition that information not supporting the intended use and "...tests, methods or assays that are used exclusively by the manufacturer" would continue to be considered CBI, there are other types of proprietary information that can be found in device submission clinical sections that should be redacted. Some examples include:

- Information on the design features (device technology) beyond the descriptions in the product labelling as this information may provide an advantage to competitors
- Detailed description or discussion of novel manufacturing process in some supporting documents that may be included in the submission (e.g. clinical evaluation report (CER), Investigator's Brochure, etc.)
- Discussion of regulatory filing status and feedback from other Health Authorities specifically when a final decision has not yet been rendered in the other jurisdictions
- Some clinical documents can include detailed analysis of post-market complaint and sales history for subject and predicate technology
- Subjective user feedback not relating to safety and effectiveness e.g. studies relating to an evaluation of workflow, knobology, human factors testing, or imaging characteristics that are not linked to hypothesis or an evaluation of device safety and effectiveness. Such studies are inherent to the device development process but not to clinical safety or effectiveness.

While the pharmaceutical industry often relies on early and broad patent protection to secure monopoly rights over valuable assets, and market exclusivity for many years, the same is often not the case for the medical device industry. Firstly, devices are not afforded the same data protection as section C.08.004.1 of the Food and Drug Regulations that provides an 8-year period of market exclusivity for innovative drugs – device market exclusivity is essentially limited to 'first to market' ability. Secondly, innovation and know-how related to medical devices may only qualify for narrow patent protection and the industry will often protect and secure monopoly rights over assets through the maintenance of trade secrets and confidential information. Furthermore, the subject matter of patents in the pharmaceutical industry will likely be chemical and biological in nature, which under patent law will often allow for sound prediction to be employed to establish utility. What this means is that pharmaceutical-related patents can be filed very early in the R&D process, likely years before any information is disclosed to Health Canada. However, this is not the case for medical devices where sound prediction is often not permitted and industry members must be able to fully demonstrate utility under Canadian law. This means that there is a greater likelihood that patents would be filed by a medical device company contemporaneous to an application for regulatory approval. This also means that Health Canada is likely to have information in its possession from a medical device company that is not only confidential but is required to establish patent rights. Under patent law, disclosure of this information before a patent is filed could extinguish any potential

patent rights a medical device company would have, resulting in significant business and financial harm. In addition, device patents can often be circumvented by competitors via minor engineering changes. As such it is critical that intellectual property in the clinical sections not directly related to the utility of the clinical data continue to be protected.

To achieve this objective, we recommend an addition to the current exemptions in the regulations under section 43.12(2). The current text specifies:

**43.12 (2)** *Subsection (1) does not apply to information in respect of a clinical study or investigational testing that*

*(a) was not used by the manufacturer in the application to support the information referred to in paragraph 32(3)(b) or (4)(b); or*

*(b) describes tests, methods or assays that are used exclusively by the manufacturer.*

Proposal:

**43.12(2)** *Subsection (1) does not apply to information in respect of a clinical study or investigational testing that*

*(a) was not used by the manufacturer in the application to support the information referred to in paragraph 32(3)(b) or (4)(b); or*

*(b) describes tests, methods or assays that are used exclusively by the manufacturer.*

*(c) describes device design, manufacturing process and/or commercial information that is not explicitly implicated as pertinent to the clinical data results.*

This addition to Section 43.12(2) would help prevent competitors from using the released information to accelerate a research program for commercial gain while enabling the goal of clinical data transparency. This addition of verbiage in the regulations that protect device design related confidential information will help alleviate MEDEC's significant concerns that manufacturers may delay the introduction of innovative products to the Canadian market for fear that their IP will no longer be protected. Furthermore, adding this additional clause will 'leave the door open' to discuss harmonization and potential device clinical data package leveraging between Health Canada and the EU Commission (as the current confidential information provisions in the EU MDR/EU IVDR texts are broader than the limited exclusions proposed in the draft regulations).

## **2. Retrospective application**

MEDEC has significant concerns with the intent to apply these regulations retrospectively as described below:

- **Global Precedent:** The extensive retrospective scope of the regulation has no global precedent for drugs nor devices. Specific for devices, the forthcoming EU MDR data transparency requirements will not apply to any submissions prior to the new regulations, and therefore any retrospective publication in Canada would be a unique global requirement for devices, even after data transparency implementation in Europe.

- **Historic Expectation of Confidentiality:** Manufacturers have made their submissions with the established expectation of confidentiality under existing Health Canada regulations. Once the new regulations are in effect, manufacturers will have the knowledge that clinical information will be publicly disclosed and can take this into account when writing documents for submission. For instance, manufacturers can structure future submissions by excluding confidential information from the clinical data/clinical section if it is not required for analysis of the clinical data. Industry is of the view that the retrospective application of these regulations amounts to an overreach, and an expropriation of acquired rights.
- **Consent Form Disclosure:** Current device clinical trial consent forms may not address this type of data disclosure - patients may not have been informed that study data would be made publicly available when they consented to clinical study participation. We are concerned that Health Canada has not fully considered the implications of public disclosure related to the integrity of the informed consent process and protection of patients' privacy rights. While the proposed disclosure process would use redaction techniques to minimize the risk of re-identification of patients, the act of "de-identifying" is itself considered a use of data under Canadian privacy law. Arguably company consent forms could be updated to include a statement in regards to this use of the data, but that would only mitigate prospective use of the participant's data for future trials. Publishing clinical data in the public web portal that stems from clinical trials where consent has not been granted by the participants (such as for retrospective submissions) is extremely concerning. Industry and/or Health Canada may face potential litigation as a result of such retrospective application of data releases in the absence of proper consent.

Considering that the retrospective application of the public disclosure of clinical information has no global precedent, violates the historic expectation of confidentiality, and does not consider the lack of appropriate past clinical trial consent forms, we would like to propose that the "Transitional Provisions" section of Gazette Part I notice be excluded from the Gazette Part II publication when sections 43.11 – 43.13 are added to the Canadian Medical Devices Regulations.

### **3. Burden on Industry and Phased Implementation**

The RIAS indicates that the One-for-One Rule and the small business lens do "not apply to this proposal" as the "proposed amendments are not expected to increase the administrative burden on businesses" and "there are no costs to small business (or costs are insignificant)." Perhaps the draft regulations do not fall under the technical requirements of the One-for-One Rule, however it cannot be understated that introducing these requirements for devices is of significant industry burden. Identifying and redacting personally identifiable information and relevant CBI information from the clinical trial sections in new medical device applications as well as existing licence applications will require significant additional resources for device manufacturers, not to mention require significant administrative and financial resources from Health Canada and taxpayers. This unique Canadian resource burden may be another reason that manufacturers may decide not to bring innovations to Canada, leading to a delayed access to new treatment options for Canadians.

From the reference group meetings, we understand Health Canada is aiming to implement the public release of clinical information for medical devices in 2020-2021 and 2021-2022 for Class IV and Class III medical devices respectively. While we greatly appreciate that Health Canada intends to schedule the implementation of the medical device data transparency provisions for a latter phase, we would like to express the importance of aligning with the timelines of the EU MDR & EU IVDR Eudamed requirements (IVDR being 2 years behind MDR implementation) so that manufacturers can harmonize the resources required to comply with these new requirements. A later implementation along with active discussions with our European counterparts on the EU MDR Eudamed implementations provides the opportunity for harmonization of global device transparency requirements, versus earlier implementation and misaligned requirements.

In addition, to reduce the administrative burden for industry & Health Canada, and focus on the key objectives of disclosure, the proposed regulations should be scoped to only include device submissions containing new clinical data. Many device submissions do not include new clinical study data. If the clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review that analyzes relevant publications in the peer-reviewed scientific literature. Given the primary intent of clinical data transparency is to enable researcher and public access to new clinical studies for awareness and secondary analyses, the scope of public data transparency for devices should focus on submissions that include new clinical studies. This would strike an appropriate balance, achieving the key intent of the transparency initiative while reducing significant burden on industry and Health Canada by removing certain types of information from the scope of the regulation.

#### **MEDEC RECOMMENDATIONS**

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In closing, MEDEC appreciates Health Canada's request for comments on the Draft Regulations *Amending the Medical Devices Regulations (Public Release of Clinical Information)*. We look forward to continuing to work with Health Canada to ensure that the aspects unique to medical devices are considered in the

framework to ensure the protection of confidential business information and patient data while meeting clinical data transparency expectations.

MEDEC would appreciate the opportunity to discuss our comments in person. Please reach out to me directly if you have any questions on the included comments.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Lewis". The signature is fluid and cursive, with a large initial "B" and a stylized "L" followed by a period.

Brian Lewis  
President & CEO, MEDEC

**Appendix 1: Comparison of Health Canada’s proposal to the US and EU clinical data transparency initiatives for devices.**

Clinical Data Transparency Area	Health Canada White Paper Proposal	US clinicaltrial.gov (2016 Final Rule)	EU Council Directives on Active Implantable Medical Devices, Medical Devices and In Vitro Diagnostic Medical Devices (90/385/EEC, 93/42/EEC, 98/79/EC respectively)	EU Medical Device Regulation (EU MDR) Regulation 2017/745 & EU IVD Regulation (EU IVDR) Regulation 2017/746
Timing of implementation of requirements	Draft regulations released December 2017	1) Implementation of Registration requirements for studies commenced on or after January 18, 2017 2) Implementation of study result requirements with primary study completion on or after January 18, 2017	No requirements in the EU MDD for clinical data transparency	Regulation Date of Application (DOA) - May 26th 2020 & May 26th 2022 respectively. Clinical data requirements require implementing act(s) and guidelines prior to coming into force. Eudamed required to be in place either 6 months post-DOA or 6 months after independent audit report (Articles 34 & 123 of Regulation (EU) 2017/745). Anticipated that the clinical data transparency requirements will not be in force for medical devices until approximately 2020 and in vitro diagnostics by 2022.
Who uploads the data?	Health Canada uploads to web portal	Responsible party must submit data to clinicaltrials.gov (managed by NIH) according to required timelines	N/A	Manufacturer uploads clinical summary and clinical summary report (with redactions) to Eudamed database.
Is the Clinical Summary Report required to be made public?	Yes if the Clinical Summary Report was included within the medical device application (e.g. Class IV applications)	No	N/A	EU MDR: Yes, the summary and the clinical investigation report (referred to in paragraph 5 of Article 77 of Regulation (EU) 2017/745) shall become publicly accessible through the Eudamed database.  EU IVDR: Yes, the summary and the clinical investigation report (referred to in paragraph 5 of Article 73 Regulation (EU) 2017/746) shall become publicly accessible through the Eudamed database.

<p><b>What specific information within the clinical data is exempt (e.g. considered confidential)</b></p>	<p><u>White Paper:</u> Portions of the methodological details (e.g. in-house modifications or procedures to analytical, immunogenicity, bioassay, or sample size calculations methods not commonly used by the industry) should be treated as confidential. For drugs, only clinical data that provides insight into the stereochemistry that is not already known and necessary for ongoing clinical development should be treated as confidential.</p> <p><u>Technical Briefing Presentation:</u> <b>Specific categories of clinical information that may qualify for redaction:</b></p> <p>1. Proprietary methodological details Eg. Innovative test methods developed in-house and used for additional drug development.</p> <p>2. Future clinical study plans and secondary outcomes/exploratory endpoints not used to support application for use Eg. Study outcomes that reveal a new clinical indication.</p> <p><b>Out of scope:</b></p> <p>1. Information on the structure and chemistry of the therapeutic product Eg. Undisclosed stereochemistry of a molecule.</p> <p>2. Other commercial information Eg. Contract information, names of suppliers.</p>	<p>Personally identifiable information, trade secrets and confidential commercial information are redacted.</p> <p><u>42 CFR 11.48(a)(5):</u> "Responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted under this part."</p> <p><u>42 CFR 11.52:</u> "The responsible party may redact names, addresses, and other personally identifiable information or commercial confidential information contained in the final report prior to submission to NIH, unless such information is otherwise required to be submitted under this part."</p>	<p>N/A</p>	<p><u>Article 73 of Regulation (EU) 2017/745:</u> The information shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:</p> <p>(a) protection of personal data in accordance with Regulation (EC) No 45/2001;</p> <p>(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;</p> <p>(c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.</p> <p>4. No personal data of subjects shall be publicly available.</p> <p><u>Article 69 of Regulation (EU) 2017/746:</u> The information shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:</p> <p>(a) protection of personal data in accordance with Regulation (EC) No 45/2001;</p> <p>(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;</p> <p>(c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.</p> <p>4. No personal data of subjects shall be publicly available.</p>
<p><b>Can data be downloaded from the public website site?</b></p>	<p>Unknown</p>	<p>clinicaltrials.gov doesn't typically include files, just what is included on the populated webpage to print (e.g. high level results summary)</p>	<p>N/A</p>	<p>TBD</p>