DENTAL INDUSTRY ASSOCIATION OF CANADA
ASSOCIATION CANADIENNE DE L'INDUSTRIE DENTAIRE

September 28, 2021

Bureau of Policy and International Programs
Medical Devices Directorate
Health Products and Food Branch
Health Canada

Sent via e-mail: hc.mddpolicy-politiquesdim.sc@canada.ca

Re: Proposal to Introduce a Unique Device Identification (UDI) system for medical devices in Canada.

To Whom it May Concern:

Thank you for opening up to consultation the feasibility of introducing a UDI system in Canada including options for development of a UDI database, leveraging internal existing infrastructure.

DiAC is a not for profit federally incorporated association. Since 1978 we have been advancing oral health, through the manufacture and distribution products for the oral health community. We also represent commercial dental laboratory services and businesses that provide general services to support dental professionals in Canada. We represent over ninety (90) businesses which include large global manufacturers, large and small local and global distribution businesses, commercial dental laboratories and finance, software, and service industries all focused on providing high quality products and services to patients across Canada.

Patient safety and oral health promotion as a key to overall health has been the focus of our industry. DiAC supports Health Canada's mission to protect the public health by assuring the safety and security of medical devices and providing industry with predictable, consistent, transparent and efficient regulatory pathways ensuring consumer confidence in devices marketed in Canada.

As a general comment the members of the Dental Industry Association, who have replied to our request for consultation, understand the need for a UDI system in Canada. Many of our members have European or U.S. parent companies, jurisdictions that have Harmonization on a

global basis under the International Medical Devices Regulators Forum (IMDRF) to standardize identification of medical devices on a risk-based system through the UDI identifier.
We are concerned about the implementation of UDI and the challenges that exist.

- Cost of UDI implementation will be significant to both government and business;
- Database management and integration and consistency with current global standards, and Health Canada systems and processes is essential;
- The benefits of UDI are only fully accrued if all players in the system adopt UDI including healthcare professionals, medical and dental offices, hospitals;
- Risk based implementation process and timeline;
- The establishment of a UDI database, either public or private would require significant investment to build and maintain. Our preference would be a public repository of data to ensure security of data, global consistency of approach and data integrity;
- Integration with existing medical device processes (MDALL);
- Application of UDI to medical devices as defined may be too broad based;
- Define and establish guidelines and standards for potential exemptions;
- Class 1 and direct to consumer products exemptions consistent with EU and US;
- Over the counter class 1 and 2 medical devices purchased at the retail level is already sufficiently tracked through stock keeping units (SKU's) and universal product codes (UPC);
- Over the counter medical devices are not dispensed and integrated into the healthcare system in the same way as prescribed devices, a UDI requirement would not contribute to reduced medical errors nor would it be integrated into electronic health records to support the collection of real-world data etc.;
- Global Harmonized labelling - SKU and UPC code identifiers as the means to identify and track off the shelf products;
- Global consistency of products defined as medical devices;
- Healthcare professional education and instruction -breadth/depth and cost of education will be critical
- Consumer/patient education and instruction also critical to an effective UDI system.

These are some of the general concerns of our membership. We will address specific questions.

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1. ***Do you support the establishment of a UDI system in Canada that is based on the IMDRF template?***

   If Health Canada determines that a UDI system is required then we strongly recommend that it be based on the IMDRF template and that any system being considered if fully integrated within the global framework, including global definitions of medical devices, risk-based implementation, clear definitions of exemptions and exclusion and format/labelling of all products.

2. ***If the Canadian implementation fully aligns with the IMDRF guidance what will the impact be?***
   - Alignment with IMDRF will most likely allow for alignment with jurisdictions that have already implemented, however we do note that there are differences in some countries that will cause some concerns;
   - Labelling differences is one example, medical device product definition another;
   - Ability to leverage work done by the EU and US regulators would reduce some of the challenges in adopting UDI in Canada;
   - Each unique Canadian UDI requirement will increase the impact to manufacturers who already comply with other jurisdictions. Global harmonization will be a key factor to adoption;
   - Database integration with manufacturers, connectivity, translation, technical specifications all elements of concern as well as integration with existing Health Canada databases.
   - A number of our members are U.S based companies who would prefer alignment with the FDA.

3. **While it is highly desirable to align internationally do you have proposals for possible exemptions from UDI requirements? Do you have comments on what devices should be exempt from UDI requirements? Do you agree with Health Canada's proposal to exempt custom-made devices and Class 1 devices?**

   - We strongly encourage Health Canada to align its UDI system on the global IMDRF platform for consistency and ease of implementation;
   - Health Canada should adopt all global definitions and risk classification for medical device products to ensure consistency of application and labelling;

- Implementation of UDI should be on a risk basis, high risk medical devices used in hospitals should be given top priority;
- Standardized processing for most classes, that are not direct to consumer
- We agree that custom-made devices and Class 1 devices be exempt from UDI classification given that Health Canada acknowledges the current well-defined processes by Class 1 manufacturers which include the broadly accepted identification standards at the SKU level via the UPC code is effective at enabling timely traceability, recall management and incident reporting.
- There needs to be an exemption process. We also would suggest that any over the counter (OTC) *sold to the consumers only through the retail environment, both e-commerce or physical retail* also be exempt from UDI and that SKU/UPC codes continue to be used for tracking, recall and incident reporting;
- Consistent global standards for labelling.

4. **It is proposed that Health Canada establish and manage the Canadian UDI database. Are there any concerns with this proposal? Are there alternative organizations that could establish and manage the Canadian UDI database? What are the advantages and disadvantages of these alternatives?**

    - We support Health Canada's adoption of the IMDRF UDI system and the management of that system for Canada.
    - We believe this is the best approach for integrity of data, systems maintenance, collaboration with the EU and US and general harmonization of the system;
    - Our members are global companies, it would be advantageous to reduce the number of regulatory databases our members need to use.
    - External management of the system could lead to loss of data integrity, security concerns, cost concerns and integration concerns with Health Canada's other databases on medical device information.
    - UDI database should be linked to current HC databases such as the medical adverse event database, MDALL, HC's recall database etc. thus furthering HC's goal of collecting real world data.
    - Health Canada should work with Canada Customs to ensure that once UDI's are implemented in Canada that there is consistent treatment either they are part of enforcement or they are not part of the enforcement at the border. Companies that import medical devices are aware that there is a SINGLE

WINDOW INITIATIVE (SWI) that was implemented last year between HC and Canada Customs to have Canada Customs check that devices requiring medical device licensing have them prior to importation into Canada. Most of our members have worked and continue to work with our customs brokers to ensure the disruption to business is minimal.

5. ***Are there any other issues and questions we need to consider when implementing this change? Are there impacts to your organization of which you would like Health Canada to be aware?***
    - Clear standardized definition of Medical Devices and Risk categories
    - Alignment with data elements established by the FDA and EU.
    - Bi-Lingual
    - Connectivity to manufacturers existing systems and easy user interfaces
    - Global labelling standards
    - Staged implementation - high risk products first
    - Class 1 exempt, *OTC MDs sold via retail should be exempted*
    - Health Care professional education and adoption
    - Consumer/patient education and adoption
    - No unique Canadian fields to avoid duplication of work for global producers
    - Clarity on process and implementation for manufacturers
    - What is the responsibility of private label manufacturers? Whose responsibility will UDI be? The generic manufacturer or the owner of the private label?

6. **What core data elements and other relevant information should be entered into the Canadian UDI database?**

    - aligned with IMDRF documents
    - bi-lingual
    - avoid unique Canadian attributes
    - MDALL link
    - leverage existing data in other jurisdictions
    - non-critical element changes (size, storage, handling) should not require new DI

7. How should we link the Canadian UDI database to other related databases within the Canadian health care system?

- fully integrated and seamless to the manufacturer
- UDI database should be linked to current HC databases such as the medical adverse event database, MDALL, HC's recall database etc. thus furthering HC's goal of collecting real world data.
- connected to FDA and EU databases for ease of downloading information already obtained in other jurisdictions

8. What impacts (financial or other) or obstacles do you anticipate for your organization and other stakeholders?

- Could be substantial if manufacturers have to implement another database to maintain.
- Global Harmonization is a key to cost management
- Supply chain management will be impacted as healthcare providers, distributors, retailers, IT will need to invest in the implementation of UDI, integration with existing HC systems will be a key driver of cost reduction
- Existing inventory needs to be managed outside of UDI requirements
- System implementation, maintenance and upgrades
- Additional staff to implement

9. What are the benefits of the GMDN in your organizations and how is it being used?

- Many of our members are global companies - harmonization of the implementation of a Canadian UDI would be beneficial
- Post market surveillance and the ability to appropriately identify all medical devices.
- Enhance internal supply chain efficiencies better track devices that are not direct to consumer
- Enhanced public safety for high risk medical devices

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These are our comments based on input from our membership. We support Health Canada's efforts to align with global standards and efforts to work with other jurisdiction to ensure the implementation of UDI in Canada is not burdensome.

Yours truly
Dental Industry Association of Canada

Rhonda Lawson
Executive Director

cc. Board of Directors, Regulatory Subject Matter Committee