Medtech Canada

Position Paper

February 2024

Unique Device Identifiers (UDI) for Medical Devices in Canada

As Health Canada deliberates on the pathway for the implementation of Unique Device Identifier (UDI) requirements for medical devices in Canada, Medtech Canada has drawn on its members' global experiences with the implementation of these requirements in other jurisdictions and this paper provides recommendations based on these experiences for the successful implementation in Canada.

Medtech Canada strongly supports the global initiative led by regulators under the guidance of the International Medical Devices Regulators Forum (IMDRF), which aims to standardize the identification of medical devices by requiring that certain medical devices carry an internationally recognized UDI.

Background

The ground rules for the establishment of a UDI system within regulatory frameworks were established and published in 2013 by the IMDRF[1], and have begun to be adopted by governments around the world. The first implementation happened in the US in a phased approach between September 2014 and September 2023, based on regulations issued by the US Food and Drug Administration (FDA). The European Union is implementing a UDI system as part of their new Medical Device Regulations (MDR), which came into effect in May 2021. At this time, Health Canada has indicated that they plan to implement UDI in Canada, however the process and timelines have not been set.

According to the IMDRF UDI framework, UDIs are intended to provide a single, globally harmonized system for positive identification of medical devices. Once implemented, a UDI system can enhance the ability of health care professionals and patients to identify a medical device and its key attributes. UDIs will also allow industry and regulatory authorities to more rapidly identify medical devices involved in adverse events.

This system may also help clinicians more safely select and use the proper medical device for a patient, as well as facilitating and simplifying the documentation of medical device use in various patient records including traditional, as well as electronic health records and registries.

UDI implementation for the tens of thousands of medical devices available in Canada may utilize bar codes compliant with ISO/IEC standards such as the GS1 Global Trade Item Number (GTIN), as defined by the IMDRF.

Medtech Canada endorses the adoption of a global system of standards in health care, such as GS1.

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Many Medtech Canada members are multinational enterprises (MNEs) and these companies currently provide the majority of the medical devices used in Canada. Large numbers of these companies are already utilizing machine-to-machine data publishing systems to manage their data through their global offices. As the US is a substantial source of medical devices for the Canadian market, the use of a common database and barcoding system with the US would enhance supply chain flow between the two countries.

Current Challenges

Global harmonization of the use of UDI is essential to realizing the benefits of this system in the area of safety monitoring. Increasingly there are instances of divergence from the original intent of the global UDI harmonization (IMDRF) standards. For example, UDI requirements, such as Device Identifier triggers (rules requiring creation of a new Device Identifier) are not globally harmonized. This is causing an unnecessary increase in complexity to the system due to the proliferation of Device Identifiers being created and registered.

Industry continues to work with regulators through the IMDRF to promote harmonization of requirements as each country implements the UDI system.

While great progress has been made internationally with the use of Global Medical Device Nomenclature (GMDN) being used to name and group similar medical devices and individual UDI GTINs that are already appearing on products, there continues to be a lack of focused education and regulatory requirements for UDI implementation for health care delivery organizations, which will result in a lack of expected benefits from the global implementation. Health care delivery organizations have been slow to adopt UDI because their systems are not prepared to consume the UDI information according to the standards used to create UDI. Additionally, UDI implementation is an expensive undertaking. Without national regulatory requirements or oversight, the decision to implement has been left to individual health care providers.

Recommendations to Health Canada for the Implementation of UDI:

1) Instead of creating a Canada-only database, leverage existing databases (such as the FDA GUDID)

2) Utilize a phased approach to implementation, similar to the approach taken by the FDA, whereby timelines were phased-in, based on device classification.

3) Incorporate a risk-based approach (such as consumer vs professional) when implementing UDI requirements.

The above recommendations are aligned with the intent of the IMDRF around a global, centralized and harmonized UDI system.

In Summary

Patient safety is a key focus for Medtech Canada members, regulators and health care providers, and a global UDI system supports this goal. Regulators, medical device manufacturers, health care providers, supply chain partners and standards organizations all play a critical role in ensuring the success of this initiative.

During and following the Health Canada consultation on the future of UDI in Canada, Medtech Canada members would be pleased to work with Canadian health care providers and regulators to implement an effective, global UDI system in Canada that will achieve these goals both within Canada and internationally.

1. **IMDRF website:** http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf

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ABOUT MEDTECH CANADA

Medtech Canada is the national association representing Canada's medical technology companies. 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 health care systems.