Unique Device Identifiers (UDI) for Medical Devices in Canada

MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICAL

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MEDEC strongly supports the global initiative led by Regulators under the umbrella of the International Medical Devices Regulators Forum (IMDRF) currently underway to standardize identification of medical devices by requiring that medical devices carry a Unique Device Identifier, or UDI. The ground rules for the establishment of a UDI system within regulatory frameworks have been set and were published in 2013 by the IMDRF[1]. The first implementation will happen in the US in a phased approach between September 2014 and September 2018, based on regulations issued by the US Food and Drug Administration. Following statements from the Canadian Regulator, Health Canada, MEDEC understands that they are currently monitoring UDI implementation in the US, as well as other countries. Further stemming from these statements, MEDEC is also of the understanding that Health Canada intends to regulate the Canadian UDI system for medical devices in the future and that at such time, they will not be prescribing a Canadian-specific registry, but will be aligning the regulation with the concept of a global UDI system, as is the case in the US.

The primary aims of the initiative are to enhance patient safety (through more accurate reporting of adverse events, reduction of medical errors, and more effective management of medical device recalls) and to provide a foundation for a global, secure distribution chain that supports efficient healthcare delivery[2]. Patient safety is a key focus for both healthcare providers and MEDEC members, and a global UDI system supports patient safety. It provides the benefits of enhanced monitoring of the performance of medical technologies in the global market, more efficient management of adverse events with improved patient outcomes and decreased healthcare system costs. Regulators, medical device manufacturers, healthcare providers, supply chain partners and standards organizations all play a critical role in ensuring the success of this initiative.

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). The GTIN is one of of the key building blocks of the GS1 Global System of Standards. MEDEC endorses the adoption of this Global System of Standards (or other similar, Regulator-approved systems) in healthcare and the deployment of these standards within the framework of the Global Data Synchronization Network (GDSN), a GS1 Communication Standard that is another key element of the GS1 System of Standards[3]. The GDSN is built around the GS1 Global Registry, GDSN certified Data Pools, the GS1 Data Quality Framework and GS1 Global Product Classification, which, when combined, provide a powerful environment for secure and continuous synchronization of accurate data[4]. The objective of the GDSN is to provide an assured, secure, seamless, point-to-point information exchange between manufacturer, distributor and healthcare provider. The GS1 Global System of Standards ensures a single solution that provides the highest level of accuracy and data integrity for the global healthcare world.

A global GDSN Implementation Committee has been struck by GS1 Global, and Brian Lewis, MEDEC's President and CEO is pleased to be a member of that committee, along with other Canadian representatives from global medical device manufacturers. The committee is focused on the harmonized introduction of GS1 standards across the world, attempting to minimize local country differentiation from the standard, taking into account local needs, while operating within the GDSN certified system.

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GS1 Canada's ECCnet Registry is an out-of-network product information catalogue service that is proprietary to GS1 Canada; it is not GDSN certified (certification would require GDSN compliance). ECCnet operates outside of the GDSN[5] and is therefore isolated from the global market and global standards. As a result, ECCnet requires separate legal contracts for use and is not subject to 3rd party security audits or certification in the same way that GDSN Data Pools are. In MEDEC's opinion, this isolated service potentially jeopardizes patient safety by introducing an extraneous, local-market-only step into the global information exchange process.

The GS1 System of Standards is global, robust, multi-sector, user-generated, and scalable, and it is used today by millions of companies across dozens of industry sectors[6]. MEDEC fully supports compliance to this System of Standards. Many MEDEC members are Multinational Enterprises (MNEs) and these companies currently provide approximately 80% of the medical devices used in Canada[7]. Large numbers of these companies are already utilizing the GDSN to manage their data through their global offices. Since ECCnet operates outside of this System of Standards (GDSN), and given MEDEC's understanding that Health Canada has indicated that when they move forward with a UDI system for Canada it will be aligned with the systems of other global regulators and based on global standards, MEDEC therefore does not support the use of ECCnet for healthcare.

MEDEC supports the goal of enhanced patient safety and the notion of collaboration between trading partners to provide for a more effective and efficient transfer of information. MEDEC members would be pleased to work with Canadian healthcare providers and regulators to implement an effective, global UDI system such as the GS1 Global Standards.

(1) IMDRF website: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance.pdf
(2) FDA website:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification
(3) The Value and Benefits of the GS1 System of Standards, GS1:
http://www.gs1.org/docs/GS1_System_of_Standards.pdf
(4) The Value and Benefits of the GS1 System of Standards, GS1:
http://www.gs1.org/docs/GS1_System_of_Standards.pdf
(5) GS1 Canada Website: http://www.gs1ca.org/page.asp?intNodeID=56&intPageID=441
(6) The Value and Benefits of the GS1 System of Standards, GS1:
http://www.gs1.org/docs/GS1_System_of_Standards.pdf
(7) Industry Canada Website: http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html

ABOUT MEDEC

MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical device technologies that enhance patient care and advance patient outcomes. The medical technology industry in Canada employs over 35,000 Canadians in close to 1,500 corporate facilities, and has sales of nearly $7 billion per annum. We are committed to ensuring that Canada has a strong and vibrant medical technology industry.

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