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Introduction to Medical Device Identification, Nomenclature and Classification

Governments and industry around the world have worked to establish a harmonized international standard and related protocols to facilitate the unique identification and classification of medical technologies, principally for the prioritized purpose of **Regulatory and Quality** (protecting human health and safety through device traceability required for monitoring, maintenance, upgrades, safety recalls, et al). This effort has achieved significant successes in the form of the **Global Medical Device Nomenclature (GMDN)** used to operationalize **Unique Device Identification (UDI)**.

Some governments have additionally sought to repurpose such a standard, or do develop their own country-unique standard, for purposes of **Health System Management** including uses such as medical device public procurement, tendering, and/or health system payment, reimbursement and functions related to economic regulation or procedure coding.

The success of the effort regarding **Regulatory and Quality** suffers risk of global regulatory divergence, with derivative costs to public health and the medtech supply chain, in part due to a lack of understanding in its function combined with a misuse of this system for other purposes including for **Health System Management**.

With a view to improving a general understanding of the subject as it supports global public health, this paper provides a summary of the successes and challenges to this global effort:

Successes

- For **regulatory and quality** purposes, a global standard exists in the form of the Global Medical Device Nomenclature (GMDN). The GMDN is an international standard developed and maintained by the international community through the GMDN Agency. Use of the GMDN is free of charge to governments and is used in over 80 countries.
- The GMDN is a globally harmonized nomenclature used to operationalize **Unique Device Identification (UDI)**.
- The GMDN design architecture is principally focused on use for **regulatory and quality** purposes to protect human health and safety.
- There is a **broad global consensus** of many (but not all) governments, particularly the medical device regulatory authorities focused on **regulatory and quality,** that the GMDN is the most technically appropriate standard for this purpose.
- There is a **broad global consensus** of the global medical technology industry, supply chain and health care providers that the GMDN is the most technically appropriate standard for purposes of **regulatory and quality**.
- This broad consensus on a medical device nomenclature between the parties is consistent with international medical device regulatory convergence and regulatory reliance which are high-level objectives of the International Medical Device Regulators Forum (IMDRF), the World Health Organization (WHO), the Global Harmonization Working Party (GHWP) and the World Trade Organization (WTO). The existence of an international medical device nomenclature standard in

the form of the GMDN optimizes patient access to medical technologies and lowers costs to health systems by eliminating the need for medical device manufacturers to comply with hundreds of non-compatible, non-interoperable and redundant nomenclatures required in applications such as device design, labelling, regulatory certification/approval, regulatory registration and/or quality management systems.

Challenges

- While GMDN is the most widely used medical device nomenclature standard in the world, it is not universal. Most notably, the European Union recently developed its own Medical Device Nomenclature system (EMDN) despite having been one of the architects of the GMDN[1,2].
- The GMDN design architecture was not originally intended, nor is it currently optimized for, use for **Health System Management**. More fundamentally, the architecture of an identification / nomenclature / classification system designed to maximize efficacy for purpose of **regulatory and quality** is inherently different than one designed for purpose of **Health System Management.**
- There is a desire by some governments, particularly health authorities focused on **Health System Management** to have a medical device nomenclature that can effectively be used for non-regulatory purposes including medical device public procurement, tendering, and/or health system payment, reimbursement, and related functions.
- Unlike the harmonized approach of using nomenclature for purposes of **regulatory and quality** applications, there is a significant divergence of positions on the need, associated device definitions and appropriate form of a global medical device nomenclature between governments, particularly those health authorities focused on **Health System Management.**
- Several governments have developed, or have proposed developing, their own region-unique or country-unique medical device nomenclatures for **Health System Management.** Examples include systems in China, Japan, Turkey the proposed Colombian Semantic Standard.
- The development of most, if not all, of these **Health System Management** medical device nomenclatures has been done without application of **Good Regulatory Practices**[3] including a **Regulatory Impact Assessment** examining:
    - The effects on patient access to medical devices that may eventually need to comply with hundreds of different and country-unique **Health System Management** nomenclatures, whether the impact will be in the device design, labelling, regulatory registration, certification/approval, or quality management system requirements.
    - Whether a higher-level classification of GMDN codes could be used for this purpose.

[1] The technical rationale for the EU regulatory divergence away from the GMDN via the EMDN have not been made public. The issuance of such regulatory rationale is generally a recommended element of Good Regulatory Practices as outlined by the OECD.
[2] It is possible that the EU development of the EMDN constitutes a technical barrier to trade in violation of the World Trade Organization Technical Barriers to Trade Agreement, in particular articles 2.4 and 2.2.
[3] Including the GRP guidance of the WHO.

- How the development of a region or country-unique nomenclature is consistent with the health objectives of the IMDRF, WHO, GHWP.
- How the development of a region or country-unique nomenclature is consistent with the trade objectives, international treaty obligations and domestic legal requirements deriving from membership in the WTO and other regional, sub-regional and bilateral trade agreements.
- Exhausting one of the above options, examining whether it would be a better use of public health resources to utilize the existing **Health System Management** nomenclature of another country (taking into consideration the WHO guidance on reliance[4] and relevant trade flows and supply chains).
- The resources required to maintain a country-unique nomenclature in a comparison of other health outcomes that could be achieved – considerations including IT systems, staff hiring qualifications, training, and retention of trained staff et al.

- For **regulatory and quality** or **Health System Management** purposes, the subject of medical device nomenclature is highly technical – complicating easy understanding and/or easy analysis and comparison between systems. The GMDN alone involves multiple definitions, acronyms, systems, protocols, and standards. Examples include: UDI, UDI-DI, UDI-PI, GS1, AIDC, HCT/P, GTIN, DPM, GSMP, UDID, GDSN, et al.
- There remains considerable confusion deriving from a lack of understanding and proper differentiation between the concepts of medical device **identification, nomenclature** and **classification (non-risk and risk)**.

The following information is provided to assist in the clarification and understanding of terminology regarding GMDN and Unique Device Identification (UDI)

Description of data used to identify Medical Devices

Unique Device Identification (UDI). This is a code allocated by a manufacturer to a product. The code must conform to a recognised international standard and follow a format allocated to the manufacturer by an organisation that is internationally recognised, such as GS1 (https://www.gs1.org/industries/healthcare/udi) or HIBCC (https://www.hibcc.org/). These standards organizations are referred to as UDI Issuing Entities (or Agencies). Usually, the code (which can be numeric and alpha-numeric) is printed on the product or packaging in both human readable and machine-readable format, e.g., barcode (referred to as a data carrier). This facilitates the auto-identification and data capture of the code via the use of scanners to read the code on the device label.

Because the code is globally unique, it removes the potential for confusion caused by various manufacturers choosing the same model number for different devices.

[4] https://www.interamericancoalition-medtech.org/regulatory-convergence/wp-content/uploads/sites/4/2021/06/GRelP_WHO_TRS_1033-Annex-10.pdf

The cost of using an international standard to identify a medical device is absorbed by the manufacturer. Many device manufactures have been using the standards for many years to track and control devices in the global supply chain. There are many benefits to using these international standards, but the benefits can only be realized if they are recognized globally. National or Regional standards add complexity and cost for each market.

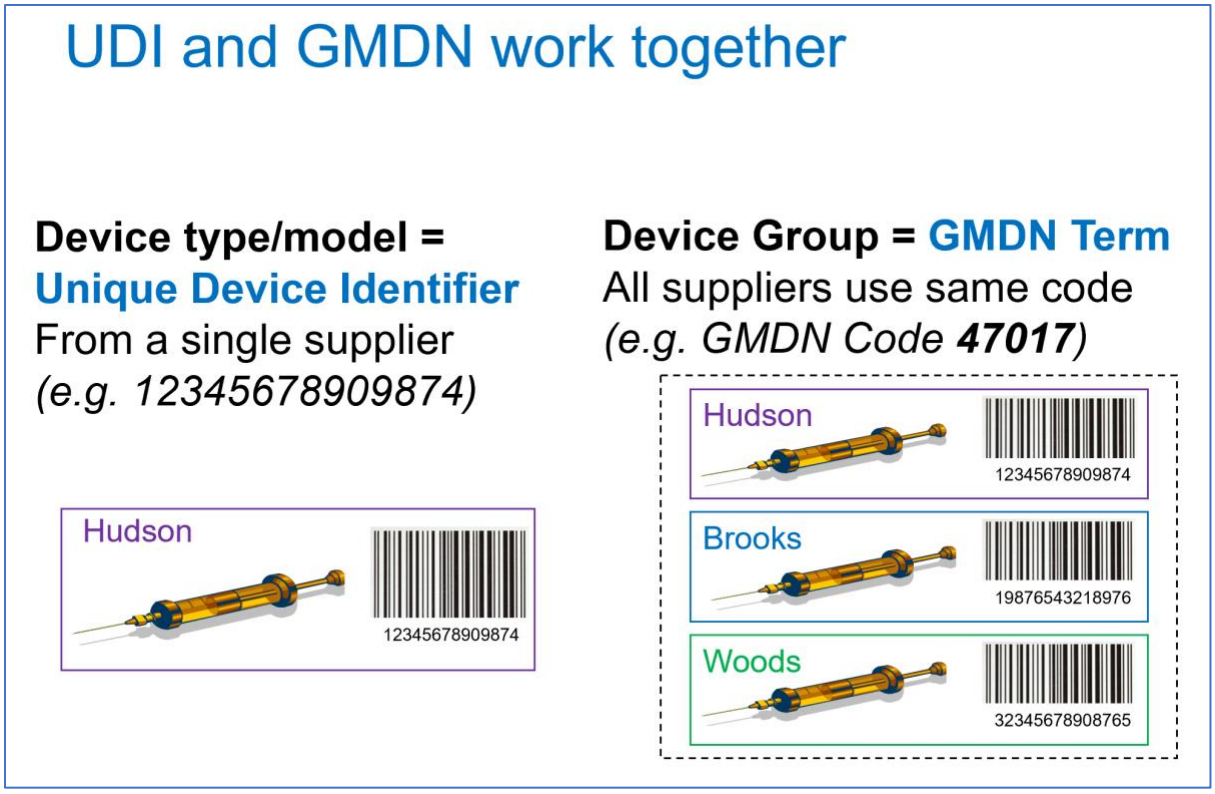
UDI-Device Identifier (UDI-DI). This is the part of the UDI code that identifies the version or model of the device. The global company prefix (assigned to the manufacturer) and format of the UDI code is provided by the Issuing Entity to the manufacturer to create the Unique Device Identifiers. The UDI-DI is normally listed in a national register of devices. An example of a UDI-DI Issuing Entity's standard is the GS1 GTIN: (https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf).

In the terminology of the IMDRF, the Device Identifier of the UDI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. This mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package configuration. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code).

UDI-Production Identifier (UDI-PI). This is the part of the UDI code that contains more specific information about the production control method used by the manufacturer for a particular device. Depending on the method, either the batch number, expiration date or serial number of the product may be provided. The UDI-PI is not included in a national register of devices. The UDI-DI and UDI-PI are used when the manufacturer has identified a problem with a device and needs to recall it. An example of the types of production identifiers that are used for the UDI-PI in the GS1 standard is available here (https://www.gs1.org/industries/healthcare/udi).

Nomenclature. This is a standardized name given to a type of device, irrespective of the manufacturer. The nomenclature should help identify medical devices that have the same function and similar design. The nomenclature should be up to date and represent the latest medical technology available and be in the local language. A medical device's nomenclature is stored in a database and is not part of labelling as it is not static. The most used nomenclature for medical devices is the GMDN (www.gmdnagency.org).

Only the GMDN maintains translations in the Spanish and Portuguese languages.
Access to the GMDN is free of any charge for all users, including manufacturers.



Risk Classification. This is a coding given to a medical device by a regulatory body. It denotes the product has risk characteristics that determine the most appropriate regulatory procedure to follow, in order that the product's safety can be assessed. Most regulators use a system with 3 or 4 risk groups. A medical device's risk class is stored in a database and is not part of labelling as it is not static. An example of a risk classification is the US FDA classification (https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device).

Product Classification. This is a coding given to a product or service as part of an asset management or financial inventory systems often found in a healthcare setting. It usually covers a wide range of products and services, such as medical devices, drugs, nutrition, clothing and can include labour and overhead costs. Due to the wide range of products, the descriptions tend to be simple and not suitable for other purposes, such as product safety assessment. A medical device's product classification is stored in a database and is not part of labelling as it is not static. An example of a product classification system is UNSPSC (https://www.unspsc.org).

Unique Device Identification Database (UDID). The UDI-DI should be stored by the manufacturer in a national device register. The UDI-DI should act as a key in a UDI Database to find information about the device including the manufacturer's identity, manufacturer's device description, nomenclature and regulatory approval information. It is recommended that a UDID is used to create an effective national register of devices. An example of a national device register is the US FDA GUDID (https://accessgudid.nlm.nih.gov).