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Comparative Study of GMDN (Global Medical Device Nomenclature) & EMDN (European Medical Device Nomenclature)

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KEYWORDS

GMDN, EMDN, unique code names, medical device nomenclature, etc.

ABSTRACT:

In order to adequately define and categorize the numerous major advancements and breakthroughs in the field of medical devices in recent years, a thorough nomenclature system is needed. This article compares the global medical device nomenclature (GMDN) with the European medical device nomenclature (EMDN) and gives an overview of medical device nomenclature. A standardized method of identifying and categorizing medical equipment, known as medical device nomenclature, ensures uniformity and promotes efficient communication among healthcare practitioners, governing authorities, manufacturers, and other stakeholders. It is important to managing the medical equipment as a whole, post-market surveillance, and regulatory approval processes. It offers a thorough framework for giving medical devices distinctive code names depending on its intended application, technology, and feature. The European Medical Device Nomenclature (EMDN), in contrast, is a system that concentrates primarily on the naming and categorization of medical devices inside the European Union (EU). The European nomenclature incorporates extra standards and specificities relevant to the EU market while ensuring conformity with the global nomenclature.

While establishing a standardized framework for categorization and identification is a goal shared by both global and European medical device nomenclatures, there are some discrepancies between them. The discrepancies are mostly caused by differences in regulatory standards, geographical peculiarities, and the necessity to deal with particular problems within each jurisdiction. To promote international collaboration and trade, efforts are undertaken to preserve alignment and harmonization between the two nomenclatures.

Introduction:

A medical device, as opposed to a pharmaceutical or biologic, works by means of physical, structural, or mechanical activity as opposed to chemical or metabolic action on the body or within it. It can be a device that is used to detect, prevent, lessen, treat, cure, or monitor an illness or other problems. Examples of these include instruments, apparatuses, machines, implants, tools, and in vitro reagents.

Some example of medical devices:

- One time use supplies, such as syringes, catheters, face masks, bandages, and so forth.
- Implantable (including artificial heart valves, pacemakers, intraocular lenses, prosthetic limbs,etc.)
- Imaging (including X-rays, MRIs, CT scanners, ultrasounds, etc.)
- Medical supplies (such as nebulizers, patient monitors, hemodialysis machines, and anesthesia devices).
- Computer-aided diagnostic software.
- In-vitro diagnostics, such as glucose meter, COVID-19 testing, HIV tests, etc.
- Personal protection equipment, such as a mask,

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gloves, and gowns.

• Instruments for surgery and laboratories (forceps, scissors, surgical sponge, etc.) [1, 2]

All medical devices and associated health products are categorize and identified using a naming and categorization system called the nomenclature of medical devices. Medical devices can be classified into one of five thousand or twenty-four thousand different kinds, depending on the categorization and terminology. They range from the most basic to the most sophisticated, affordable to highly pricey medical gadgets now on the market. The number and variety of medical devices are expanding daily, necessitating the use of accurate medical device nomenclature for their supply, tracking, and procurement.

The existence of several nomenclatures makes it challenging to share crucial information between people and organizations, this can impact not just a person's wealth and society, but also their health. It complicates the tracking of medical equipment supply, trade, and acquisition. Lack of a standardized nomenclature has a negative impact on some significant data, including:

Patient safety, intended medical device use, and regulatory status are all important. Technical details, negative outcomes, accessibility, and other.

Standardizing medical device categorization and nomenclature is essential for recording and reporting medical devices at all levels of healthcare, for a wide range of applications, and throughout the whole healthcare system. Therefore, WHO is attempting to create a system of medical device nomenclaturethat is accessible, transparent, and standardized worldwide.

Standardization is essential for:

1. Classification for regulatory approval processes
2. Grouping and evaluating innovative technology
3. Supporting device descriptions for universal health coverage benefit packages
4. Streamlining procurement
5. Grouping of devices in electronic health records and other health information system[1,2]

According to the WHO, the following criteria must be met by medical device nomenclaturesystems:

1. An open approach and methods.

2. A clear process for regular update (e.g. Annually)
3. Categorized and subcategorized hierarchies to fulfil stakeholder demands

4. The usage of medical devices outside of highly regulated nations;

5. The use of terminology that are mutually exclusive; and

6. The availability of phrases in other languages. [1, 3]

GMDN:

In accordance with ISO 15225, the Global Medical Device Nomenclature (GMDN) code was developed in cooperation between the EU, EFTA, USA, and Canada. The GMDN terms can betranslated using specialized software, however they are only available in English. A medical device must be registered in order to use this naming system. [1]

Here are a few significant moments in GMDN's history:

1.1991 saw the first worldwide workshop on standardizing the nomenclature for medicalequipment.

2. A global standard nomenclature for medical equipment has been under development by ISOsince 1996. GMDN is established.

3. In order to build the GMDN dataset based on the worldwide standard, a project council wasconstituted in 1997: "ISO 15225, Nomenclature," is a guidelines for a medical device nomenclature system that facilitates the sharing of regulatory information and other amendments have also been made[9]

Six already-existing nomenclatures of specific standing were used in order to speed up the preparation of the GMDN. These terms, which collectively amounted to 13,500, defined an extensive selection of health care

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products and medical equipment. The six nomenclatures were as follows:

(1) Medical Device Classification Names (CNMD) and in vitro diagnosis product. USA'sFood and Drug Administration (FDA) developed it.

(2) The classification of product used for in vitro diagnosis, by the European Diagnostic Manufacturers Association (EDMA). European use.

(3) Technical Aids for Disabled Persons Classification according to ISO 9999. Use internationally.

(4) JFMDA, the Japanese Medical Device Nomenclature. Applied in Japan.

(5) The Norwegian Nomenclature is known as Norsk Klassifisering Koding and Nomenclature (NKKN),

(6) The Universal Medical Device Nomenclature System is known as UMDNS. Created by ECRIin the USA.

On the November, 1st, 2001, the GMDN was published as a CEN Report CR 14230 and asISO.TS 20225. [4]

The GMDN's main objective is to provide a single, global nomenclature system that the government may use to control medical devices. The main consumers of medical devices, which include healthcare professionals, as well as suppliers, manufacturers, conformity assessment organizations, and other related parties are impacted by this. As a result, there will only be one method available to assist patient safety with generic product descriptions. [1, 5]

The GMDN code is used for secure data sharing between authorized authorities and other parties, research, medical record keeping, e-commerce, post-market surveillance information exchange, and inventories. serves as the generic descriptor to standardize device identification globally. [4, 6]

Benefits of international medical device naming: It provides a common nomenclature that makes communication and information sharing between international regulatory partners concerning medical devices easier. In addition to the advantages to the nation, a uniform nomenclature is supplied, enabling the government authorities and the industry to efficiently interact and exchange medical device data. Regarding the regulatory body, the GMDN provides guidelines for appropriately and consistently identifying the device groups and creating descriptive definitions that are unique to each device group. In particular, authorities' use Of them will help to advance data management for post-market operations and nomenclature practices that are consistent across generations. Global terminology for medical devices.

The ISO 15225 Nomenclature - Medical device nomenclature data structure standard outlines the standards that must be met for the GMDN's overall structure. The fundamental structure of the GMDN data is seen in Figure 1. Three levels of the data are used to characterize it, together withan external fourth level, and each level include information that varies in level of precision. [4]

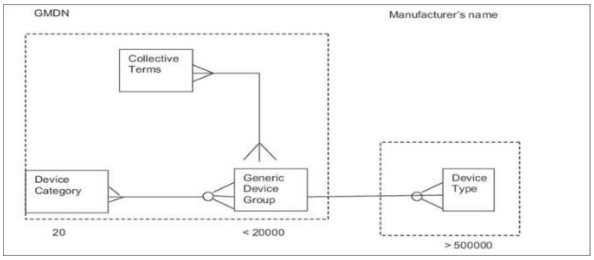

Fig. Organization of GMDN data.

The device category has the most GMDN data. It divides the whole medical device product market into the highest level categories based on device application, technology, or other common characteristics. Although the standard allocates codes for up to 20 categories, there are now 16 recognized categories for devices. The categories of medical equipment are as follows. [4, 6]

Generic collection of devices the most detailed level of product aggregation, depends on shared technology or goal, is the general equipment group. The generic device groups are related to four distinct GMDN term types. These words with their alpha-identifiers consist of thefollowing:

1. Template term (T) and 2. Preferred term (P)

3. Multiple-linked synonyms (MS) and 4. Synonyms (S) [4, 6]

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Each phrase in the GMDN has been given a special code. This offers protection in the event of misunderstand, linguistic difficulties, or differences in data systems. The code is a five-digit cardinal number that increases incrementally and sequentially starting at 10000. In all references to the GMDN or data transaction, the code should always be utilized and referred to as the information's bearers.

01-Active implantable devices	10- Single use devices
02- Anesthetic and respiratory devices	11- Assistive products for persons with disability
03- Dental devices	12- Diagnostic and therapeutic radiation devices
04- Electromechanical medical devices	13- Complementary therapy devices
05- Hospital hardware	14- Biological derived devices
06- In vitro diagnostic devices	15- Healthcare facility products and adaption
07- Non active implantable devices	16- Laboratory equipment
08- Ophthalmic and optical devices	17, 18, 19, 20 Reserved
09- Reusable devices	

1 Codes in the 1–9999 range: The GMDN does not include codes in the 1–9999 range. These may be assigned by any end user and utilized as each user sees fit in their local data system, as described in the standard.

2 Codes between 10,000 and 30,000: In the GMDN, codes between 10,000 and 30,000 are represented, and they have been set aside solely to signify the ECRI organization's original code for its USDNS phrases that have been adopted for use in the GMDN. The goal isto automatically transfer the UMDNS term represented by the ECRI code to the GMDN term now represented by the same GMDN code for the benefit of GMDN users.

3 Codes over the 30000 range: All codes above the range of 30000 were created by GMDN. [4,6]

Table 1. Example of a GMDN Preferred Term for medical devices.

MDN Code: 35965 GMDN

Term Name: Hydrocephalic valve

GMDN Definition: A non-active implantable device that functions as part of a hydrocephalic shunt system and is used to reduce the increased pressure from the excessive accumulation of cerebrospinal fluid (CSF) around the brain, by controlling the flow of the fluid. The operating pressure is typically pre-set prior to implantation (by the manufacturer or the surgeon), and the valve is activated when the ventricular (brain) pressure rises above the pressure setting of the valve. Some valve designs may facilitate re-adjustment of the pressure settings in situ using, e.g. a dedicated programmer [5].

2. Information in the form of a 5 digit numeric GMDN Code is cross-referenced to a precisely defined Term Name and Definition, as seen in this example:

- GMDN Term Name: Scalpel, single-use
- GMDN Code: 47569
- GMDN Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

EMDN:

EMDN was started on November 1st, 1999. In Europe and the European Union, medical devicesare coded and categorized using the EMDN system, which is also used in numerous regulatory processes including product registration and tracking. It offers a uniform method for classifying and identifying medical devices within the EU.

The way in which Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (IVDR) are implemented in relation to the European database on medical devices (EUDAMED).
Manufacturers will utilize it, among other things, to register medical devices in EUDAMED, where each Unique Device Identifier - Device Identifier (UDIDI) will be connected to it.

As it primarily serves regulatory purposes to support MDR and IVDR requirements, the EMDN is essential to MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance, and post-market data analysis, among other things. It provides patients with crucial information about any medical devices they may have on the market that are already registered with EUDAMED, in addition to the information about their own devices. [10]

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In accordance with criteria and requirements set by the European Commission and EU regulators in the Medical Device Coordination Group (MDCG), as well as based on orientations provided by the MDCG, the EMDN was established in response to a notice from the European Commission indicating the utilization of the Italian Ministry's "Classificazione Nazionale Dispositivi medici (CND)" as the basis for the future EMDN. Stakeholder discussions and CND preparation work were conducted with relevant experts during 2019 and 2020. On May 4, 2021, the EMDN's firstversion was made public.

The EC and EU authorities together established certain essential core concepts on which theEMDN is built. These guidelines involve, but are not limited up to:

(a) Regulators-led: Regulators are limited to the management, validation, updating, and advice of the nomenclature system.

(a) Structured: The nomenclature has clear grading that allows words and codes to be usefully grouped into different types and groups.

(c) Expected: The nomenclature's organization and content are steady enough to support a range of regulatory purposes while yet allowing room for future technical advancement.

(d) Transparency: The process for revising terms and definitions in the nomenclature is sound and take the needs of regulators and the greater healthcare sectors into consideration.

(f) All-inclusive: based on practical application and palpable requirements, the periodic evaluations are available to all.

(f) Accessible: All users have complete access to the words, explanations, and codes.

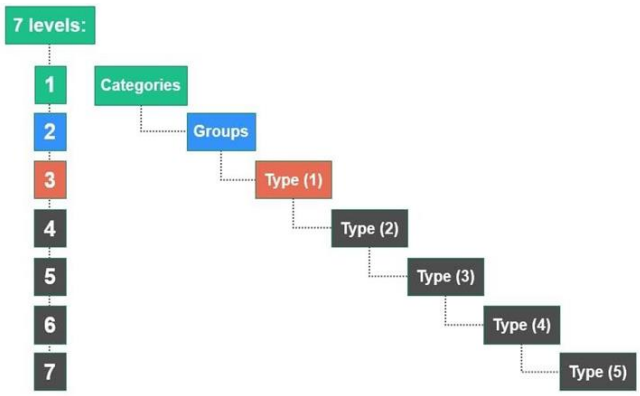
(g) Accessible: No producer, natural or legal person, many be subjected to price adjustments or discrimination when using the nomenclature in contrast to other operators.

(h) International: at the time of the MDR/IVDR's application date, recognized globally. [10, 11,14]

The alphanumeric structure of the EMDN, which is built at the seven-level hierarchical tree,defines it. The grouping of medical equipment is divided into 3 levels:

Groups are at the second level of the hierarchy, whereas categories are at the first level.

- Types: the 3 hierarchical level, which, when required, develops into the 1º, 2º, 3º, 4º, and 5ºlevels of detail.



It groups medical device each alphanumeric code starts with alphabet designating the device's"CATEGORY," followed by two digits designating its "GROUP," and a string of numbers designating its "TYPE." 13 is the maximum permitted number of digits. [10, 11, 12, 13]

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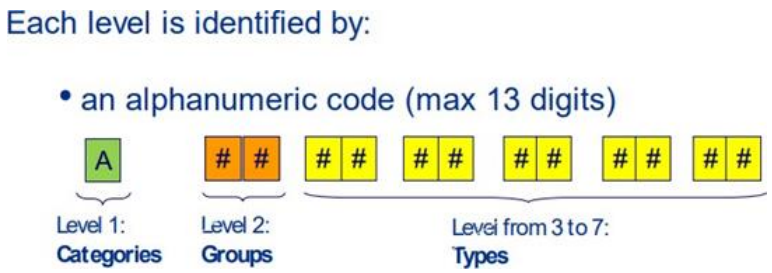

Comparison of GMDN and EMDN:

	Global medical device nomenclature(GMDN)	European medical device nomenclature(EMDN)May 2021
Organization owner	GMDN Agency	European Commission
Governance	Private	Public
Transparent methodology to define terms.	Defined by agency with input from members, including industry.	Defined by MDCG, with open input
Hierarchical organization	Multiple	Single
Free available as global public good	No	Yes
Translations (available languages)	25	3
Supports Unique Device Identifier (UDI)	Yes	Yes
Available for use in all health-related databases (public systems).	No	Yes
Webpage	https://webgate.ec.europa.eu/dyna2/emdn/	https://www.gmdnagency.org/
Governance	Medical Device Coordination Group from EU Members States. https://ec.europa.eu/health/medical-devices sector/new-regulations/guidance-mdcg-endorsed-documents-and-otherguidance_en	GMDN agency, nonprofit private organization. Board of Trustees: https://www.gmdnagency.org/About/Board (no government representation in the Board)
License requirements	No requirement's	Requires registration GMDN and copyright; https://www.gmdnagency.org/Legal/License

Number of total terms	7,000	24,800 GMDN terms, in addition about 2,000 high level terms.
Transparent	No	Yes
Freely available, downloadable, exportable terms, codes and hierarchies	No	Yes
Non proprietary	No	Yes

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Conclusion:

A standardized approach for classifying and identifying these devices is provided by medical device nomenclature, assuring uniformity and enhancing communication between diverse stakeholders, including manufacturers, healthcare providers, regulatory agencies, and researchers. Two well-known naming schemes for medical devices are GMDN and EMDN. Both terminologies employ codes for identification, information interchange, and regulatory compliance in the medical device sector and both have hierarchical structures.

Medical device nomenclature systems provide effective regulation, post-market surveillance, and traceability while improving the safety, effectiveness, and quality assurance of medical equipment. They contribute crucial elements to the ecosystem of medical devices, fostering openness, interoperability, and patient safety in healthcare systems.

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