World Health Organization

Survey – Questions for Medical Devices Trade Associations

As mandated by WHA74 and for input towards EB 150.
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MD Industry Association	Global Medical Technology Alliance (GMTA)
Specific company	N/A
Contact information (name, email)	Janet Trunzo, jtrunzo@advamed.org
Website	http://www.globalmedicaltechnologyalliance.org/
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WHO thanks you very much for your participation in the meeting to discuss the standardization of medical devices nomenclature, as mandated by WHA74.

Please find below the survey for Medical Devices Industry Associations, as mentioned during our meeting. Please provide all the evidence required for every statement provided (for example, website screenshots, links to your website or attach the documents required).

1. What are the major problems that Industry faces when using medical device nomenclature(s)?

Currently, diverging nomenclatures mean increased cost and burden for manufacturers. The variety of nomenclatures defeats the primary purpose of a nomenclature on a global level, that is to provide a universally accepted means of identifying every medical device on the market according to its intended use and/or other characteristics. Challenges include:

- different methodologies to assign terms
- effort in familiarizing with the various systems in order to determine the applicable codes
- difficulties in keeping up with all the changes (for example, as the EUDAMED database is in process of being released for UDI module, our members find themselves needing to learn and map out existing GMDN and FDA PT codes to EMDN and developing training and ensuring all documentation will have the correct coding for registration. Additionally, these members need to work with their service providers to update IT systems and documentation, validation, and post market surveillance systems)
- effort in maintaining an up-to-date overview of codes that are assigned to a device
- IT and documentation impact in case of changes
- review of DoC or relevant conformity declarations (that usually carry one or more codes)
- impact on other stakeholders in healthcare, public procurement, reimbursement systems, Market Surveillance systems
- no link between names used by regulatory agencies, supply chain and final users
- difficulties in exchanging information about a medical device between stakeholders
- difficulties maintaining SOP's; product registrations; UDI systems; risk management; Post Market Surveillance; procurements; distribution and other places where codes are used.

- The inherent differences between GMDN and EMDN: More detailed versus overarching systems.
- New additional costs, in cases where codes are revised or added – this now has costs for updating regulatory documentation, CE certificates (depending on class) and EUDAMED updates, along with the possible need for international re-registrations as a secondary consequence.
- Risk of use of nomenclatures for purposes different for which they were designed or in not applicable scopes. (e.g., proposal of use GMDN to grouping devices for applying price controls in Colombia).

In jurisdictions where a large portion of medical devices are manufactured elsewhere, it is important to keep in mind that in addition to issues faced by manufacturers, importers and distributors are also impacted. In addition to the problems reported by DITTA, we identify the following challenges:

- Incorporate different nomenclature systems in their data bases, SOP´s, processes etc. for equivalent products, according to the nomenclature system adopted by different manufacturers.
- Implementation of nomenclature systems required by local authorities despite products already having a name or code provided by the nomenclature system used by the manufacturer.
- Requirements for use of nomenclatures for purposes different for which they were designed or in not applicable scopes.

One example of the last point could be the project of semantic standardization in Colombia, where one of the proposals in evaluation is associating the nomenclature system to price control initiatives by using e.g. GMDN code for grouping products to apply price ranges; this kind of practices make impossible to differentiate service or supply models like reverse logistics. Also regarding this last point, multiple purpose nomenclatures could pose challenges because of divergent priorities/goals of different uses that would be competing and conflicting at the updates of the coding. Nothing prevents that a Regulatory driven nomenclature is used for other areas listed: but the governance of the nomenclature should serve only one purpose which would drive the update/creating of new codes

Other difficulty related to nomenclature in our region is that some regulators use it to address the registration process, like in Peru where registration is made by common name; if it changes it´s necessary to regrouping or splitting active sanitary licenses during lifecycle or renewal. The use of GMDN as a common name currently affects the number of licenses that must be submitted to register a system. When UMDNS is used to group, the code assigned by the manufacturer sometimes is outdated or erroneous with respect to the official database.

Time and effort to become able to utilize the various systems in order to determine the applicable codes. For example, as the EUDAMED database is in process of being released for UDI module, there is a need to learn and map out existing GMDN and FDA PT codes to EMDN and developing training and ensuring all documentation will have the correct coding for registration. Additionally, it is required to work with service providers to update IT systems and documentation, validation, and post market surveillance systems to do the same.)

2. Do you find the WHO work on medical device nomenclature convergence useful? Please justify.

Worldwide, many jurisdictions use at least one official nomenclature system, like GMDN or EMDN or developed nationally, other states use more than one system and others do not have any. A standardized, unambiguous and globally accepted system for naming and coding medical devices at the global level would be extremely beneficial, not only for manufacturers.

A consistent unique global and harmonized nomenclature could improve several areas related to medical devices, such as:

- allow the same code to be used across jurisdictions
- exchange information about a medical device between stakeholders, including generation of reports and big data management
- encourage use of single terminology throughout the lifetime of a device
- support quality, safety, efficiency and traceability in device registration
- integration of EHRs and PHRs with home monitoring devices
- procurement
- inventories
- refurbishment
- decommissioning
- reports of adverse events
- descriptions and interpretations of data to monitor incidents and to identify root causes and "systematic" failures
- PMS and vigilance activities
- comparison of data from different devices within one nomenclature group
- support of benchmarking between countries by using more consistent aggregation rules

For jurisdictions where economic limitations impact the provision of healthcare services, a standardized and globally accepted system for naming and coding medical devices will:

- promote the adherence of the different stakeholders to initiatives of harmonization, transparency, and ethics
- facilitate the reporting of information related to medical devices to health authorities
- contribute to the improvement of traceability and patient safety
- facilitate the implementation of post-market surveillance programs
- streamline business process, registration, and data maintenance
- reduce costs and burden generated by the implementation, use and maintenance of diverse nomenclature systems and optimizing resources along the E2E supply chain
- single terminology will also eliminate differences between nomenclature for interpretation and would increase the terminology bank by many folds, greatly reducing the amount of new code requests
- identification and processing of changes to nomenclatures including handling of code obsolescence and new code requests requires manual work. This increases the risk of errors and the negative impact on data quality and consistency of nomenclature, thereof the need for convergence
- In addition multiple nomenclature systems add further efforts to manufacturers, particularly for those with a wide ranging product portfolio.

- Convergence of nomenclature via existing systems as GMDN is also important to prevent the need for mapping which is labor intensive and difficult to keep current.

3. What are your proposals for WHO regarding nomenclature of medical devices?

GMTA believes that the WHO should not develop its own, separate, nomenclature for medical devices but instead promote an existing one. The decision for the specific nomenclature should be taken by the jurisdictions in WHO, in consultation with the International Medical Device Regulators Forum based on the following desired characteristics:

- Clear purpose and scope of use
- Univocal (having only one meaning)
- Unambiguous (a single clearly defined meaning, including rules for the use multiple codes if applicable)
- Identifiable by codes and terms
- Provided with definitions
- Available in different languages (meaning that also updates need to be done in all languages, keep up with conflicts in the translations)
- Free of charge (freely available to all the stakeholders, like manufacturers to link their devices with a specific term and add this term to UDI databases, but also conformity assessment bodies or healthcare providers)
- No restrictions for its use through copyrights.
- Easy to use
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- Inclusive (inclusion of all medical devices defined as such in some countries but not in others, and new innovative devices)
- Provided with performant IT system (able to handle multiple requests at the same time, downloadable, easy to search, simple user interface, multi-language system, send notifications for updates)
- Endowed with helpdesk (for user support)
- Regularly maintained (procedure for a periodic review to keep it up to date, to take into account new requests for new technologies and it needs to be transparent and defined, it needs to handle obsolescence)
- Transparent (transparent methodology to create/assign new codes)
- Stable (it cannot change continuously but it needs to have consistency)
- Provided with mechanism for regular stakeholder feedback (review structures in place to ensure that all stakeholders (experts, regulators, procurers, and users) from different regions are able to regularly provide feedback according to the global needs and able to comment and discuss on proposed modifications)
- Global (accepted worldwide) with international agreement it would replace existing nomenclature used for device identification.

Regarding a possible mapping between nomenclatures (EMDN and GMDN), we would like to point out that:

- A one-to-one mapping will likely be very difficult, as several codes in one nomenclature may be mapped onto several codes in a different nomenclature
- Any mapping between systems would have to be constantly updated due to changes of the respective nomenclatures which would require considerable dedicated resources at WHO

We understood that an initial mapping of EMDN and GMDN was developed when EUDAMED was set up. It would be useful if this mapping could be made available publicly in an easily accessible format. We are not aware of an available, accurate mapping between the EMDN and GMDN (and note that any mapping would be accurate for only a limited time without constant updates). We also believe that any mapping exercise should identify and misalignments or challenges.

4. Is your organisation willing to participate in WHO's work on nomenclature? If yes, in what way and in what area?

GMTA is happy to continue participation in discussions on this topic. However, GMTA does not currently have the resources to systematically invest in any mapping exercise ourselves. If WHO decides to conduct a mapping exercise, GMTA may be available to provide expertise on an ad-hoc basis in case input is needed on the mapping of specific codes related to devices in the GMTA members product portfolio

5. Have you had any experience working with Unique Device Identifiers? If so, please describe any nomenclature-related work in this area.

Yes, the GMTA and its members has been very active in the development of UDI systems across the globe, and has dedicated significant time and energy to advocating for a single, harmonized approach to UDI adoption, consistent with the IMDRF. A copy of the GMTA UDI white paper can be found here: http://www.globalmedicaltechnologyalliance.org/papers/GMTA%20UDI%20White%20Paper.pdf.

6. General comments

II. Work for convergence/ standardisation /access

1. Please describe the ways your organization currently is willing to support WHO in the work for convergence and standardisation of medical device nomenclature by completing the following.

2. Does your Agency map to other existing Nomenclatures? (Please select the applicable option(s), when applicable). Not in most instances, but some do.

Nomenclature	Yes	No	N.A.
EMDN			X
GMDN			X
UMDNS			X
UNSPSC			X

3. If you answered "yes" to the question 3 of section II, please indicate the periodicity of mapping updates. Please provide your answer in the table below, when applicable:

	Periodicity of mapping updates				
Mapping with the following nomenclature	**Once a year**	**Twice a year**	**Quarterly**	**Other**	**Comments**
EMDN					**As needed**
GMDN					**As needed**
UMDNS					
UNSPSC					

4. If you answered "yes" to the question 3 of section II, please indicate if you fully or partially mapped nomenclature(s). If it is a partial mapping, please be so kind to indicate which section(s) were mapped.

	Extent of mapping		
Mapping with the following nomenclature	**Full mapping**	**Partial mapping**	**Sections mapped (if partial mapping)**
EMDN			**Insufficient response time to address this question**
GMDN			**Insufficient response time to address this question**
UMDNS			
UNSPSC			

5. Please describe the challenges you face for mapping for the specific products that you commercialize

Described above.

6. Has your organization calculated the costs of mapping to other existing nomenclatures? Please present your estimates. No

Nomenclature to be mapped against your nomenclature	**Estimate cost of mapping (in dollars)**
EMDN	
GMDN	
UMDNS	
UNSPSC	