Survey – Questions for Medical Devices Trade Associations
As mandated by WHA74 and for input towards EB 150. August 2021

<table>
<thead>
<tr>
<th>MD Industry Association</th>
<th>DITTA</th>
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</thead>
<tbody>
<tr>
<td>Specific company</td>
<td></td>
</tr>
<tr>
<td>Contact information</td>
<td>Annika Eberstein, <a href="mailto:eberstein@cocir.org">eberstein@cocir.org</a></td>
</tr>
<tr>
<td>(name, email)</td>
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<tr>
<td>Website</td>
<td><a href="https://www.globalditta.org/">https://www.globalditta.org/</a></td>
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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
- 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.

Examples of challenges for specific nomenclatures:
GMDN – finding the right code or having to submit a new code request when a code is not available; also having to track when a code becomes obsolete and an alternative is not identified;
EMDN – finding the right code; knowing to which level the code must be identified on a submission or a DoC.
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, others 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
- 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

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

DITTA supports that WHO should not develop their 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:

- 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
- Granular (but not too much) (have hierarchies by which terms and codes could be meaningfully grouped into categories and subcategories, defined on different criteria, like intended use, anatomy, reusability, etc.)
• 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 obsolescences)
• 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)

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 certainly be useful if this mapping could be made available publicly in an easily accessible format.

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

DITTA does not currently have the resources to systematically invest in any mapping exercise ourselves. If WHO decides to conduct a mapping exercise, DITTA would 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 DITTA 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.

Several DITTA member associations have contributed or are currently contributing to the development of UDI systems and / or nomenclatures for medical devices in their respective jurisdictions.


In addition, our member companies are actively engaged with UDI and jurisdictional requirements across the globe, including the use of different nomenclatures.

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).

<table>
<thead>
<tr>
<th>Nomenclature</th>
<th>Yes</th>
<th>No</th>
<th>N.A.</th>
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<tbody>
<tr>
<td>EMDN</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>GMDN</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>UMDNS</td>
<td>X</td>
<td></td>
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<tr>
<td>UNSPSC</td>
<td>X</td>
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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:

<table>
<thead>
<tr>
<th>Periodicity of mapping updates</th>
<th>EMDN</th>
<th>GMDN</th>
<th>UMDNS</th>
<th>UNSPSC</th>
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<tbody>
<tr>
<td>Once a year</td>
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<td>Twice a year</td>
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<td>Quarterly</td>
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<td>Other</td>
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<td>Comments</td>
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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.

<table>
<thead>
<tr>
<th>Extent of mapping</th>
<th>EMDN</th>
<th>GMDN</th>
<th>UMDNS</th>
<th>UNSPSC</th>
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<tbody>
<tr>
<td>Full mapping</td>
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<tr>
<td>Partial mapping</td>
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<tr>
<td>Sections mapped (if partial mapping)</td>
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5. Please describe the challenges you face for mapping for the specific products that you commercialize
6. Has your organization calculated the costs of mapping to other existing nomenclatures? Please present your estimates.

<table>
<thead>
<tr>
<th>Nomenclature to be mapped against your nomenclature</th>
<th>Estimate cost of mapping (in dollars)</th>
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<tbody>
<tr>
<td>EMDN</td>
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