World Health Organization

Survey – Questions for the Nomenclature Agencies

As mandated by WHA74 and for input towards EB 150. August 2021

Agency / Organization	**European Medical Device Nomenclature (EMDN)**
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Date	**10/09/2021**

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 the Nomenclature Agencies, 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).

I. General questions on nomenclature structure, access, and copyright

1. Please provide an overview of the processes used for: code development and maintenance, requests for updates, change control procedures, communication, and distribution of update versions. Who performs them and the periodicity?

Code development and maintenance of the European Medical Device Nomenclature (EMDN) is managed by the Medical Device Coordination Group (MDCG) subgroup on Nomenclature (NOM WG), where representatives by each EU Member State is represented. In addition to Member State representatives, stakeholder and patient organisations are also active participants in this working group.

Requests for updates can come from various actors through the use of a public platform. Therefore input could be submitted Member States, Notified bodies, industry, other stakeholders, WHO, etc. Member States evaluate requests coming from additional actors. The platform is public and open to all.

Change control procedures are established and overseen by the Member States in the NOM WG. The policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community. The proposals are assessed and a proposal is agreed upon by the NOM WG. The final approval is then agreed upon by the governing body MDCG.

Communication and distribution of update versions is managed by the European Commission and is made through an official communication through our communication platforms, including the MDCG. In addition, the communication campaign maintained by the European Commission will offer an option for users to sign up for a communication channel related to the EMDN.

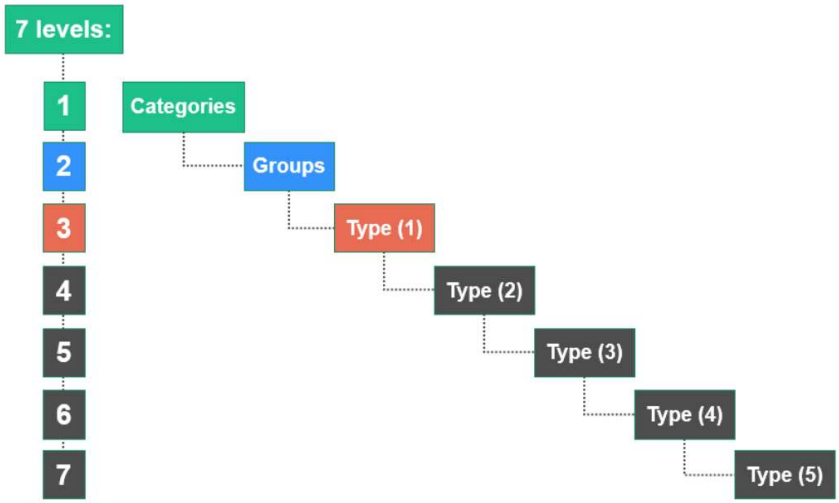
Periodicity of updates are foreseen on an annual basis. An ad-hoc update procedure is currently under discussion with Member States, which should only be utilised on an established need basis.

Please find in this link more information about the EMDN:
https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-12_en.pdf

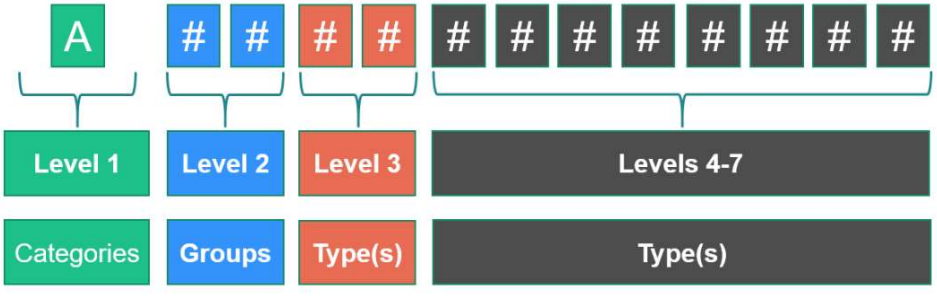
2. Please describe in detail the structure of your nomenclature - hierarchy, levels, etc.

The EMDN is characterised by its alphanumeric structure that is established in a seven-level hierarchical tree. It clusters medical devices into three main levels:

- Categories: the first hierarchical level,
- Groups: the second hierarchical level,
- Types: the third hierarchical level (which expands into several levels of detail (1°, 2°, 3°, 4° and 5°), where necessary.



Each alphanumeric code begins with a letter referring to the 'CATEGORY' for which the device falls under, followed by two numbers indicating the 'GROUP' and a series of numbers which refer to the 'TYPE'. The maximum number of digits is set at 13.



3. Please provide a copy of your license agreement including any subscription or other costs associated with the use of your nomenclature.

The EMDN has no license agreement or require any subscriptions or costs associated with its use. Three of the essential principles of the EMDN are transparency, inclusivity, availability and accessibility (see question 3 in the following Q&A:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-12_en.pdf)

Transparent: the policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community.

- Inclusive: the periodic reviews are open to all the stakeholders listed in point 1,, based on real-world use and demonstrable needs.
- Available: the terms, descriptions and codes are available, in full, to all users.
- Accessible: no manufacturer or natural/legal person should be subject to fee or suffer from any discrimination, compared to other operators, in relation to the use of the nomenclature.

The NOM WG is currently discussing the potential need to ask users who wish to utilise EMDN on a more extensive basis (more than identifying appropriate codes for individual devices) to simply inform us and provide us with a contact point. This could be useful from the perspective of update communication. In this manner, we can ensure that those users utilising EMDN on a more extensive basis are appropriately informed and appraised of any changes/updates/issues related to the nomenclature.

4. Please describe how codes, names and descriptions are accessed by user groups.
4.1 Is a login/ registration/ subscription required?
No login, registration or subscription required. As highlighted above, organisations who wish to use the EMDN on a more extensive basis could be asked to simply provide a notification and a contact point.

4.2 Are their APIs available ?
Yes

4.3 Is the full dataset (codes, names, descriptions, hierarchies) downloadable?
4.3.1. No, explain
4.3.2. yes, only partial, explain conditions
4.3.3 Yes, only with previous registration or login, explain. 4.3.4. Yes, can be open and downloaded by anyone, anywhere. Yes, the EMDN can be downloaded in its entirety with no previous subscription or login of any sort. The link for the download is the following: Download EMDN (download full list)

4.4 Is the information freely available? Yes, all information and support related to the EMDN is completely free available, including guidance documents etc. In addition, a UDI/Nomenclature helpdesk has been established and is primarily aimed at supporting users with UDI and EMDN questions they may have. This helpdesk is also completely freely available. If not, please specify which are the costs associated with the access of your nomenclature?
4.5 Which electronic platform are you using?

Commission created electronic platform: https://webgate.ec.europa.eu/dyna2/emdn

II. Work for convergence/ standardisation /access

1. Please describe the ways your organization currently supports WHO in the work for convergence and standardisation of medical device nomenclature by completing the following.
   Please select the applicable options you make available (open access) and describe any conditions tied to that option.
   b) _x___ the codes
   c) _x___ the terms
   d) _x___ the definitions*
   e) __x__ the hierarchy

2. For each item not checked above, please describe how you will be willing to make each item available to support convergence and meet WHO Member States requirements.

* Currently, only the CND (predecessor of EMDN) codes/terms have definitions readily available, to be updated as a consultation instrument different from the nomenclature. Work is currently underway to update those codes to reflect the newly created or amended EMDN codes. Those definitions will also be freely available.
Note: In the updated version of CND and in the EMDN , we no longer refer to terms but rather descriptions.

3. Does your Agency map to other existing Nomenclatures? (Please select the applicable option(s), when applicable).

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

4. 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					
GMDN				**x**	The draft partial mapping which currently exists only gives a snapshot in time and is only applicable to some CND codes. Validation of this partial mapping has yet to be conducted by the GMDN Agency.

UMDNS					
UNSPSC					

5. 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			
GMDN		**x**	Only applicable to predecessor of EMDN – CND. Registries in elenco (Italian registry of medical devices), and only for some levels in different categories. As noted above, this has yet to be validated by GMDN.
UMDNS			
UNSPSC			
EDMA/GIVD		**X**	A partial mapping of EDMA/GIVD nomenclature with EMDN category W has been performed, with a full correspondence reflected in section W01.This mapping is not validated by GIVD.

6. Please describe the challenges you face for mapping

Maintaining the mapping that reflects the needs of regulatory authorities and of the huge Health community, accurate and up to date where other nomenclature systems are changing on frequent basis. In order for a mapping to be of use, it must be agreed upon/validated by the other agencies. However, given that the frequency of updates for the EMDN is only on an annual basis, supportive informative actions by other agencies would be necessary to keeping the mapping accurate.
Additionally, copyright issues are a limiting factor to making a mapping publically available.

7. Has your agency calculated the costs of mapping to other existing nomenclatures? Please present your estimates.

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

III. Translations to other the official Languages of the UN

1. In which languages is your nomenclature available?

Currently, the EMDN has been produced in Italian and translated to Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenia, Slovene, Spanish and Swedish.

A translation validation exercise by regulatory authorities of those countries is currently underway to approve these draft translations and render them available within EUDAMED.

2. Is your agency willing to work on translations?

N/A

3. Has your agency calculated the cost of translating your nomenclature into the six UN official languages (English, Spanish, French, Russian, Chinese, and Arabic)? If yes, please provide the estimates in the table below.

Six UN official languages	Estimate cost of nomenclature translation (in dollars)
English	**n/a**
Spanish	**n/a**
French	**n/a**
Russian	**n/a**
Chinese	**n/a**
Arabic	**n/a**

4. Is your Agency willing to work on mapping to other existing nomenclatures? (Please select the adequate option(s), when applicable).

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

IV. Unique Device Identification

1. Have your nomenclature terms been assigned UDI-DIs (device identifiers of UDIs)? (Please select below the applicable answer)

Yes	x
No	

2. If yes, please indicate if the following sentences are true or false (Yes or No) and provide the solicited elements, if applicable:

   a. *Our nomenclature is required in UDI regulatory requirements.* Please provide a link to the regulation

Regulation (EU) 2017/745 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
Regulation (EU) 2017/746 on in vitro diagnostic medical devices:

https://eur-lex.europa.eu/eli/reg/2017/746/oj
b. *Our nomenclature is not required in UDI regulatory requirements. However, we have assigned some or all of our nomenclature terms to UDI-DIs.* Please provide a file with this assignment.

3. If not, are you willing to work to assign UDI-DIs to your Nomenclature terms? (Please select below the applicable answer)	
Yes	
No	

V. Financial information

1. How is the development, maintenance and updating your nomenclature funded (please describe what are the sources and mechanisms of funding)?
Funding is currently sustained by the Italian Ministry of Health. Translations and validations have been conducted through EU budget. As for technical assistance to the transition from CND to EMDN, this was facilitated by the EU MDCG Working Group on Nomenclature.

2. What is the cost of development, maintenance and updating your nomenclature per year? (please select the adequate statement).	
Less than 100.000 dollars	
Between 100.000 and 250.000 dollars	
Between 250.000 and 500.000 dollars	
Between 500.000 and 1.000.000 dollars	
Between 1.000.000 and 2.000.000 dollars	
More than 2.000.000 dollars	
Comment:	N/A

3. How many FTE annually do you need for the development, maintenance and updating your nomenclature?
8-10 units of dedicated specialized personnel are employed in the development, maintenance and updates of the nomenclature.

3.1 Is the electronic platform used for (please select the applicable options)?	
a) only nomenclature of medical devices	x
b) other products related to medical devices	x
c) other products besides medical devices d) comments:	

3.2 When was the latest update on your electronic platform?
June 2021

3.3 How often do you update the data?
Annual update – technical significant changes Minor changes – as necessary (could be spelling mistakes or bug fixes)

VI. Nomenclature use to promote public health/patient safety/device evaluation

1. Has your agency developed initiatives with governments/regulatory agencies to promote public health/patient safety/device evaluation
N/A. The European Commission works jointly with regulatory agencies of medical devices on these topics.

VII. Nomenclature to be used in WHO document and electronic platforms

2. Are you willing to provide access to code, name, definition or hierarchy to WHO so that it can be used in:
WHO publications? Yes WHO electronic platforms? Yes a. MEDEVIS https://medevis.test.evidenceprime.com/ b. EDL https://edl.medevis.test.evidenceprime.com/ c. UHCC https://www.who.int/universal-health-coverage/compendium#:~:text=The%20UHC%20Compendium%20is%20a,health%20services%20and%20health%20interventions. d. ICD 11 https://icd.who.int/en WHO supports open access to the published output of its activities as a fundamental part of its mission and a public benefit to be encouraged wherever possible. More info: Copyright (who.int) Please comment:

VIII. Final comments, if any
