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Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General

1. This report presents an update on the work of the Secretariat in November and December 2021, as well as the outcomes of the information session for Member States held on 16 December 2021,[1] including with regard to the nomenclature used by countries; the characteristics of their nomenclature systems; a feasibility mapping exercise; and consultations with stakeholders.

COUNTRY DATA

2. The 2021 Country Survey on Medical Devices, which will be presented in the 2021 Global atlas of medical devices, with updated information to December 2021,[2] found that 10.6% of countries had a nomenclature system based on the Universal Medical Devices Nomenclature System (UMDNS),[3] 11.1% had one based on the Global Medical Device Nomenclature (GMDN)[4] and 2.8% had one based on the European Medical Devices Nomenclature (EMDN).[5] Moreover, 10.6% of countries had more than one nomenclature, 43.9% did not have an official nomenclature and 21.1% had a nationally developed nomenclature. In analysing the information, the WHO Secretariat has noted that some Member States "based" their national nomenclature on a proprietary one (such as GMDN) but due to licence and copyright issues created an adaptation for use by national stakeholders, which created multiple slight variations from the original nomenclature.[6] Based on the most recent consultation, the number of Member States that do not have an official nomenclature system has increased to 43.9%,

[1] See document EB150/14, para. 23.

[2] Data as at 10 December, with updated information to be presented in the 2021 Global atlas of medical devices in the first quarter of 2022 (https://www.dropbox.com/s/abdnyp2okoyifsa/GAMD_20210827_all.pdf?dl=0) (accessed 29 December 2021).

[3] See https://www.ecri.org/solutions/umdns (accessed 17 November 2021).

[4] See https://www.gmdnagency.org/ (accessed 17 November 2021).

[5] See https://webgate.ec.europa.eu/dyna2/emdn/ (accessed 17 November 2021).

[6] See EB150/14, para. 7.

which indicates the important need to establish an open nomenclature available for all Member States and stakeholders.[1]

CHARACTERISTICS OF THE FOUR NOMENCLATURE SYSTEMS

3. WHO recognizes that EMDN was only launched in 2021. Nevertheless, as EMDN needs to be used by all manufacturers when registering their medical devices in the EUDAMED database,[2] the number of devices in EUDAMED is continuously growing. The EMDN is the only one among the four nomenclature systems that is freely available, with no copyright licence required, and is governed by European Member States.

4. EMDN and the United Nations Standard Products and Services Code (UNSPSC) have only one hierarchical structure, in comparison with the polyhierarchical structure of UMDNS and GMDN. The EMDN translations are in process but are still not available.[3]

FEASIBILITY MAPPING EXERCISE BETWEEN THE FOUR NOMENCLATURE SYSTEMS

5. During the information session held on 23 September, the WHO Secretariat proposed carrying out a feasibility study of a mapping from October to December 2021, for only a sample of about 10% of type of devices existing in the market, as a proof of concept. For this specific pilot project, WHO selected a number of medical devices, with a particular focus on those related to COVID-19, and conducted an innovative machine learning automated mapping process, using multiple public data sources.

6. The pilot mapping was carried out using the assignment of nomenclature codes/terms to 13 129 identified medical devices in public databases, representing 510 manufacturers. In this feasibility process, 100% of the sample nomenclature assignments were successfully mapped across EMDN, GMDN and UNSPSC. And only a total of 426 items (only 3% of the sample) were not assigned to UMDNS codes and those items could not be automatically mapped to the other nomenclatures.

7. The results of the mapping were tested by a WHO medical devices team and terms were included in the MeDevIS[4] platform, and in a lower-middle-income country. The mapping exercise included the use of machine learning models to flag nomenclature assignments for expert review of the mismatched items. Due to time constraints, feedback on the flagged items was not included in initial model testing but will be used to improve future mapping results.

[1] See data from the 2017 Global atlas of medical devices (https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices) (accessed 29 December 2021) and the 2021 Global atlas of medical devices to be issued in the first quarter of 2022 (https://www.dropbox.com/s/abdnyp2okoyifsa/GAMD_20210827_all.pdf?dl=0) (accessed 29 December 2021).

[2] See https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf (accessed 28 December 2021).

[3] The EMDN can be accessed and downloaded in pdf and excel format at: https://webgate.ec.europa.eu/dyna2/emdn/ (accessed 11 December 2021).

[4] See https://medevis.who-healthtechnologies.org/ (accessed 16 December 2021).

8. The outcome of this innovative mapping exercise was very positive, as more than 90% of codes were automatically obtained. The numbers of nomenclature assignments to unique device identification-device identifiers (UDI-DIs) that were flagged for review were as follows:

EMDN: 208 devices or 1.6% of the sample set

GMDN: 61 or 0.5% of the sample set

UMDNS (reviewed by UMDNS): 550 or 4.2% of the sample set

UNSPSC (reviewed by GS1 and Symmetric): 673 or 5.1% of the sample set.

9. Initial results indicate that the mapping methodology proposed, which relies on publicly available nomenclature assignments to items (UDI-DIs), will decrease the overall costs of nomenclature mapping; increase the accuracy of mapping; allow for measurable improvement over time through expert feedback on the automated results; and improve the quality and consistency of nomenclature assignments to trade items in public UDI databases.

10. Now that the methodology and outcomes have been presented to the stakeholders, studies are being conducted to compare manual individual exercises with the automated process, with feedback from the community of stakeholders and open access to all.

OTHER CONSULTATIONS

11. Between November and December 2021, a total of 29 consultations with stakeholders were held.

12. Weekly consultations were held with the four nomenclature agencies (EMDN, GMDN, UMDNS and UNSPSC) to share mapping methodology and receive their agreement as nomenclature experts that the WHO approach was sound and to obtain and incorporate their feedback on mapping results in order to improve the automated process. The initial sample mapping results illustrate that is possible to automatically map between EMDN, GMDN, UMDNS and UNSPSC using the assignment of nomenclatures at the item level (device identifier of UDI or UDI-DI), matching algorithms across public data sources and machine-learning to assist in rolling up item-level assignments into optimal category groupings.

13. On 9 and 10 December, participants were informed of the progress made in the mapping exercise. Health technology managers and biomedical and clinical engineers were invited to a meeting held in December and the following entities will do usability testing of the mapping in their institutions: Department of Health, South Africa; Andhra Pradesh Medtech Zone (AMTZ) Ltd, India; Colegio de Ingenieros Biomédicos de México (CIB) A.C., Mexico; the United Nations Office for Project Services (UNOPS); Médecins Sans Frontières International (MSF). The latter institutions have conducted a mapping exercise for their products, which will allow the system to be tested.

14. Consultations with other regulatory networks continued through December 2021, including presentations at: the African Medical Devices Forum, the Global Harmonization Working Party, the Network of regulators from the Region of the Americas and the South-East Asia Region, and their input has been considered.

15. Various rounds of meetings were held with two organizations from the medical device industry, the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT

and Radiation Therapy Trade Association (DITTA), which are also non-State actors in official relations with WHO. The mapping tables were shown to them along with the list of unmatched terms and their help was requested to work with their manufacturers. GMTA requested more meetings and DITTA will continue the work in January 2022. Other individual manufacturers or industry regional organizations are willing to provide feedback to the mapping exercise. WHO intends to post the tables for global consultation in 2022.

16. The mapping, with approval from the four nomenclature agencies, was tested using procurement data from a lower-middle-income country. It was also approved and tested by loading the mapping into a WHO platform, so that it could be used by all stakeholders (MeDevIS).[1] It should be noted that the codes and names in the MeDevIS exercise and for the open consultation have to bear the wording "Copyright by GMDN agency" and "ECRI with reserved rights"; nevertheless, the mapping exercise made progress thanks to the willingness of the four nomenclature agencies and the support of stakeholders. The more organizations that volunteer to work on the mapping, the faster the information will be available and disseminated.

17. At the information session held on 16 December, some Member States asked for a return to the original concept of having a single nomenclature only, as the one recommended by WHO, especially for Member States that do not have a nomenclature system. Therefore, WHO will draft considerations for a selection process, indicating the characteristics and uses of each of the four systems so that Member States can select according to their needs. The usability testing described above can further inform the selection process based on the specific requirements.

18. If the mapping continues to expand to include more than 80% of types of available medical devices in the market by 2023, it will constitute a WHO database that allows all stakeholders to find the related terms for each type of medical device. It will also become a convergence tool for those that have different systems in their region, country or within their institutions. It should be noted that the mapping should be an ongoing process.

19. The WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices,[2] which was issued in 2017 is being reviewed by a drafting group. It includes a nomenclature section looking towards harmonization and convergence. The drafting group has proposed to help develop a decision tree to support Member States in deciding which nomenclature is better suited to their needs.

20. If the Executive Board so decides,[3] the mapping exercise will continue and an updated version could be made available to all Member States in 2023. Additionally, the Secretariat will finalize and make available to Member States a process to support the selection of an appropriate nomenclature, including an updated version of the WHO Global Model Regulatory Framework for Medical Devices This package could also be made available to all Member States in 2023. An assessment of the financial and administrative implications for the Secretariat is provided in a separate document.[4]

[1] See https://medevis-nomenclaturemapping.test.evidenceprime.com/ (accessed 16 December 2021).

[2] See https://apps.who.int/iris/handle/10665/255177 (accessed 13 December 2021).

[3] See document EB150/14, para. 25.

[4] Document EB150/14 Add.2.

ACTION BY THE EXECUTIVE BOARD

21. The Board is invited to note this report and provide guidance as to whether the mapping exercise should continue and be made available in the WHO Medical Devices information system (Medevis), so that countries can use it as a nomenclature reference tool.

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