World Health Organization

EXECUTIVE BOARD
150th session
Provisional agenda item 14

EB150/14
8 December 2021

Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General

1. In May 2021 a report on standardization of medical devices nomenclature was submitted to the Seventy-fourth World Health Assembly.[1] This topic had previously been discussed by the Executive Board at its 145th session in May 2019[2] and at its 148th session in 2021.[3]

2. The present report provides details of the Secretariat's continuing work in this area, which includes collected country data, the outcomes of multiple consultations, and a proposal for a first step towards convergence. This proposed first step would be a feasibility study on the challenges and benefits of using innovative mapping techniques to allow information of four of the most widely used nomenclatures to be publicly available on WHO platforms for use by Member States as a way towards standardization.

BACKGROUND

3. As stated in document EB148/13, medical devices, including in vitro diagnostic medical devices, are health products that are required for protection, prevention, diagnosis, treatment, rehabilitation and palliation and that do not have a pharmacological function. They are crucial for timely diagnoses, monitoring disease and well-being, providing treatment and ensuring good quality of life. Medical devices are essential for the attainment of the triple billion targets of WHO's Thirteenth General Programme of Work, 2019–2023, since they underpin universal health coverage, are central to responses to emergencies, and are required to monitor well-being.

4. As has been previously discussed in documents EB145/3 and EB148/13, the goal is to have a standardized international classification, coding and nomenclature for medical devices that would be available to all Member States and that would support: patient safety; access to medical devices for universal health coverage; emergency preparedness and response; efforts to increase quality of health care; and achievement of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). The system would facilitate the selection, regulation, assessment and management of medical devices, enabling them to reach the market faster, increasing availability and resilience of supply in health care systems in support of better health care for all.

---

[1] Document A74/9.

[2] Document EB145/3.

[3] Document EB148/13.

5. In document EB145/3, reference was made to a concept note produced in July 2018 in which the Secretariat proposed the principles that would underpin an international classification, coding and nomenclature of medical devices,[1] which are summarized below.

(a) Governance:

  (i) will have structures in place to ensure that all stakeholders are able to provide feedback.

(b) Classification, coding and nomenclature characteristics with:

  (i) a transparent methodology and processes for updates; and

  (ii) terms in other languages.

(c) Access of information, which:

  (i) can be referenced and used by regulators, procurers, managers and all users;

  (ii) is freely available and considered a global public good;

  (iii) can support the Unique Device Identifier system;

  (iv) facilitates simple and intuitive search; and

  (v) is available for use in all health-related database systems.

6. The 2021 Country Survey on Medical Devices, which will be presented in the 2021 Global atlas of medical devices,[2] found that 7% of countries had a system based on the Universal Medical Devices Nomenclature System (UMDNS), 8% based on the Global Medical Device Nomenclature (GMDN) and 2% based on the European Medical Devices Nomenclature (EMDN). Moreover, 28% had more than one system, 35% did not have an official system and 20% had a nationally developed system. WHO has therefore recognized that while a number of countries are using one or more of the four large nomenclature systems, there are a significant proportion that do not have a system.[3]

7. The goal is to avoid Member States, health providers, non-State actors and entities of the United Nations system continuing to develop their own nomenclatures because of a lack of available appropriate solutions to meet their needs, which will cause more divergence and future complexity for all stakeholders. The proposal, therefore, is for more collaboration, harmonization and convergence. Some Member States based their system on existing ones but, owing to limitations in licence agreements, had developed their own coding system, which complicates interoperability among all stakeholders.

[1] Request for input and collaboration towards international classification, coding and nomenclature of medical devices (concept note https://cdn.who.int/media/docs/default-source/medical-devices/conceptnotenomenclaturemedical devicesv13forconsultation.pdf?sfvrsn=e4174670_7, accessed 4 October 2021).

[2] Data as at 4 October, with updated information to be presented to Member States in December 2021 and reported in document EB150/14 Add.1.

[3] See https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices and https://www.dropbox.com/s/abdnyp2okoyifsa/GAMD_20210827_all.pdf?dl=0 (accessed 4 October 2021).

8. As indicated by the Director-General in his intervention on the subject made to the Executive Board at its 145th session, a global standard for naming medical devices is a perfect example of WHO's core normative standard-setting work.[1]

9. As stated in document EB148/13, having a nomenclature system in place for medical devices would be in line with the Health Assembly's mandate to the Secretariat, as contained in resolution WHA60.29 (2007) on health technologies, "to work … on the development … of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies, in particular medical devices".

MEMBER STATES' REQUESTS TO WHO

10. During the discussion on this topic at the Seventy-fourth World Health Assembly,[2] broad support was expressed for WHO's initiative to foster an accessible, transparent, harmonized and international standardized nomenclature of medical devices, with a transparent procedure for engaging stakeholders, including industry, and developing mapping between nomenclature systems.

11. In document EB148/13, WHO recognized that out of the four existing nomenclature systems used by more than one Member State – namely, the European Medical Device Nomenclature (EMDN),[3] the Global Medical Devices Nomenclature (GMDN),[4] the Universal Medical Devices Nomenclature System (UMDNS)[5] and the United Nations Standard Products and Services Code (UNSPSC)[6] – only the EMDN fully complies with WHO principles of governance, transparency and access. At the Seventy-fourth World Health Assembly, Member States therefore requested the Secretariat to explore mapping possibilities between EMDN and GMDN, and the need to further consult with regulators and industry. [2]

WHO'S RESPONSE TO MEMBER STATES' REQUESTS

12. The 2021 Global Atlas of medical devices is being updated and a survey and desk review was carried out.[7] All the documents have been posted for consultation. Meetings of the WHO Secretariat were also held to discuss information technology solutions (the WHO Priority Medical Devices information system (MeDevIS) and the platform of the International Statistical Classification of Diseases 11th Revision (ICD-11)).

13. Between July and 1 October, a number of consultations with stakeholders (29) were organized by the Secretariat at both global and regional levels. The following stakeholders were involved: nomenclature agencies (13); medical devices industry associations (3); entities of the United Nations

1 See document EB145/2019/REC/1, summary record of the first meeting, section 2.

2 See summary records of the Seventy-fourth World Health Assembly; Committee A, ninth meeting and tenth meeting, section 2.

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

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

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

6 See https://www.unspsc.org/ (accessed 17 November 2021).

7 2021 Country Consultation and Desk Review (https://www.who.int/publications/m/item/draft-for-review---overview-of-nomenclature-systems-for-medical-devices-in-who-member-states.-2021-country-consultation-and-desk-review, accessed 9 November 2021).

system and nongovernmental organizations (5); and health technology managers and biomedical and clinical engineers (3). Regional meetings of regulators in the African Region, Region of the Americas and European Region have begun and will continue in October and November 2021, and will be expanded to include regulators in other regions.

14. Consultations (13) were held with four nomenclature agencies, including three rounds of bilateral meetings with each nomenclature agency (EMDN, GMDN, UMDNS and UNSPSC) and one joint meeting with all the agencies. The agencies completed a survey addressing several aspects of the nomenclature, including willingness to work with WHO and to map, as well as addressing cost issues. Survey responses have been published on the WHO website.[1] The outcomes of the meetings were positive, with all agencies are now showing willingness to collaborate with WHO on convergence efforts and openness to working together. Moreover, some agencies are making efforts to comply with WHO principles, including transparency, full access and free availability.

15. Two rounds of bilateral meetings were held with the following seven entities: IAEA, UNDP, UNFPA, UNHCR, UNICEF, UNITAID and the United Nations Office for Project Services (UNOPS); and with six non-State actors in official relations with WHO, namely: the Clinton Health Access Initiative, the International Committee of the Red Cross, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Médecins Sans Frontières International, PATH, and the Stop TB Partnership. Their surveys are available on the WHO website.[1] In general, 50% of the entities consulted have developed their own catalogue/codification system, but these do not reflect any of the four nomenclatures, 64% were using for internal use only some aspects of the four relevant nomenclatures for reference in planning, budgeting, procurement and for their enterprise resource planning systems. None of the four nomenclatures were used for external matters, 21% of the entities do not use any of the four relevant nomenclatures and most have no experience of working with the unique device identifier system.

16. Regulatory agencies provided input to the country survey. The International Medical Device Regulators Forum organized a meeting in September 2021 to discuss and provide an update on the status of the nomenclature system. A meeting with the regulatory network from AMRO had also taken place on 1 October, where the urgent need to have a nomenclature system with terms in Spanish with synonyms and codes that could be used throughout the health care system and industry had been expressed. Consultations with other regulatory networks would continue through October and November 2021 and a report on status was planned for the next information session for Member States in December 2021.

17. Health technology managers and biomedical and clinical engineers were invited to two rounds of bilateral meetings, and one joint meeting with other stakeholders. Engineers from different regions expressed their concern at not having a harmonized nomenclature and how to address the challenges of having multiple nomenclatures existing globally and even within countries, as well as about the issue of languages and free accessibility. Engineers responded jointly to the survey through the International Federation for Medical and Biological Engineering – Clinical Engineering Division, published on the website.[2] They fully support WHO efforts towards nomenclature convergence. Many of the engineers from low- and middle-income countries stated that they had been forced to develop their own codification/nomenclature system, which was used primarily for computerized maintenance

[1] July–October 2021 – WHO consultation on nomenclature systems for medical devices, survey responses (https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature, accessed 9 November 2021).

[2] The International Federation for Medical and Biological Engineering is a non-State actor in official relations with WHO. The responses reflect the opinion of the engineers participating and are not part of an official country-level statement.

management systems and inventory, but this solution did not work for traceability of medical devices from planning to budgeting, procurement, regulation, comparison, health facilities assessment, health technologies assessment and techno-vigilance.

18. Three rounds of meetings were held with two organizations from the medical device industry, the Global Medical Technology Alliance and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association, which are also non-State actors in official relations with WHO. Both organizations had responded to the surveys, addressing the challenges of using the current nomenclatures, the need for convergence and the willingness to continue working with WHO on these matters, acknowledging the importance of nomenclature convergence/standardization and appreciating the fact that WHO will work with existing nomenclatures instead of creating a new nomenclature. They fully support WHO's efforts towards nomenclature convergence. Although not in a position to systematically dedicate resources to creating the mapping between nomenclature systems, they would be willing to provide feedback to the feasibility study as needed and, are available to provide expertise in specific areas.

19. At an information session for Member States held on 23 September, the Secretariat presented the status and findings from consultations and the next steps.[1] Various stakeholders were invited to make presentations, including the four nomenclature agencies, the medical technology industry, one United Nations agency and one non-State actor. The participants expressed willingness to continue working with WHO in this effort. A follow-up information session is scheduled for 16 December 2021 to present the mapping and WHO proposals.

20. During the information session, on 23 September, the WHO Secretariat proposed carrying out a feasibility study and mapping exercise from October to December 2021. Mapping and display of all four nomenclatures on WHO platforms is a first step towards improving nomenclature transparency, interoperability and convergence. The feasibility study will use an automated mapping process incorporating multiple public data sources (for example, the United States Food and Drug Administration's Global Unique Device Identification Database and the European Commission's European database on medical devices, or its surrogate, the *Elenco dei dispositivi medici*, Ministero della Salute, Italy). Data science principles will be applied to the mapping results, allowing the mapping to be used on WHO platforms. Lessons learned, study results and conclusions will inform the next steps and the long-term use of this approach.

THE WAY FORWARD

21. As requested by Member States during the 145th and 148th sessions of the Executive Board, and during the Seventy-fourth World Health Assembly, WHO will not be creating a new nomenclature system, but will continue working with the four most widely used nomenclature systems to work towards the WHO principles of governance, transparency and access, support mapping and harmonization.

22. Acknowledging that WHO hosts the ICD-11, on an electronic platform that allows consultation, synonyms, hierarchies and relations, and also includes a section on medical devices, WHO proposes to use this platform to display the mapping of the four nomenclature systems.[2] A set for COVID-19 devices using the EMDN is already available and further work will continue in 2021. The other two electronic

[1] Member States second information session on medical devices nomenclature (accessed 15 November, 2021)

[2] EMDN, GMDN, UMDNS, UNSPSC.

platforms, one that hosts the WHO model list of in vitro diagnostics (eEDL)[1] and MeDevIS,[2] which hosts the WHO list of priority medical devices, could display the nomenclature in their systems and link with the ICD-11 platform. These medical devices platforms will be linked to the universal health coverage platform.[3]

23. The outcomes of the information session for Member States in December 2021 will be reported in an addendum.

24. The proposed mapping of nomenclatures in WHO platforms, and publications, subject to agreement on the part of nomenclature agencies, is intended to support WHO's mandate to improve the accessibility, availability and affordability of safe and high-quality medical devices in order to support the achievement of universal health coverage and well-being and enhance emergency response.

ACTION BY THE EXECUTIVE BOARD

25. The Board is invited to note the report and consider the following draft decision:

> The Executive Board, having considered the report on standardization of medical devices nomenclature and the draft steps towards standardization referred to therein,[4]
>
> Decided to request the Director-General:
>
> (a) to continue the mapping and the use of the four nomenclature systems in WHO platforms and publications, with stakeholders collaboration;
>
> (b) to submit a report on progress made on the steps towards the standardization of medical devices nomenclature to the Seventy-sixth World Health Assembly in 2023.

= = =

[1] See https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1 (accessed 17 November 2021).

[2] See https://www.who.int/activities/prioritizing-medical-devices (accessed 17 November 2021).

[3] Universal Health Coverage Compendium (https://www.who.int/universal-health-coverage/compendium, accessed 17 November 2021). This includes the actions and tasks for benefits packages for Member States.

[4] Document EB150/14.