World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY **A75/11**
Provisional agenda item 14.8 **18 May 2022**

Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General

1. The Executive Board at its 150th session in January 2022 considered an earlier version of this report[1] and adopted decision EB150(10) on standardization of medical devices nomenclature.[2] The present document provides an update on the intersessional work of the Secretariat since that session of the Board, including the information session for Member States held on 31 March 2022. It addresses the need for standardization with the aim of having an international nomenclature based on existing ones, the possibilities of mapping, and the need to define a way forward during intersessional meetings with Member States.

BACKGROUND

2. Medical devices include thousands of types of medical technologies with purposes including protection, prevention, diagnosis, treatment, monitoring and palliation.[3] They are used across the health care system, from primary health care level to specialized care, and range from surgical masks to complex radiotherapy equipment. Their value chain includes: manufacturing, regulation, selection, assessment and management together with procurement, supply, training, maintenance, safe use and decommissioning. The Secretariat and many Member States have recognized the urgency of moving towards standardization of a nomenclature that will enhance the access to all types of medical devices for universal health coverage, outbreaks and emergencies and well-being, in line with the objectives of the Thirteenth General Programme of Work, 2019–2023.

3. In May 2018, the Seventy-first World Health Assembly considered a report by the Director-General on addressing the global shortage of, and access to, medicines and vaccines and adopted a decision on the subject, in which the elaboration of a road map report was requested.[4]

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[1] Documents EB150/14, EB150/14 Add.1 and EB150/14 Add.2.

[2] See decision EB150(10); see also the summary records of the Executive Board at its 150th session, eleventh meeting, section 4.

[3] For more information, see the WHO medical devices webpage: https://www.who.int/health-topics/medical-devices#tab=tab_1 (accessed 14 April 2022).

[4] See decision A71(8) (2018) and document A71/12; see also see also document WHA71/2018/REC/3, summary records of second and fifth meetings.

4. That report was submitted to and noted by the Seventy-second World Health Assembly;[1] it described milestones for a nomenclature, codification and classification of medical devices, which were later published in the WHO publication, *Road map for access to medicines, vaccines and other health products 2019–2013: comprehensive support for access to medicines, vaccines and other health products*.[2]

5. In 2018, WHO proposed principles aligned with all WHO's other data and guidelines: transparent, inclusive, publicly available, and accessible to all,[3] and took the first steps towards a proposed WHO standardized nomenclature.

6. The following resolutions of the World Health Assembly call for work on medical devices that will be enhanced by the standardization of nomenclature codes and terms for an eventual international nomenclature:

- WHA60.29 (2007) on health technologies (in particular, medical devices to develop norms and standards on medical devices);
- WHA67.20 (2014) on regulatory system strengthening for medical products, which specifically includes strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;
- WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, to support the exchange of information;
- WHA72.6 (2019) on global action on patient safety as a critical element of quality of health care;
- WHA72.8 (2019) on improving the transparency of markets for medicines, vaccines, and other health products including medical devices;
- WHA74.4 (2021) on reducing the burden of noncommunicable diseases through prevention and control of diabetes, recalling the WHO's global action plan for the prevention and control of noncommunicable diseases; and
- WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, to ensure quality, safe, effective and affordable technologies.

7. In order to support organized and standardized information for policy-makers the Secretariat sees the need for a move towards convergence of coding and nomenclature of medical devices in a standardized international classification in order to link with WHO's other international classification systems, such as the International Statistical Classification of Diseases and Related Health

[1] Document A72/17(https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf, accessed 21 April 2022).

[2] WHO. Road map for access to medicines, vaccines and other health products 2019–2023: comprehensive support for access to medicines, vaccines and other health products. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/330145/9789241517034-eng.pdf?sequence=1&isAllowed=y, accessed 14 April 2022).

[3] Request for input and collaboration towards international classification, coding and nomenclature of medical devices. Thirteenth version. Concept note, 24 July 2018 (https://cdn.who.int/media/docs/default-source/medical-devices/conceptnotenomenclaturemedicaldevicesv13forconsultation.pdf?sfvrsn=e4174670_7, accessed 14 April 2022).

Problems, the International Classification of Functioning, Disability and Health, the International Classification of Health Interventions, and the International Non-proprietary Name for pharmaceutical substances.

8. The Secretariat has submitted reports on the need to have a standardized international Nomenclature to four sessions of WHO's governing bodies and continuously updates the WHO website to present latest information.[1] These reports are listed below:

- In 2019, in document EB145/3, the Secretariat proposed a standardized international classification code and nomenclature system for medical devices. Many members of the Executive Board urged the Secretariat to work on the matter while others called for the Secretariat not to develop a new system but use one of the existing ones.

- In 2021, in document EB148/13, in response to the Board's request at its 145th session, the Secretariat stated not to develop a new nomenclature but instead to explore the potential uptake of the European Medical Devices Nomenclature. Some Board members then requested the Secretariat to work on a mapping of nomenclatures, define costs and perform consultations. Therefore, the Secretariat hosted multiple meetings and consultations with stakeholders, including an information session for Member States in September 2021,[2] meetings with the four most used nomenclature agencies, and more than 40 consultations (which are described in document EB150/14). The Secretariat developed a new method to map the nomenclatures of medical devices[3] and presented the WHO pilot feasibility study at the third information session for Member States in December 2021.[4]

- Document A74/9: the Seventy-fourth World Health Assembly noted the report, discussion of which continued to underline the importance of nomenclature and the challenges.[5]

- Document EB150/14 submitted details of the Secretariat's work done in 2021 and requested guidance on the next steps towards standardization. The Board adopted decision EB150(10), requesting the Director-General: (1) to continue the mapping and use of the four nomenclature systems in WHO's platforms and publications, with stakeholder collaboration, [and with the purpose of drafting a plan on the development of a WHO global nomenclature of medical devices] and (2) to submit a report on progress made on the steps towards the standardization

[1] For more information, see the WHO health product and policy standards webpage (https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature, accessed 14 April 2022).

[2] Member States second information session on medical devices nomenclature, 23 September 2021 (https://www.who.int/publications/m/item/member-states-second-information-session-on-medical-devices-nomenclature, accessed 14 April 2022).

[3] For more information, see the WHO nomenclature of medical devices webpage (https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature see section December 2021 mapping methodology description, video and results.

[4] Member States third information session on medical devices nomenclature, 21 December 2021 https://www.who.int/publications/m/item/member-states-third-information-session-on-medical-devices-nomenclature, accessed 14 April 2022).

[5] See document WHA74/2021/REC/3, summary records of the Seventy-fourth World Health Assembly, ninth and tenth meetings (https://apps.who.int/gb/ebwha/pdf_files/WHA74-REC3/A74_REC3-en.pdf#page=1, accessed 14 April 2022).

of medical devices nomenclature to the Seventy-sixth World Health Assembly in 2023. The Board also asked for intersessional meetings before the Seventy-fifth World Health Assembly.[1]

INTERSESSIONAL WORK DONE BY THE SECRETARIAT SINCE THE 150TH SESSION OF THE EXECUTIVE BOARD

9. Further to previous requests from the Board (at its 145th and 148th sessions) to consider the nomenclature systems in existence in order to avoid creating yet another one, the Secretariat continued to meet with the three private-sector agencies (the Global Medical Device Nomenclature, the Universal Medical Device Nomenclature System, and the United Nations Standard Products and Services Code), whose governance is not open to the public and whose procedures to define terms, additions, deletions or modifications are not publicly accessible, and with the European Commission. The most recent updates, as of 10 April 2022, are as follows:

- The Global Medical Device Nomenclature, managed by the non-profit GMDN Agency, launched a new five-year strategy in February 2022. Because it maintains a closed governance as before,[2] with licence and limited access only granted to registered users with copyrights,[3] and given the fact that it is not possible to use the code in public documents, it therefore cannot be considered a global public good.[4] The Agency updates its numbers daily, but it has 24 800 GMDN terms, in addition about 2000 high-level terms.

- The Universal Medical Device Nomenclature System, managed by the non-profit organization ECRI,[5] has begun modifying its system so as to be freely available and to post the list of medical devices on its site for public open access; this is still in process.[6] This system has no publicly available data that link to the unique device identifier to support automatic mapping. In March 2022, it included more than 43 000 terms: 30 608 entry terms and 13 025 preferred concepts, in English.

- The European Medical Device Nomenclature, governed by the Medical Device Coordination Group of Member States of the European Union,[7] continues to evolve to include more terms in the EUDAMED database[8] as well as more definitions. The translations are a work in progress

[1] See the summary records of the Executive Board at its 150th session, eleventh meeting, section 4.

[2] GMDN Agency Board (https://www.gmdnagency.org/About/Board, accessed 14 April 2022).

[3] GMDN, Licence agreement (https://www.gmdnagency.org/Legal/License, accessed 14 April 2022).

[4] As per definition provided in the Health Data Governance Summit (June 2021) document: pre-read: Health Data as a Global Public Good (https://www.who.int/data/events/health-data-governance-summit/introduction, accessed 30 April 2022).

[5] ECRI (https://www.ecri.org/about/, accessed 14 April 2022).

[6] ECRI. UMDNS (https://www.ecri.org/solutions/umdns, accessed 14 April 2022).

[7] European Commission. Guidance - MDCG endorsed documents and other guidance (https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en, accessed 14 April 2022).

[8] European Commission. The European Medical Device Nomenclature (EMDN) (https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf, accessed 14 April 2022).

but are not yet available.[1] The information is publicly available, and anyone can provide feedback. It includes about 7000 terms in 22 categories.

- The United Nations Standard Products and Services Code reports no changes.[2] It includes 3800 terms for medical devices, in English.

10. The 2021 Country Survey on Medical Devices, described in document EB150/14 Add.1 (paragraph 2) and whose results will be included in the 2022 Global atlas of medical devices with updated information to May 2022, had found that 43.9% of Member States did not have an official nomenclature and 21.1% had a nationally developed nomenclature.[3]

MAPPING POSSIBILITIES TOWARDS A STANDARDIZED NOMENCLATURE

11. In 2021, the Secretariat performed a pilot mapping exercise and did a feasibility study, mapping the four nomenclatures mentioned in paragraph 9 above for a sample of about 10% of the types of devices existing in the market, as a proof of concept.[4]

12. It should be noted that the four agencies showed support for the process, but the exercise cannot be continued unless:

- each agency is willing to make assignment of their nomenclature to the product's unique device identifier or other product identifier publicly available for use by the mapping tool;
- for the Global Medical Device Nomenclature, the unique device identifiers assigned by manufacturers are publicly downloadable from the United States Food and Drug Administration's public Global Unique Device Identification database through its identification system, AccessGUDID – preferably the codes should be available;
- for the European Medical Device Nomenclature, the unique device identifiers assigned by manufacturers are being populated in the European Commission's European database on medical devices, EUDAMED, but the contents are not yet publicly available; and
- each agency is willing to allow the results of the mapping with a full display of their codes and terms to be made publicly available on WHO's platforms.

13. It should be recalled that each system has different hierarchies, classification, coding and definitions and different processes to expand their lists, as described above (paragraph 9). Therefore, the automated mapping using machine learning, as demonstrated in the pilot project, would be the most efficient way forward.

14. Through some regional meetings and country surveys, the Secretariat confirmed that some Member States based their national nomenclature on a proprietary one (such as the Global Medical

[1] The European Medical Device Nomenclature can be accessed and downloaded in pdf and excel format at: https://webgate.ec.europa.eu/dyna2/emdn/ (accessed 14 April 2022).

[2] UNSPSC (https://www.unspsc.org/subscribe, accessed 14 April 2022).

[3] These data are currently being updated following Member States' request that the consultation period should be prolonged.

[4] See document EB150/14 Add.1 for detailed information.

Device Nomenclature) but because of licence and copyright issues created an adaptation for use by national stakeholders. The result has been the creation of multiple slight variations from the original nomenclature, which hinders interoperability, especially when using different languages.[1]

WHO'S PLATFORMS TO HOST MAPPING RESULTS

15. The Secretariat updated the electronic platform of WHO's Priority Medical Devices Information System (MeDevIS) only with the results of the pilot mapping project[2] so that it can be used by stakeholders as a reference and can host the results of any further mapping if that is done.

16. The Secretariat updated the extended codes of the International Classification of Diseases (11th revision) to including a section on medical devices, considering the 22-hierarchy structure of the European Medical Devices Nomenclature.[3] This can also be expanded and linked to MeDevIS and could display the Global Medical Device Nomenclature codes, if they are approved by the Global Medical Device Nomenclature agency.

17. WHO's electronic platforms will have interoperability between MeDevIS, the International Classification of Diseases (11th revision), and the UHC compendium,[4] thereby providing Member States with a comprehensive platform, not only for the characteristics and types of medical devices but also for their use in health interventions.

NEXT STEPS

18. Following further analysis, the Secretariat proposes to continue the automated mapping using the unique device identifier databases, with not all four systems but only the two that were discussed by the Executive Board at its 150th session – the European Medical Devices Nomenclature and the Global Medical Devices Nomenclature – and to present them on WHO's platforms in a standardized system.

Information sessions

19. The Secretariat held an information session for Member States on 31 March 2022, where Member States were informed about: the status of the respective nomenclature systems by the three private-sector agencies and by the European Commission for its public system; and the advances made by the Secretariat in 2021 and 2022 in placing the results of the pilot mapping project on WHO's platforms; and the outcomes of meetings held to discuss the algorithm for selecting a nomenclature in the update of the WHO Global Model Regulatory Framework for medical devices including the in vitro diagnostic medical devices[5] update.

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[1] See document EB150/14, paragraph 7.

[2] For more information, see WHO website. MeDevIS – Priority Medical Devices Information System (https://medevis.who-healthtechnologies.org/, accessed 18 April 2022).

[3] The example of the hierarchical structure, terms and coding for dialysers can be seen in the ICD-11 portal, see: https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f93666629 (accessed 18 April 2022).

[4] For more information, see WHO webpage. UHC Compendium – health interventions for universal health coverage (https://www.who.int/universal-health-coverage/compendium, accessed 18 April 2022).

[5] WHO. WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255177, accessed 18 April 2022).

20. The Secretariat has launched a call for members of the newly created Strategic and Technical Advisory Group on Medical Devices, whose terms of reference include developing strategic recommendations on the nomenclature of medical devices.[1]

21. A second information session for Member States took place on 29 April 2022. In line with decision EB150(10), further informal consultations will be held on 13 May 2022 in order to reach agreement on the draft steps towards standardization and to propose a way forward.

ACTION BY THE HEALTH ASSEMBLY

22. The Health Assembly is invited to note this report and to provide guidance on the way forward.

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[1] 2022 Call for experts: Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) (https://www.who.int/news-room/articles-detail/call-for-experts-STAG-MEDEV-2022) (accessed 22 April 2022).