

Standardization of medical devices nomenclature

Report by the Director-General

1. In May 2019 an item on standardization of medical devices nomenclature was on the agenda of the Executive Board at its 145th session, and the Board considered a report on the matter.¹ At the conclusion of its discussions,² the Board agreed to request the Secretariat to undertake further work on the matter, including consultations with Member States, and if necessary, to place the item on the agenda of a later session of the Board. The present report is submitted in line with the Board's request. It provides details of the Secretariat's response, which includes further analysis of existing nomenclature systems and the proposal for WHO to have an international nomenclature system that would be available for use by Member States.

BACKGROUND

2. As indicated in document EB145/3, the goal is to have an international classification, coding and nomenclature for medical devices (INMD) 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).

3. As indicated by the Director-General in his opening remarks to the Executive Board at its 145th session, the new approach of developing and adapting a global standard for naming medical devices is a perfect example of WHO's core normative standard-setting work.³

¹ Document EB145/3.

² See document EB145/2019/REC/1, summary records of the first meeting, section 5.

³ See document EB145/2019/REC/1, summary records of the first meeting, section 2.

4. Medical devices,¹ including in vitro diagnostic medical devices,² 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.

5. Having a nomenclature system in place for medical devices would facilitate efforts to strengthen the assessment, regulation and management of, and access to, medical devices. Establishing such a system would also 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”.³

MEMBER STATES’ REQUESTS TO WHO

6. During the Board’s discussion on this topic at its 145th session, broad support was expressed for WHO’s initiative to foster an accessible, transparent, harmonized and international standardized nomenclature of medical devices – noting the urgency of the task and the challenges to be faced – including the creation of an expert group on medical devices, the use of a transparent procedure for engaging all stakeholders, and the establishment of an online database of available medical devices with information on nomenclature and use.

7. The Secretariat was requested to provide a complete analysis of existing nomenclature systems, specifically the Global Medical Device Nomenclature (GMDN),⁴ and requested WHO to work with the International Medical Devices Regulators Forum⁵ in order to develop a harmonized approach.

¹ A medical device is an article, instrument, apparatus or machine (including mobile medical applications and software) that is intended by the manufacturer to be used alone or in combination in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. See Global Harmonization Task Force, document GHTF/SG1/N071:2012 (<http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search=>, accessed 13 October 2020).

² A subset of medical devices, defined as devices which, whether used alone or in combination, are intended by the manufacturer for the examination in vitro of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. They include reagents, calibrators, control material and test kits. See Global Harmonization Task Force. Definition of the terms medical device and in vitro diagnostic (IVD) medical device. Geneva: World Health Organization; 2012 (<http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf>, accessed 23 November 2020).

³ See document WHASS1/2006-WHA60/2007/REC/1 (<https://apps.who.int/iris/handle/10665/21893>, accessed 12 January 2021)

⁴ What is GMDN? Oxford: GMDN Agency; 2020 (<https://www.gmdnagency.org/Services/GMDN>, accessed 13 October 2020).

⁵ International Medical Devices Regulators Forum (<http://www.imdrf.org/>).

8. In view of the above, the Secretariat was asked to undertake further comprehensive analysis of existing systems and to propose a system which is transparent, accessible, free and internationally harmonized.

9. In document EB145/3, reference was made to a concept note produced in July 2018 in which the Secretariat had proposed the principles that would underpin an international classification, coding and nomenclature of medical devices, and invited input and collaboration.¹ Since then, WHO has been searching for a solution that complies with those principles, which are summarized below.

(a) Governance

- (i) Organizational and review structures should be in place to ensure that all stakeholders from different regions are able to provide feedback according to global needs.

(b) Classification, coding and nomenclature characteristics

The following are required:

- (i) a transparent methodology and processes;
- (ii) a transparent mechanism for regular updates (e.g. once per year);
- (iii) hierarchies grouped into categories and subcategories to meet stakeholder needs;
- (iv) medical devices used outside highly regulated countries;
- (v) mutually exclusive terms;
- (vi) availability of terms in other languages

(c) Access to information

Information should:

- (i) be capable of being referenced and used by regulators, procurers, managers and all users of medical devices (hospitals/health care workers and patients);
- (ii) be freely available and considered a global public good;
- (iii) support unique device identifier system;
- (iv) be accessible through simple and intuitive search;
- (v) be available for use in all health-related data base systems.

¹ Request for input and collaboration towards international classification, coding and nomenclature of medical devices. Concept note (https://www.who.int/medical_devices/priority/ConceptNoteNomenclaturemedicaldevicesv13forconsultation.pdf?ua=1, accessed 13 October 2020).

ANALYSIS OF EXISTING NOMENCLATURE SYSTEMS

10. As requested by Member States, during 2019 and 2020 WHO participated in various meetings, workshops and conferences, presenting the options and needs for standardized nomenclature. These included teleconferences hosted by the International Medical Device Regulators Forum.

11. WHO hosted a meeting at WHO headquarters in December 2019 for representatives of the four most widely used nomenclature systems: the Universal Medical Devices Nomenclature System, GMDN, SNOMED CT¹ and the National Classification of Devices (CND),² which was adopted by the European Commission and will form the basis of the European Medical Devices Nomenclature for the future European Medical Device Database.³ The objective was to define the characteristics of their systems and alignment with the WHO principles.

12. The WHO analysis concluded that, of the analysed nomenclatures, the one that complies with the WHO principles for international classification, coding and nomenclature of medical devices mentioned above, is the CND. Subject to the Board's consideration, the Secretariat is of the view that the other three nomenclature systems, including GMDN, which was mentioned as a possible option by some Member States during the discussions at the Executive Board in May 2019), would not be consistent with the WHO principles.

13. An online survey was launched through the WHO medical devices newsletter in November 2019.⁴ The preliminary results indicated that respondents found lack of compatibility/inter-operability, accessibility, awareness and definitions to be the most important challenges in the existing nomenclature systems.

THE WAY FORWARD

14. As requested by Member States during the 145th session of the Executive Board, WHO will not be creating a new nomenclature to be added to the existing ones, but will select from the available ones which one can be hosted, made available to all Member States and after a transition period, managed by WHO. Therefore, all previous proposals for coding systems developed by WHO in 2018 and presented at the Fourth WHO Global Forum on Medical Devices (Visakhapatnam, India, 13–15 December 2018)⁵ have been removed from the webpage of the Eleventh Revision of the

¹ The value of SNOMED CT. London: SNOMED International; 2020 (<http://www.snomed.org/snomed-ct/why-snomed-ct>, accessed 13 October 2020).

² Classificazione Nazionale di dispositivi medici (http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione, accessed 11 December 2020).

³ The CND Nomenclature. Brussels: European Commission; 2020 (https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_cnd_general_principles_en.pdf, accessed 13 October 2020).

⁴ WHO Medical Devices Newsletter, November 2019 (https://www.who.int/medical_devices/publications/WHO_Medical_Devices_November_2019_Newsletter.pdf?ua=1, accessed 13 October 2020).

⁵ Fourth WHO Global Forum on Medical Devices (https://www.who.int/medical_devices/global_forum/4th_gfmd/en/, accessed 12 January 2020).

International Statistical Classification of Diseases and Related Health Problems (ICD-11)¹ to avoid any confusion or duplication of efforts.

15. In order to advance the international classification, coding and nomenclature for medical devices (INMD), collaboration between WHO and the European Union has been ongoing and discussions related to the potential uptake of the European Medical Devices Nomenclature, once finalized by the European Union, have taken place. A transition period is foreseen until the European codes and definitions are available in English and translated into European languages, and then also made available in the ICD-11 nomenclature section.

16. WHO has initially added the 22 categories of the CND nomenclatures and all the terms related to the priority medical devices for COVID-19² to the WHO ICD-11 platform as a first step in convergence, which will ensure its compatibility with other WHO international classifications and web-based clearinghouse mandated by resolution WHA60.29, such as the Essential Diagnostic List (e-EDL), the Priority Medical Devices information system (MeDevIS), and subsequently the Universal Health Coverage Compendium³ and other systems.

17. It is required that the international classification, coding and nomenclature of medical devices (INMD) hosted by WHO will be supported by well-established technical resources and an expert advisory group. The system will be open to all users and will include the possibility of submitting queries and requiring new codes, in a similar way to that of ICD-11. The new section will be a global good and will allow for future convergence with other existing nomenclatures, as appropriate. This measure is intended to foster 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

18. The Executive Board is invited to note this report, and to provide guidance on the next steps for advancing the work described herein.

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¹ <https://icd.who.int/browse11/1-m/en#/http%3a%2f%2fid.who.int%2fid%2fentity%2f706313621> (accessed 30 November 2020).

² <https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2> (accessed 30 November 2020)

³ <https://www.who.int/universal-health-coverage/compendium> (accessed 3 January 2021).