

## **Standardization of medical devices nomenclature**

### **International classification, coding and nomenclature of medical devices**

#### **Report by the Director-General**

1. In May 2022, the Seventy-fifth World Health Assembly considered two reports on standardization of medical devices nomenclature.<sup>1</sup> This topic had previously been discussed by the Executive Board, initially at its 145th session in May 2019<sup>2</sup> and then at its 148th session in 2021,<sup>3</sup> and by the Seventy-fourth World Health Assembly in May 2021.<sup>4</sup> At the conclusion of the discussions in May 2022, the Health Assembly adopted decision WHA75(25).

2. The present report is submitted in response to the request made in decision WHA75(25). It provides details of the Secretariat's activities on the collection and integration of information related to medical devices in WHO platforms, and related activities to support this process.

#### **BACKGROUND**

3. As stated in document A75/11, medical devices are health products which are required for protection, prevention, diagnosis, treatment, rehabilitation and palliation and which do not have a pharmacological function.

4. WHO selects various medical devices in an evidence-based assessment process and disseminates their details in lists of WHO priority medical devices for: reproductive, maternal, newborn and child care;<sup>5</sup> cancer management;<sup>6</sup> coronavirus disease (COVID-19);<sup>7</sup> and cardiovascular diseases and

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<sup>1</sup> Documents A75/11 and A75/11 Add.1.

<sup>2</sup> See document EB145/3.

<sup>3</sup> See document EB148/13.

<sup>4</sup> Document A74/2.

<sup>5</sup> Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2016 ([https://apps.who.int/iris/bitstream/handle/10665/205490/9789241565028\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/205490/9789241565028_eng.pdf), accessed 30 October 2022).

<sup>6</sup> WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017 (<https://www.who.int/publications/i/item/9789241565462>, accessed 30 October 2022). Licence: CC BY-NC-SA 3.0 IGO.

<sup>7</sup> Priority medical devices list for the COVID-19 response and associated technical specifications. Geneva: World Health Organization; 2020 (<https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>, accessed 30 October 2022).

diabetes.<sup>1</sup> The list is continuously being expanded. To facilitate dissemination and ease of data management, the list is hosted in the WHO medical devices clearinghouse, “MEDEVIS”,<sup>2</sup> following the requests made in resolution WHA60.29 (2007) and decision WHA75(25). The list includes common names and can be used to populate national essential or priority lists for procurement and reimbursement of medical devices. As requested in decision WHA75(25), the various nomenclature names, including term, code and definition (if available), will be added to serve as a reference to stakeholders and Member States.

5. These priority medical devices need to be quality-assured and to be used safely; they also need to be affordable, available and accessible for the people who need them. They are essential for the attainment of the triple billion targets of WHO’s Thirteenth General Programme of Work, 2019–2025, since they underpin universal health coverage, are central to emergency response and are required to monitor well-being.

6. In both WHO publications and WHO databases, the medical devices are grouped by type of use and setting or conditions of use. Medical devices for diagnosis include those that measure a physiological condition – not only in-vitro diagnostics, but also in-vivo basic clinical assessment devices,<sup>3</sup> such as stethoscopes, oximeters, electrocardiographs, blood pressure measurement devices, all radiology equipment and other imaging like ultrasound and magnetic resonance, up to complex diagnostics. For the protection function, personal protective equipment is indispensable for infection prevention and has been essential in the COVID-19 pandemic. For the therapeutic function, medical devices for treatment include ventilators and haemodialysis, radiotherapy and surgical equipment, among many others. Medical devices also include all types of capital medical equipment<sup>4</sup> that require maintenance and incur operating expenses.<sup>5</sup> Two other important types of medical device are implantable devices – such as pacemakers and hip prostheses, which are considered high-risk devices – and single-use medical devices.<sup>6</sup>

7. As previously discussed by the Health Assembly and Executive Board,<sup>7</sup> the goal is to create a standardized international classification, coding and nomenclature for medical devices that would be available to all Member States and would support patient safety, access to medical devices for universal health coverage, emergency preparedness and response, efforts to increase the quality of health care, and achievement of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for

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<sup>1</sup> WHO list of priority medical devices for management of cardiovascular diseases and diabetes. Geneva: World Health Organization; 2021 (<https://www.who.int/publications/i/item/9789240027978>, accessed 30 October 2022).

<sup>2</sup> MEDEVIS: WHO Priority Medical Devices Information System. In: MEDEVIS [website]. Geneva: World Health Organization; 2022 (<https://medevis.who-healthtechnologies.org/>, accessed 30 October 2022).

<sup>3</sup> Selection of essential in vitro diagnostics at country level. Geneva: World Health Organization; 2021 ([www.who.int/publications/i/item/9789240030923](http://www.who.int/publications/i/item/9789240030923), accessed 3 November 2022).

<sup>4</sup> Human resources for medical devices, the role of biomedical engineers. Geneva: World Health Organization; 2017:10 (<https://www.who.int/publications/i/item/9789241565479>, accessed 30 October 2022). Licence: CC BY-NC-SA 3.0 IGO.

<sup>5</sup> Medical equipment maintenance programme overview. Geneva: World Health Organization; 2011:6 (<https://apps.who.int/iris/bitstream/handle/10665/44587/9789241501538-eng.pdf>, accessed 30 October 2022).

<sup>6</sup> WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017 (<https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf>, accessed 30 October 2022). Licence: CC BY-NC-SA 3.0 IGO.

<sup>7</sup> See document EB145/2019/REC/2, summary record of the first meeting, section 5; document EB148/2021/REC/2, summary record of the twelfth meeting, section 1; and document WHA74/2021/REC/3, summary record of the ninth meeting and the tenth meeting, section 2.

all at all ages). The mapping and dissemination on WHO platforms of available information on medical devices would enable the standardization of information for their selection, regulation, assessment and management.

8. Document EB145/3 references a concept note of July 2018,<sup>1</sup> in which the Secretariat proposed the principles of an international classification, coding and nomenclature of medical devices. The principles, which are summarized in paragraph 9 below, will be considered in the mapping process in 2023 and beyond for dissemination on WHO platforms.<sup>2</sup>

9. Under the principles, the international classification, coding and nomenclature of medical devices would need:

- (a) to ensure that all stakeholders from different regions can provide feedback;
- (b) to provide classification, coding and nomenclature characteristics with a transparent methodology and processes for updates; and
- (c) to provide a source where information will:
  - (i) be capable of being referenced and used by regulators, procurers, managers and all users;
  - (ii) be freely available and considered a global public good;
  - (iii) support the Unique Device Identification system;
  - (iv) be accessible through a simple and intuitive search; and
  - (v) be available for use in all health-related database systems.

10. As decision WHA75(25) is implemented, available information on names, codes, definitions, technical specifications, training material and regulatory information on WHO platforms available to all stakeholders and Member States will be enhanced. The system is intended to be interoperable with other WHO electronic platforms, such as the Eleventh Revision of the International Statistical Classification of Diseases and Related Health Problems and the electronic Essential In Vitro Diagnostics List (eEDL).<sup>3</sup> The aim is to avoid institutions developing their own information and naming systems because of a lack of access to international standardized information for decision-makers.

## **MEMBER STATES' REQUESTS TO THE SECRETARIAT**

11. 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

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<sup>1</sup> Currently available at [https://cdn.who.int/media/docs/default-source/medical-devices/conceptnotenomenclaturemedicaldevicesv13forconsultation.pdf?sfvrsn=e4174670\\_7](https://cdn.who.int/media/docs/default-source/medical-devices/conceptnotenomenclaturemedicaldevicesv13forconsultation.pdf?sfvrsn=e4174670_7) (accessed 6 November 2022).

<sup>2</sup> The mapping process involves establishing cross-references between the different nomenclature systems.

<sup>3</sup> Selection, access and use of in vitro diagnostics. In: World Health Organization [website]. Geneva: World Health Organization; 2022 (<https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/selection-access-and-use-in-vitro>, accessed 30 October 2022).

devices is a perfect example of WHO's core normative standard-setting work.<sup>1</sup> Resolution WHA60.29 (2007) on health technologies requests the Secretariat 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".

12. Following its discussion of this topic, the Seventy-fifth World Health Assembly adopted decision WHA75(25), in which it requested the Director-General "to integrate available information related to medical devices, including terms, codes and definitions, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and to link the database and clearinghouse to other WHO platforms, such as the Eleventh Revision of the International Statistical Classification of Diseases and Related Health Problems, to serve as a reference to stakeholders and Member States".

## SECRETARIAT RESPONSE TO MEMBER STATES' REQUESTS

13. **Update of the Global atlas of medical devices.** At the request of Member States, the consultation on the update of the Global atlas of medical devices, 2017 edition,<sup>2</sup> was extended until mid-2022. The new information provided by Member States has been added. The *Global atlas of medical devices 2022* has been published.<sup>3</sup> Every country profile includes the information related to national policies, including national lists for procurement and/or reimbursement, regulatory agencies, units responsible for health technology management and health technology assessment, official nomenclature, among other indicators, which will be updated in the Global Health Observatory.<sup>4</sup> The previous editions were published in 2011<sup>5</sup> and 2017.

14. **The Global model regulatory framework.** The framework, published in 2017, has been re-edited in a thorough consultation process initiated in May 2022.<sup>6</sup> Section 4.3.1.4 of the document is entitled "Select and implement a medical device nomenclature system". The updated version was approved by the Expert Committee on Biological Standardization at its October 2022 session.<sup>7</sup> It is due to be published in early 2023.

15. **Mapping.** In September 2022, the Secretariat issued a request for proposals on the United Nations Global Marketplace for a suitable contractor to provide mapping of medical devices nomenclature data

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

<sup>2</sup> Global atlas of medical devices. Geneva: World Health Organization; 2017 (<https://apps.who.int/iris/handle/10665/255181>, accessed 30 October 2022). Licence: CC BY-NC-SA 3.0 IGO.

<sup>3</sup> Global atlas of medical devices 2022. Geneva: World Health Organization; 2022. (<https://apps.who.int/iris/handle/10665/364709>, accessed 24 November 2022)

<sup>4</sup> See, for instance, Health technology (medical device) national policy. In: Global Health Observatory [website]. Geneva: World Health Organization; 2022 ([https://www.who.int/data/gho/data/indicators/indicator-details/GHO/health-technology-\(medical-device\)-national-policy](https://www.who.int/data/gho/data/indicators/indicator-details/GHO/health-technology-(medical-device)-national-policy), accessed 30 October 2022).

<sup>5</sup> Baseline country survey on medical devices 2010. Geneva: World Health Organization; 2011 (<https://www.who.int/publications/i/item/WHO-HSS-EHT-DIM-11.01>, accessed 30 October 2022).

<sup>6</sup> WHO global model regulatory framework for medical devices including IVDs (GMRF) [draft]. Geneva: World Health Organization; 2022 ([https://cdn.who.int/media/docs/default-source/biologicals/call-for-comments/global-model-regulatory-framework-medical-devices\\_final\\_sj\\_draft\\_2-may.pdf](https://cdn.who.int/media/docs/default-source/biologicals/call-for-comments/global-model-regulatory-framework-medical-devices_final_sj_draft_2-may.pdf), accessed 30 October 2022).

<sup>7</sup> Main outcomes of the meeting of the Expert Committee on Biological Standardization held from 24 to 28 October 2022, 13 November 2022, Meeting report (<https://www.who.int/publications/m/item/main-outcomes-of-the-meeting-of-ecbs-24-to-28-oct-2022>, accessed 24 November, 2022)

for integration into WHO platforms in a two-stage process.<sup>1</sup> The Secretariat has evaluated candidates and selected a provider and will convene stakeholders as needed to facilitate the mapping process.

16. The Secretariat has been involved in discussions regarding the possible conclusion of memorandums of understanding with the holders of the nomenclature systems EMDN, GMDN, UMDNS and UNSPSC. Discussions are taking place, and the legal approval process, including to ensure compliance with the WHO Framework of Engagement with Non-State Actors, is under way. The Secretariat has contacted other stakeholders, in search of information to support the mapping process.

17. **Update of MEDEVIS.** MEDEVIS,<sup>2</sup> which is a WHO clearinghouse for all WHO-selected priority medical devices – including devices for prevention, protection, diagnostics (including in vitro diagnostics), treatment and rehabilitation – has been updated with new information. As the update includes data from all types of medical devices, a link with eEDL, which presents the model list of essential in-vitro diagnostics, is being created to facilitate the exchange of information. Besides this, MEDEVIS has become the source of data for all the medical devices in the universal health coverage compendium,<sup>3</sup> the latest version of which is due to be presented on International Universal Health Coverage Day, 12 December 2022. To facilitate the definition of the sets, kits and packages of medical devices involved in a health-care intervention, a new grouping tool in MeDevIS, “MeDevPacks”, is being developed. MeDevIS will include the information available from the different nomenclature systems as they become publicly available through WHO agreements or cross-reference mapping (terms, codes and definitions).

18. The call for members of the WHO Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) was launched in April 2022.<sup>4</sup> The deadline was extended to allow for multidisciplinary global participation. A total of 156 expressions of interest were received from candidates originating from 56 Member States. A selection committee was set up and three information sessions were held for shortlisted candidates. The final list of members was approved.<sup>5</sup> STAG MEDEV will act as an advisory body to WHO on matters of global policy and strategy related to medical devices and related health technologies, and will advise WHO on global priorities and emerging issues.

## THE WAY FORWARD

19. Following the virtual information session for Member States held on 1 December 2022, further information sessions will be organized over the next two years, together with related stakeholder consultations. Furthermore, in accordance with decision WHA75(25), the Secretariat will submit another substantive report on progress made in implementing that decision to the Executive Board at its 156th session in January 2025.

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<sup>1</sup> Reference 2022/MHP/MDD/002 (<https://www.ungm.org/Public/Notice/183294>, accessed 30 October 2022).

<sup>2</sup> MeDevIS, (<https://medevis.who-healthtechnologies.org/>, accessed 24 November 2022).

<sup>3</sup> UHC compendium: health interventions for universal health coverage. In: World Health Organization [website]. Geneva: World Health Organization; 2022 (<https://www.who.int/universal-health-coverage/compendium>, accessed 30 October 2022).

<sup>4</sup> 2022 call for experts: Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV). In: World Health Organization [website]. Geneva: World Health Organization; 2022 (<https://www.who.int/news-room/articles-detail/call-for-experts-STAG-MEDEV-2022>, accessed 30 October 2022).

<sup>5</sup> Strategic and Technical Advisory Group of experts on medical devices (<https://www.who.int/groups/strategic-and-technical-advisory-group-of-experts-on-medical-devices-%28stag-medev%29>, accessed 9 December 2022)

## **ACTION BY THE EXECUTIVE BOARD**

20. The Executive Board is invited to note this report and to provide its views on the value of the proposed way forward and on any adjustments that it might consider necessary, in particular with respect to the integration of available information related to medical devices – including terms, codes and definitions – into WHO platforms.

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