

## Standardization of medical devices nomenclature

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

#### Report by the Director-General

1. The present document provides additional information on the intersessional work asked for the Executive Board at its 150th session in order to permit discussion on the text of decision EB150(10) contained in square brackets.<sup>1</sup> An informal consultation was held on 29 April 2022. The text as it stood following that consultation is attached in the Annex. A further informal consultation was held on 12 May 2022, following which the Secretariat prepared a consensus text at the request of Member States.
2. The proposed consensus text is set forth below:

The Seventy-fifth World Health Assembly, having considered the report by the Director-General on standardization of medical devices nomenclature: international classification, coding and nomenclature of medical devices,<sup>2</sup> and re-affirming WHO's role in the development, in a transparent and evidence-based way, of norms, standards and a standardized glossary of definitions relating to medical devices, as requested in resolution WHA60.29 (2007),

Decided to request the Director General:

- (1) to integrate publicly 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 now available as the Medical Devices Information System (MEDEVIS);<sup>3</sup> and to link this to other WHO platforms, such as the International Classification of Diseases, (ICD-11)<sup>4</sup> to serve as a reference to stakeholders and Member States;
- (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023.

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<sup>1</sup> See the summary records of the Executive Board at its 150th session, eleventh meeting, section 4.

<sup>2</sup> Document A75/11.

<sup>3</sup> MeDevIS available at <https://medevis.who-healthtechnologies.org/> (accessed 13 May 2022).

<sup>4</sup> ICD-11 available at <https://www.who.int/standards/classifications/classification-of-diseases> (accessed 13 May 2022).

## ANNEX

### STANDARDIZATION OF MEDICAL DEVICES NOMENCLATURE

**PP1** The [Executive Board (del EU)] / [Health Assembly (EU)], having considered the report[s (del EU)] by the Director-General on standardization of medical devices nomenclature; [end para here (EU)] and the draft steps [towards standardization (del AUS, USA, GBR, IND, CAN; retain EU, RWA)] / [to make [the (del EU, RUS)] / [of a WHO global (EU, RUS, RWA)] nomenclature available to [all (EU, RUS, IND, RWA)] Member States (AUS, CAN, USA, GBR, KEN, IND)] referred to therein;

- NOTE: FN from original EB text is missing (FJI)

[**PP2** Confirming WHO's goal to develop an international classification, coding and nomenclature for medical devices (INMD) that is a global public good, publicly available and accessible to all stakeholders in all Member States and that is based on a transparent methodology; (EU, RWA; reserve CAN, GBR, KEN, USA, AUS)]

- NOTE: Add FN to reference WHO's goal, providing mandate (FJI)
- NOTE: Insert FN after the word "methodology" reading: "Cf resolution WHA60.29" (EU)

**OP1** Decided to request the Director-General:

[**OP1.1** to continue the mapping and use of the four nomenclature systems in WHO 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] (del AUS, CAN, USA, GBR)];

[**OP1.1 alt** to continue the mapping, with stakeholder collaboration, between and the use of those nomenclature systems that are publicly available and associated with Unique Device Identification (UDI), in WHO platforms and publications, (EU, GER, RUS, FRA, ITA; del AUS)]

- NOTE: Proposal that OP1.1 *alt* should be the only OP1.1, rather than OP1.1, OP1.1 *alt alt* or OP1.1 *alt alt bis* (EU; prefers to continue working with 1.1 *alt alt* and OP1.1 *alt alt bis* CAN)

[**OP1.1 alt alt** to continue to explore the feasibility of mapping of the two nomenclature systems (EMDN and GMDN) (AUS, CAN, USA, GBR, KEN, IND; del EU, RUS, GER, FRA)]

[**OP1.1 alt alt bis** to explore the accessibility of the nomenclature systems for the Member states via the WHO platforms and publications (AUS, CAN, USA, GBR, KEN, IND; del EU, GER, RUS, FRA)]

[**OP1.2 new subpara**: to draw up, in consultation with Member States, a plan to integrate a WHO [standardized (EU; del USA)] international nomenclature of medical devices, based on existing ones (EU, GER, RUS, KEN, ITA)]

[**OP1.3** 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. (del AUS, CAN, USA, GBR; retain RUS, GER, FRA, ITA)]

[**OP1.3 alt** to submit a progress report to the Seventy-sixth World Health Assembly in 2023 (AUS, CAN, USA, GBR, EU; del FRA, GER, ITA)]

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