Request for input and collaboration towards international classification, coding and nomenclature of medical devices.

Objective:

To identify an international classification, coding and nomenclature system of Medical Devices (ICMD) to support the access to medical devices for better health care delivery in line with the Sustainable Development Goal #3 and the WHO Thirteenth General Programme of Work (2019–2023)[1], including universal health coverage, response to health emergencies and better health and wellbeing.

Rational

WHO is the leading health agency of the UN and is responsible for the following health related nomenclature and classification systems:

INN: International Nonproprietary name for pharmaceuticals[2]
ICD: International Classification of Diseases, Version ICD11 just released June 2018[3]
ICHI: International Classification of Health Interventions (draft in development)[4]
ICF International Classification of Functioning Disability and health [5]

The World Health Assembly resolution WHA60.29 [6] on medical devices, requests WHO to:

"(1) to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices;(6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region"

In order to develop the database and related clearing house a classification, coding and nomenclature system of Medical Devices is required. This system would relate the medical devices to the other WHO international classification systems.

The international classification, coding and nomenclature of medical devices system (ICMD) would support patient safety, better allocation of resources and health outcomes by supporting:

- faster regulatory process;
- facilitate product selection;
- improve procurement and supply management;
- increase trade and better asset management in health facilities, and
- post market surveillance.

[1] http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf?ua=1
[2] http://www.who.int/medicines/services/inn/en/
[3] http://www.who.int/classifications/icd/en/
[4] http://www.who.int/classifications/ichi/en/
[5] http://www.who.int/classifications/icf/en/
[6] http://www.who.int/healthsystems/WHA60_29.pdf

Benefits of an international classification, coding and nomenclature system could be: facilitate functional inventories, availability, monitoring and evaluation of medical devices; along with the unique devices identification (UDI) implementation, track usage of implantable medical devices and track donated/ refurbished equipment; facilitate market authorisation and streamline trade, taxes, and customs coding.

An additional advantage would be the improved collaboration between health care facilities, industry, national authorities and international organisations dealing with medical devices to increase access to required medical devices, especially in low and middle income countries or special situations like outbreaks and emergencies.

Background

The WHO Atlas on Medical Devices, 2017, describes that 90 WHO Member States (52%), use at least one official nomenclature system for medical devices. In contrast, 84 WHO Member States do not have any official national nomenclature. Out of the 90 countries which have an official nomenclature system: 26% have developed a national nomenclature, 12% use Universal Medical Device Nomenclature System (UMDNS) only, 10% use Global Medical Device Nomenclature (GMDN) only, and 3% use more than one system. [7]

None of the above nomenclature systems has been mapped between themselves. Besides the above, there are plenty of national nomenclatures and classification systems, some even shared with more than one country.

Currently UN organizations as UNICEF, UNOPS, WHO, UNFPA and Non-governmental organisations, namely ICRC, MSF, Global Fund, each has its own nomenclature systems for classifications and coding of medical devices. Not matching to any other, therefore interagency documents do not have a harmonized coding, which complicates procurement, listing and supply and access of medical devices.

Within the EU, in accordance with the new European Regulations on medical devices and in vitro diagnostic medical devices[8], the European Commission shall make available a medical device nomenclature to manufacturers and other natural or legal persons required by the Regulations to use that nomenclature. The nomenclature code shall be submitted to the future EU UDI database by the relevant economic operator when registering its device. Criteria for nomenclature providers to meet the regulatory needs of the sector in accordance with the provisions for a medical devices nomenclature set out in the European device Regulations have been recently elaborated by the European Commission, in cooperation with the EU Competent Authorities, and published[9]. The designation of a suitable provide is foreseen around early 2019 and the nomenclature system will be applicable from May 2020.

[7] http://www.who.int/medical_devices/priority/mde_nomenclature/en/
[8] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
[9] https://ec.europa.eu/docsroom/documents/28668

Definitions

Medical device as an article, instrument, apparatus or machine (also including Mobile Medical applications and Software as a Medical Device) that is used 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.

In vitro diagnostic, (IVD) is a subset of medical devices, whether used alone or in combination , intended for the in-vitro examination of specimens derived from the human body solely to provide information for diagnostic, monitoring or compatibility purposes. It includes reagents, test kits, etc.[10]

Classification (also called categorisation) refers to the different categories that can be used to characterize medical devices. For example: In vitro diagnostic, personal protective equipment, surgical instruments etc.

Coding is the assignment of a unique numeric or alphanumeric identifier to a specific medical device.

Nomenclature of medical devices is a system used to generically identify all medical devices and related health products. Having a nomenclature system in place for medical devices facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers. Such standardization is currently used in some regulatory systems but is also a prerequisite for inventory management and databases for maintenance of equipment.

Request for collaboration

WHO, is proposing the following principles and is looking forward to receive input and collaboration initiatives to support the development and availability of an international classification, coding and nomenclature of medical devices which might be used by all stakeholders globally.

Principles:

The international classification, coding and nomenclature of medical devices would need to ensure

a. Governance
    i. Have organisational and review structures in place to ensure that all stakeholders (in particular experts, regulators, procurers and users) from different regions are able to regularly (at least annually) provide feedback according to the global needs.
b. Classification, coding and nomenclature characteristics
    i. A transparent methodology, processes for the classification, coding and establishment of nomenclature terms
    ii. A transparent and defined regularly update mechanism (e.g. once per year)
    iii. Nomenclature should have hierarchies by which terms and codes could be meaningfully grouped into categories and subcategories to meet the various needs of its stakeholders including regulatory and supply systems
    iv. Non-discriminatory, inclusion of medical devices used outside highly-regulated countries
    v. Mutually exclusive,
    vi. Possibility to have translation for official UN and other languages
c. Access of information
    i. Can be referenced and used by regulators, procurers, managers and all users of medical devices (hospitals / health care workers or patients)
    ii. Is freely available, considered a global public good
    iii. Has to be useful when being implemented into unique device identifier (UDI)
    iv. Allows easy and intuitive search
    v. Can be used in all health-related data base systems, acknowledging the source

[10] GHTF. Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device. 2012'. Available at: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search=. Last accessed: 15/02/2018

vi. That the codes could be used with software systems for regulation, registration, procurement, inventories, adverse event reporting, refurbishment , decommissioning or others as necessary.

WHO timeline

January 2018: Discuss with UN agencies: UNICEF, UNFPA, UNOPS, UNDP, as well as World Bank and the following NGOs: ICRC, MSF, IFMBE, IFHE, PATH. Develop specifications of ideal global nomenclature to submit for global consultation, and publish a survey to collect nomenclature information from stakeholders

February - March 2018: Collect survey results and conduct key informant interviews with relevant stakeholders. Present needs, use cases and specifications.

July 2018: Publication of principles for classification and nomenclature for public consultation and request for proposal.

September – November 2018: Review proposals for classification and nomenclature. Select successful supplier(s)/system(s). Develop a pilot project of the classification, coding and nomenclature to be presented in the 4th WHO Global Forum of Medical Devices in India 13-15 December 2018.

December 2018: Present results of pilot test of classification, coding and nomenclature system for discussion.

Expected results:

An international classification, coding and nomenclature of medical devices available for all WHO Member States to support access to medical devices for Universal Health Coverage and achievement of Sustainable Development Goal # 3: Ensure healthy lives and promote well-being for all at all ages.

Respond by 24 of August 2018.

If interested to collaborate please fill in the "template for comments" and send to: *medicaldevices@who.int*

More information at http://www.who.int/medical_devices/priority/mde_nomenclature/en/

Nomenclature survey at https://extranet.who.int/dataform/admin/survey/sa/view/surveyid/788481

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