Member States Information Session on Standardization of medical devices nomenclature

5th March, 2024

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Team Lead Medical Devices
1. Why is nomenclature important?
2. Responding to Member States.
3. Searching a solution having 2 systems.
There are thousands of types of Medical devices... used at all levels of health care.

- In vitro diagnostic, laboratory
- Medical equipment
- Surgical instruments
- Single use medical devices
- Implantable medical devices
- Some assistive devices
- Some personal protective equipment
- Software as medical device
- Medical imaging

**World Health Organization**

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**HEALTH FOR ALL**
Harmonized Nomenclature improves access to safe, quality, affordable medical devices, towards increased quality of health care everywhere.

- **R&D**
  - Academia and Industry
  - Manufacturing and trade

- **Regulations**
  - National Regulatory Agencies
  - Lists of approved MD for marketing in country.

- **Assessment**
  - MOH (HTA): Selection of National Lists of MDs for reimbursement or procurement
  - Health care benefit packages, national policies
  - *(WHO Essential in vitro Diagnostics and Priority Medical Devices)*

- **Management**
  - Health care providers
  - Procurement, Installation, training, maintenance, safe use, operating costs
  - Post-market surveillance and adverse event report
  - Decommissioning, Replacement

Patient safety
Quality of health care
Save lives
Increase quality of life
We have come a long way, uphill, approaching, but still not there... need to ensure everyone has access to naming system for medical devices, to avoid multiple developments.

Med Devices Global Fora
- 2010 1st GFMD
- 2013 2nd GFMD
- 2017 3rd GFMD

2018
- WHO principles: towards governance, transparent process, access as global public good
- MS requested WHO not to develop yet another nomenclature but to work with the available ones.

2019
- EB 145/3
- 2021 WHA74
- 2021 Multiple consultations with nomenclature agencies MS, NGOs
- Member States update of Global Atlas of Medical Devices

2021
- EB 148/13
- 2021 WHA74
- Multiple consultations with nomenclature agencies MS, NGOs

2022
- EB150 Decision EB150(10)
- 2022 Consultations and pilot mapping EMDN- GMDN- UMDNS- UNSPSC
- 2022 WHA75 Decision WHA75(25)
- Upon request of some Member States during WHA and EB.
- 2023 WHA76

2023
- EB152
- Cross reference EMDN- GMDN
- Work with GMDN upon request of some Member States during WHA and EB.

2024
- Agreement WHO with GMDN towards open policy access.
- Addition of GMDN terms, codes and definitions in WHO platforms. (2500 types of devices)
- MS info session 5th March 2024.
Decision approved 28 May 2022 in WHA 75 on Standardization of medical devices nomenclature: WHA75(25)

• Member States request to 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 now available as the Medical Devices Information System (MEDEVIS); and to link this to other WHO platforms, such as the International Classification of Diseases, (ICD-11) 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, and its 156th session in January 2025
Medical Devices Nomenclature systems most used.

**European Medical Devices Nomenclature (EMDN)**
- Last update September 2021.
- Ongoing public consultation until March 2024.
- Has free access of information for everyone.
- Governed by MDCG.
- Anyone can comment.

**Global Medical Devices Nomenclature (GMDN),**
- Continuous updates
- About 25,000 codes
- Requires membership and the system and accepts licence.
- Free for some, including governments and public health providers.

**Universal Medical Devices Nomenclature System (UMNDS),**
- Monthly updates.
- About 43,000 terms
- Requires that user registers in their system and accepts licence.
- Not free
- Mostly used in hospitals for health technology management

**The United Nations Standard Products and Services Codes (UNSPSC),**
- Includes medical devices plus other multiple types of products and services.
- Mostly used for procurement.
- UNGM.
Goal: 1. to include naming, codes, definitions in all WHO publications and electronic platforms, for public reference and 2. that all Member States can also use nomenclature widely.

https://medevis.who-healthtechnologies.org/
Mapping process and results

- **Goal:** 5,200 EMDN-GMDN pairs
- **Source:** initially: AccessGUDID and EUDAMED
- **Time:** 7 months (finalize September 2023)
- **Method applied:** Automatic matching tools, similarity of term/definitions
- **Final result:** 7,500 pairs (table available to MS only as reference)
- **Challenges:** Multiple:
  - The continuous updating of the GMDN nomenclature code/terms, unless it continues in real time with everyone’s collaboration.
  - Unable to perform automated creation of EMDN-GMDN pairs using UDI system as a source.
  - It is possible to establish relationships between nomenclatures, even though the different granularity of the nomenclature, but it would not be one to one.
Collaboration with EMDN 2023.

Meetings
Medical devices
policy officers EC to:
Agree on the use of
the EMDN codes and
terms in all WHO
publications.
• Shared the outcomes
of the mapping
exercise and
challenges faced.

Q3
EMDN codes and
terms were
added to all the
WHO Priority
Medical Devices
and in Medevis,
with the
corresponding
disclaimer
and link to the
EMDN page.

28 September
Presented the
status of work on
nomenclature to
the IMDRF
management
committee, upon
request of the EC
as chair.

22 November
WHO presented
update to The EC
Medical Devices
Coordination
Group (MDCG-
NOM) and agree
to future
collaboration.

WHO provide
input to MDCG
NOM, on annual
revision
Collaboration with GMDN 2023-24

Meetings to share concerns and define collaboration

• March to December 2023
• Definition of technical and legal aspects
• Scope

Agreement:

• Licence open access, noncommercial, for publicly available information, reached February 2024. WHO adding disclaimer and link to GMDN website.

The scope:

• Terms, codes and definitions of the WHO selected medical devices.
• 1. WHO model list of essential in vitro diagnostics
• 2. WHO Priority Medical Devices lists, other associated subsets.
• 3. WHO would not publish the whole GMDN list

Funding:

• Financial compensation to GMDN for the management of 3,000 initial codes, annual expansion.
License of MeDevIS, using Creative commons non-commercial was agreed to host the GMDN codes, terms and definitions.

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Status of nomenclature (terms and codes) of medical devices (22 February)
Outcomes of mapping has been shared with the 3 agencies (EMDN, GMDN, UMDNS).

<table>
<thead>
<tr>
<th>WHO-EMDN</th>
<th>WHO- GMDN</th>
<th>WHO- UMDNS</th>
<th>WHO- UNSPSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Codes and terms already used in all WHO MeDevIS data since 2023.</td>
<td>• Inclusion of codes, terms and definitions in WHO MEDEVIS (tests in February 2024)</td>
<td>• In pause.</td>
<td>• WHO secretariat will contact in Q3. 2024.</td>
</tr>
<tr>
<td></td>
<td>• Approval for WHO open access, using Creative Commons non commercial licence.</td>
<td>• ECRI still does not have a publicly available nomenclature system</td>
<td>• They are interested.</td>
</tr>
</tbody>
</table>
The way forward, by WHO in 2024

• Organize consultations and monthly webinars*
• With the agreements achieved place codes, terms and definitions in WHO resources and make them publicly available.
• Use the nomenclature systems for any new device added in WHO Lists and publications.
• Continue collaboration with EMDN and GMDN to support MS, co-existing as the measurement system...
Next steps: Proposal to have monthly webinar on nomenclature of medical devices

1. When? First Tuesday of every month at 13:00 CET to be available to all countries. Webinar, in Teams, open to all participants

3. Who? Member States, NGOs, nomenclature agencies, etc.

4. What? Nomenclature use cases, lessons learned and challenges, examples:
   - April: WHO tools, EMDN, GMDN
   - May: Ministries of Health, policies, national lists
   - June: Regulatory agencies: registration, to post market surveillance
   - July: Procurement and supply management, NGOs and humanitarian agencies
   - August: UDI, unique device identifier
   - September: At facility level: inventories, maintenance, CMMS
   - October: HS, harmonized code, WCO,
   - November: Med tech industry
   - December: creation of communities of practice
Way forward: Nomenclature of medical devices

Towards standardization of nomenclature to support better health care provision

Use EMDN or GMDN*  
*requires registration

Support in-country and regional harmonization

WHO medical devices information to include reference to EMDN and GMDN and organize webinars

Avoid developments of other nomenclature systems
Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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20, Avenue Appia
1211 Geneva
Switzerland

medicaldevices@who.int

Medical devices website:
https://www.who.int/health-topics/medical-devices#tab=tab_1
## Comparison of EMDN and GMDN vs. WHO principles (Feb 24)

<table>
<thead>
<tr>
<th>WHO Principles medical devices nomenclature</th>
<th>EMDN</th>
<th>GMDN</th>
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<tbody>
<tr>
<td><strong>Governance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. 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.</td>
<td>MDCG, EC, and website</td>
<td>GMDN agency with their advisory groups and members only</td>
</tr>
<tr>
<td><strong>Classification, coding and nomenclature characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. a transparent methodology and processes;</td>
<td>Open website</td>
<td>For members only</td>
</tr>
<tr>
<td>1. a transparent mechanism for regular updates (e.g. once per year);</td>
<td>open to input from all stakeholders</td>
<td>Continuous update and for members only</td>
</tr>
<tr>
<td>1. hierarchies grouped into categories and subcategories to meet stakeholder needs;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1. medical devices used outside highly regulated countries;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1. mutually exclusive terms;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1. availability of terms in other languages</td>
<td>In process</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Access to information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. be capable of being referenced and used by regulators, procurers, managers and all users of medical devices (hospitals/health care workers and patients);</td>
<td>Yes</td>
<td>Yes for internal institutional use, publicly limited to licence</td>
</tr>
<tr>
<td>1. be freely available and considered a global public good;</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>1. support unique device identifier system;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1. be accessible through simple and intuitive search;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1. be available for use in all health-related data base systems.</td>
<td>Yes</td>
<td>Limited to licence</td>
</tr>
<tr>
<td><strong>More information</strong></td>
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Background

- The World Health Assembly Report by the Director-General WHA75/11 and the Decision WHA75(25).
- The Executive Board report EB152/11
- The WHA76 Consolidated report by the Director General, section 13.7
- The WHA76 - Committee A, twelfth session, on 27/05/2023, 09:15-11:30 hrs. webcast MS discussion, including Dr. Nakatani’s ADG Access to Medicines to Medicines and Health Products.
Additional complementary slides  
5<sup>th</sup> March 2024
MeDevIS, 2024 v 1.0 is being released today.

As per decision WHA75(25), “to integrate available information related to medical devices, including terms, codes, and definitions, in the web-based database and clearinghouse...”
Including EMDN and GMDN codes, terms, disclaimer, link to their website.
4th WHO model list of Essential in vitro diagnostic (EDL) is included in eEDL 2024, v 1.0

https://www.who.int/publications/i/item/9789240081093
https://edl.who-healthtechnologies.org/
4th Essential in vitro diagnostic list is being classified with EMDN and GMDN codes. Work in progress.
MEDEVIS WEBSITE

https://medevis.who-healthtechnologies.org/