1. Standardized nomenclature of medical devices
2. EB150: comments and decision
3. State of play: status quo of 4 major nomenclature systems and WHO work
4. Open discussion on the decision
Milestones

WHO EB 145, EB 148, WHA74 May 2022

- Info session
  - 23 Sept 2021
  - Mapping process

WHO EB 150 January 2022

- >40 consultations and mapping of 13,000 terms in collaboration with nomenclature agencies
- Information session
  - 16 Dec 2021

WHA 75 May 2022

- Information session
  - 31 Mar 2022
  - Decision discussion

Goal: ensure improved access to safe, good quality, affordable, appropriate, acceptable medical devices

Naming devices remain the backbone of all processes.

Industry
- Industry production to comply with regulatory bodies and procurement systems

Regulations
- Regulatory agencies: for premarket registration, tracking, post market surveillance

Assessment
- MOH, national insurance: Selection of medical devices national list for procurement or reimbursement (Essential/ priority/ positive)

Management
- Procurement and supply (trade, customs)
- Inventories, maintenance and training in Health facilities
- Patient safety
- Decommissioning

https://www.who.int/health-topics/medical-devices#tab=tab_1
Multiple systems co-existing at regional, country, facility levels and by industry and UN agencies, affect health systems and impact patients.

Data reported in 2021, by 180 MS, in country survey for Global Atlas of Medical Devices.

WHO data principles for medical devices: established in 2018 and published and discussed in EB145/3, EB148 and EB150.

(a) Governance:
   (i) will have structures in place to ensure that all stakeholders are able to provide feedback.

(b) Classification, coding and nomenclature characteristics with:
   (i) a transparent methodology and processes for updates; and
   (ii) terms in other languages.

(c) Access of information, which:
   (i) can be referenced and used by regulators, procurers, managers and all users;
   (ii) is freely available and considered a global public good;
   (iii) can support the Unique Device Identifier system;
   (iv) facilitates simple and intuitive search; and
   (v) is available for use in all health-related database systems.

Comments and decision arising from EB150
Standardization of medical devices nomenclature

The Executive Board, having considered the reports by the Director-General on standardization of medical devices nomenclature and the draft steps towards standardization referred to therein,\(^1\)

Decided to request the Director-General:

(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];

(2) 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.

Eleventh meeting, 29 January 2022

EB150/SR/11
Comments in EB by MS:

1 “transparency of Methodology for mapping ”:

Methods were explained in information sessions and then posted in the WHO website and shared in the consultations


2. “insufficiency of consultations”.

Between July and December 2021, WHO did multiple consultations, listed in the WHO website, and EB150 report, including:

13 meetings with the nomenclature agencies (EMDN, GMDN, UNDNS, UNSPSC). 3 with medical devices industry (GMTA, DITTA)
5 with UN agencies and NGOs. 3 with Biomedical engineers.

Regulatory networks: AMDF, GHWP, IMDRF; besides regulators in the following regions: PAHO, EURO and SEARO.

2 Member States information sessions: September and December 2021.

3. “consultation with the IMDRF”

Participated in 3 meetings invited by IMDRF to explain the process, the status and outcomes.

Why GMDN is not for adoption by WHO?

Public access

If the RA of the member state has adopted GMDN, can the same system be used freely by the Hospitals, manufacturer or any related organization in the said country?

GMDN can be used only by the ones that register in GMDN system and only to use internally, not in public documents. Using copyright claim.

GMDN agency

Why WHO does not adopt GMDN as International nomenclature?

Because it is owned by a private entity that makes decisions by themselves.

Because it does not comply with open access to everyone as a global public good.

IMDRF and GMDN

How many IMDRF members have adopted GMDN?

According to MS report for Global Atlas of Medical devices:

3 out of 10 Members, adopted as is.

3 others have based on it but modified it locally with local codes.
Status quo of 4 nomenclatures and WHO work up to 16 March 2022
## Comparison against WHO principles

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Organization owner</strong></td>
<td>ECRI Institute</td>
<td>GMDN Agency</td>
<td>GS1 US</td>
<td>European Commission</td>
</tr>
<tr>
<td><strong>Governance</strong></td>
<td>Private</td>
<td>Private</td>
<td>Private</td>
<td>Public</td>
</tr>
<tr>
<td><strong>Transparent methodology to define terms.</strong></td>
<td>Defined by agency, without input from industry.</td>
<td>Defined by agency with input from members, including industry.</td>
<td>Defined by agency</td>
<td>Defined by MDCG, with open input</td>
</tr>
<tr>
<td><strong>Hierarchical organization</strong></td>
<td>Multiple</td>
<td>Multiple</td>
<td>Single</td>
<td>Single</td>
</tr>
<tr>
<td><strong>Free available as global public good</strong></td>
<td>In process</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Translations (available languages)</strong></td>
<td>2</td>
<td>25</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Supports Unique Device Identifier (UDI)</strong></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Available for use in all health-related databases (public systems).</strong></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Updated as of 16 March 2022
EMDN
Transparency of code, definitions and process. Open system
willingness to map and developing translations and definitions
March: Terms, definitions, translations and hierarchies in process.

GMDN
Un-availability and license agreement and costs for some. Closed process for coding
Yes, willingness to map and to update strategy and transparency. But keep IP.
February: New strategy, new website but same IP, same governance, same licence request.

UMDNS
Copyright and fee. Closed process for coding.
Yes, willingness to map (done by ECRI) to all others and promised no fee. But keep IP
March: changed access and fee.

UNSPSC
Copyright and fee
To be placed in WHO website and to be mapped.
No changes
WHO Advances till 16 March

Pilot project mapping done using UDI and public data, and machine learning
(sample: 13,129 devices from 510 manufacturers)

Agreement from nomenclature agencies to use code, term in WHO tools.
Text and flow chart for selection of nomenclature for the Global Model Regulatory Framework was discussed for final approval

Pilot test using MEDEVIS and ICD, WHO platforms to be freely available, single code linked to the different nomenclature systems.

https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/822324204

https://medevis.who-healthtechnologies.org/
Open discussion on the decision

EXECUTIVE BOARD
150th session
Agenda item 14

Standardization of medical devices nomenclature

The Executive Board, having considered the reports by the Director-General on standardization of medical devices nomenclature and the draft steps towards standardization referred to therein,¹

Decided to request the Director-General:

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Eleventh meeting, 29 January 2022
EB150/SR/11
More information: References and links in extra slides
1. Nomenclature of medical devices, description of activities, consultations, methodologies and discussions in EB and WHA.


3. Extension codes of International Classification of diseases that include medical devices

https://icd.who.int/browse11/l-m/en/#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f822324204

2. Example of external references to EMDN for one medical device in ICD-11 maintenance platform

3. ICD-11 for Mortality and Morbidity Statistics (who.int)


5. MEDEVIS, test mapping: (proof of concept) https://medevis-nomenclaturemapping.test.evidenceprime.com/:
<table>
<thead>
<tr>
<th>Considerations</th>
<th>EMDN</th>
<th>GMDN</th>
<th>UNSPSC</th>
<th>UMDNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence requirements²</td>
<td>No requirement's</td>
<td>Requires registration GMDN and copyright; <a href="https://www.gmdnagency.org/Legal/License">https://www.gmdnagency.org/Legal/License</a></td>
<td>No requirements to download PDF but requirements for use “Copyright (c) United Nations Development Programme 2013 All rights reserved.” <a href="https://www.unspsc.org/terms-of-use">https://www.unspsc.org/terms-of-use</a></td>
<td>(ECRI required fee and copyright before 16 March, but modified requirements for access of UMDNS), <a href="https://www.ecri.org/solutions/umdns">https://www.ecri.org/solutions/umdns</a></td>
</tr>
<tr>
<td>Number of total terms</td>
<td>7,000</td>
<td>24,800 GMDN terms, in addition about 2,000 high level terms.</td>
<td>3,800 for Medical Devices</td>
<td>UMDNS March 2022 includes More than 43,000 terms 30, 608 Entry terms and 13,025 Preferred Concepts</td>
</tr>
<tr>
<td>Translations available³</td>
<td>[Already publicly available: English, French (currently available only on EUDAMED: <a href="https://webgate.ec.europa.eu/eudamed/landing-page/">https://webgate.ec.europa.eu/eudamed/landing-page/</a>), Italian](<a href="https://webgate.ec.europa.eu/eudamed/landing-page/">https://webgate.ec.europa.eu/eudamed/landing-page/</a>) Under expert peer-review (2022): Bulgarian, Croatian, Czech, Danish, Dutch, Estonian, Finnish, German, Greek, Hungarian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish</td>
<td>UN Languages Chinese (Simplified), English, French, Spanish, Russian Other Languages Bulgarian, Czech, Danish Dutch, Estonian, Finnish German, Greek, Hungarian Italian, Japanese, Latvian Lithuanian, Norwegian Polish, Portuguese (Brazilian and European), Romanian, Slovak Slovenian, Swedish</td>
<td>All version in English, some versions in different languages (Arabic, Chinese, Danish, Dutch, Finnish, French, German, Hungarian, Italian, Japanese, Norwegian, Portuguese, Spanish, and Swedish).</td>
<td>English Spanish (last version 2014)</td>
</tr>
</tbody>
</table>
## Availability vs access and copyright

3 of the nomenclatures: UMNDS, GMDN and UNSPSC require that the user registers to have a licence, to have full access to the information.

### GMDN
- Website reference: Register - GMDN Agency
- The GMDN Agency may in such circumstances grant an extension to this Licensee to allow the Licensee to allow public access to single GMDN term, but not GMDN Codes.

### UMDNS
- Website reference: https://www.ecri.org/solutions/umdns

### UNSPSC
- Website reference: https://www.unspsc.org/subscribe
- Changed copyright 16 March!
Mapping strategy to make information available to all

**WHO**
Could have: Standardized system Codes and names in WHO platforms ICD-11; MeDevIS; UHCC. Digital interoperability. Open access. Creative Commons.

**Continuous Mapping IT tools one year (e.g., AI)**

**WHO Platforms**
- ICD-11
- MeDevIS
- UHCC

**Digital Interoperability**
- Open access
- Creative Commons

**UN Agencies & NGOs**

**COUNTRIES**
- Manufacturers
- National Nomenclature Committee
- Ministry of Health
- Regulatory Authorities
- Health-care Provider
- Population/ users of medical devices

**Nomenclature systems**
- EMDN
- GMDN
- UMDNS
- UNSPSC

**Other databases**
- i.e. UDI-DI Systems
- FDA GUDID
- Other databases
Questions/ comments in EB 150

Standardized International Nomenclature:

Was proposed as the one managed by WHO, in alignment with the International Non Propietary names of medicines, and International Classification of diseases and other WHO classifications.

Issues(EB143,148,150):

1. Some EB members required WHO to develop/make available a WHO nomenclature.

2. Other EB members required WHO not to develop a new one and consider one of the existing ones.

3. WHO does not “own” any of the 4 nomenclatures that were mapped in the pilot project in 2021. 1 belong so European States, the other 3 are private entities.

4. In order to have a WHO one, proposal is to list the mapped devices and present in WHO tools with a code/name that can be used by all and link to all of them.

https://www.who.int/standards/classifications
Proposal of co-existence: WHO to be a converging platform with global governance and mapping.

Slide from 2020. Now 2022 got mapping and collaboration from agencies.

Note: Mapping will only be possible if non-restrictive access and collaboration

STANDARDIZED INTERNATIONAL CLASSIFICATION CODING AND NOMENCLATURE OF MEDICAL DEVICES (based on one and other maps to it)

2021-22- Proposal: Hosted in WHO platform (ICD sub-module)

GMDN (should allow mapping and access) 24,000 terms

EMDN (CND) 7,000 terms

GMDN 1991
UMDNS 1980
CND
UNSPSC

2020

202X....
Consensus needs to be made by all stakeholders in country