WHO Webinar: Nomenclature of medical devices: EMDN & GMDN

8 July 2024 14:00 – 15:00 CET
# Agenda

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<th>Time</th>
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<tr>
<td>14:00</td>
<td>Welcome and introduction</td>
<td>Deus MUBANGIZI Director, Health Products Policy and Standards (WHO HQ)</td>
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<td>10 min</td>
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<td>14:10</td>
<td>WHO Medical Devices Information System</td>
<td>Adriana VELAZQUEZ BERUMEN WHO Team lead for Medical Devices and In Vitro Diagnostics (WHO HQ)</td>
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<td>14:20</td>
<td>European Medical Devices Nomenclature</td>
<td>Nada ALKHAYAT Policy officer at the European Commission</td>
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<td>14:30</td>
<td>Global Medical Device Nomenclature</td>
<td>Deniz BRUCE CEO of GMDN Agency</td>
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<td>14:40</td>
<td>Q&amp;A session</td>
<td>All panellists</td>
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<td>15 min</td>
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<td>14:55</td>
<td>Closing statement</td>
<td>Deus MUBANGIZI Director, Health Products Policy and Standards (WHO HQ)</td>
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Road towards medical devices information including harmonized naming

8th July 2024

Adriana Velazquez Berumen
Team Lead Medical Devices
Agenda:

The past: WHA60.29 to create a clearinghouse for medical devices

- WHA60.29 Health technologies

The 5 Options for WHO

1. Do nothing and let stakeholders work this out on their own
2. WHO to work out glossary for health technologies, not just focused on medical devices
3. WHO to create new nomenclature
4. WHO to choose one nomenclature out of UMDNS and GMDN
5. WHO to facilitate GMDN and ECRI engagement

- Choose GMDN
- Choose UMDNS
- GMDN-UMDNS cooperation
- WHO Mapping of GMDN and UMDNS

Slide from 2010

The present: WHA75.25 medical devices information system

Future: harmonized information as a public good.

- Medical devices information system
- Essential in vitro diagnostics
- International classification of disease
1. WHO Health products Lists, a reference for national lists.

Since 1975

WHO Essential medicines list & Essential medicine list for children

Since 2005

WHO Priority medical devices list

Since 2010

WHO Priority assistive products list

Since 2015

WHO Model list of essential in vitro diagnostics

Since 2016

Since 2018

Lack of a single nomenclature

There are three key areas where a lack of standardization negatively affects the rational choice of medical device procurement—regulation, standards, and nomenclature. Harmonization towards regulation and standards are briefly mentioned in Chapter 5.1.2. However, as something so basicposes such problems for appropriately choosing medical devices, lack of a single nomenclature is discussed in detail here.

Do not have code or harmonized name
2. Multiple naming systems for the same device. Names codes, terms definitions not publicly available
3. We have come a long way, uphill, approaching, but still not there…

need to ensure everyone has access to naming system for medical devices as a global public good, to avoid multiple developments

2007-17
• WHA60.29
• 2010 1st GFMD
• 2011 nom consultation
• 2013 2nd GFMD
• 2017 3rd GFMD
• 2018 4th GFMD

2018
• EB 145/3
• MS requested WHO not to develop yet another nomenclature but to work with the available ones.

2019
• EB 148/13
• 2021 WHA74
• 2021 Multiple consultations MS, NGOs noted multiple systems.

2021
• Decision EB150(10)
• Pilot mapping EMDN- GMDN- UMDNS- UNSPSC
• WHA75(25) Decision
• Some MS support use of EMDN

2022
• Decision EB152
• Cross reference EMDN- GMDN
• Some MS support use of GMDN

2023
• 2021 WHA74
• 2021 Multiple consultations MS, NGOs noted multiple systems.
• Decision EB150(10)
• Pilot mapping EMDN- GMDN- UMDNS- UNSPSC
• WHA75(25) Decision
• Some MS support use of EMDN

2024
• Agreement WHO with GMDN towards open policy access.
• Addition of EMDN terms and codes, and GMDN terms, codes and definitions in WHO platforms.
• (2500 types of devices)
• MS info session 5th March.
• WHO open webinar with EMDN and GMDN 8th July

2025
• Report to EB156.
• Vision: Expansion on access to WHO tools, EMDN GMDN as public good....

4. 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
5. Medevis was developed and is in Beta version until 2024, to display the technical information of WHO Priority Medical Devices List and can be filtered for service delivery platform, type of use, among others, and links to WHO documents.
6. MeDevis now includes EMDN and GMDN nomenclature codes, terms, disclaimer, link to their website.

Note: thank you to the legal advisors that helped us through!
7. eEDL 2024, v 1.0 includes 4th WHO model list of Essential in vitro diagnostic (EDL) and reference table with GMDN naming (July 2024)

https://www.who.int/publications/i/item/9789240081093
8. Harmonized Nomenclature improves access to safe, quality, affordable medical devices, towards increased quality of health care everywhere.

- **Academia and industry**
  - Manufacturing and trade

- **National regulatory agencies**
  - Lists of approved MD for marketing in the country

- **Ministries of Health (policies, HTA)**
  - Selection of National Lists of MDs for reimbursement or procurement
  - Health care benefit packages, national policies

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

Medical devices can save lives and increase quality of life
9. Future: Towards interconnected, WHO information on medical devices in **open** platforms, for Member States reference.

Continue collaboration with EMDN and GMDN to support MS, (co-existing as the measurement system...)

**Vision:** that everyone, everywhere has access to medical device information, including harmonized naming system (like the diseases and medicines have).
10. Collaboration is needed from all of us.

Medical devices technology is the means, harmonized naming is important but the well being of patient is our goal!

We have a responsibility for the future generations
Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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Switzerland
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Subscribe to our Medical device monthly newsletter

Visit WHO Medical devices website
Extra slides
WHO recommends to have a selection committee so that the ministry of health, the regulatory agency and health care providers use the same nomenclature. WHO recommends EMDN or GMDN which are referenced now in WHO platforms.
Way forward: Nomenclature of medical devices

- Use EMDN or GMDN*
  *requires registration

- WHO medical devices information publicly available with reference to EMDN and GMDN and organize webinars

- Support in-country and regional harmonization

- Towards standardization of nomenclature to support better health care provision

- Avoid developments of other nomenclature systems
Guiding principles for the EMDN

- Regulators-led
- Public Availability
- Accessible
- Structured
- Predictable
- Transparent
- Inclusive
- Internationally recognised

• Download the full EMDN here: https://webgate.ec.europa.eu/dyna2/emdn/
The EMDN is characterised by its alphanumeric structure that is established in a seven-level hierarchical tree. It clusters medical devices into three main levels:

- **Categories**: the first hierarchical level,
- **Groups**: the second hierarchical level,
- **Types**: the third hierarchical level (which expands into several levels of detail (1°, 2°, 3°, 4° and 5°), where necessary.)
EMDN Structure continued

Each alphanumeric code begins with a letter referring to the ‘CATEGORY’ for which the device falls under, followed by two numbers indicating the ‘GROUP’ and a series of numbers which refer to the ‘TYPE’. The maximum number of digits is set at 13.

See MDCG 2021-12: https://health.ec.europa.eu/document/download/d90b3f63-1d62-43e6-bf5f-fb32ea7c47a2_en
• Serves as terms associated to the UDI-DI

• Supports work related to market surveillance and vigilance.

• Used for sampling basis for Class II A & B as well as Class B & C.

• Used in the implant card*

• Used on certificates*

• Used in the clinical investigation application form

• Used in the SAE reporting form

Beyond the medical device regulation (non-exhaustive):

• Empowers the patient in gaining more information regarding their device, and other devices falling within the same code.

• Can be used internally by hospitals, clinics and pharmacies in their systems

• Can play a role in other healthcare related frameworks

• Data analysis and research
- EMDN access
- Full hierarchy visibility to all
- Directly downloadable (extension of the platform)
EMDN records in EUDAMED

476803 registered devices with EMDN

268270 registered devices with EMDN

MDs:

- Class I: 120,555
- Class IIa: 59,061
- Class IIb: 36261
- Class III: 20552

MDs:

- Class I: 231,898
- Class IIa: 98,591
- Class IIb: 72,935
- Class III: 32159

IVDs:

- Class A: 21,078
- Class B: 1,333
- Class C: 1,083
- Class D: 6

IVDs:

- Class A: 16,121
- Class B: 1,333
- Class C: 1,083
- Class D: 6
Recent activities
EU4Health – 4 General and 10 Specific objectives

EU4Health will provide the means and the instruments for delivering on the EU Health policy along ten key areas of intervention

**IMPROVE & FOSTER HEALTH**
- Health promotion and disease prevention; cancer
- International health initiatives & cooperation.

**PROTECT PEOPLE**
- Prevention, preparedness & response to cross-border health threats;
- Complementing national stockpiling of essential crisis-relevant products;
- Establishing a reserve of medical, healthcare & support staff.

**ACCESS TO MEDICINAL PRODUCTS & MEDICAL DEVICES**
- Enhancement of availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products

**STRENGTHEN HEALTH SYSTEMS**
- Strengthening health data, digital tools & services, digital transformation of healthcare;
- Enhancing access to healthcare;
- Developing and implementing EU health legislation and evidence-based decision making;
- Integrated work among MS health systems.
EU4Health 2022 Work Programme and Medical Devices

BUDGET: EUR 835.3 million → 19.8 million for Medical Devices

HS-g-22-19.01 Direct grants to Member States’ authorities: reinforced market surveillance of medical devices and in vitro medical devices – Joint Action 4M

HS-g-22-19.02 Direct grants to Member States’ authorities: supporting the maintenance of the European Medical Device Nomenclature – Direct Grant 1.8 M

HS-g-22-19.03 Call for proposals to support increased capacity of notified bodies for medical devices – Competitive call for Projects open to stakeholders and authorities 4M

HS-p-22-19.04, 06, 07, 08, 09, 10 and 11 Supporting the implementation of Regulations on medical devices and in vitro diagnostic medical devices – Procurement actions 9.9 M
SMEMDN project

WP1 – Management and Coordination
Aimed at managing and coordinating the dissemination, activities and results of the project

WP2 – Communication and dissemination
Includes communication and training activities with Member State authorities and stakeholders to respond to requests for information and clarification on nomenclature, publicly present project information and support collaboration between the European Commission and the WHO

WP3 – Evaluation
Participation in the activities foreseen in the other WPs and the set of actions to evaluate the quality of the results produced

WP4 – Sustainability
Ensures that the results produce the expected impact and benefits even at the end of the 36-month project duration

WP5 – EMDN management
Concerning technical/operational activities on EMDN such as updating the nomenclature and the development of tools to support its correct use
WP2: Communication & Dissemination

T2.2 Training activities: the planning of the first training event in Q4 2024

Main objectives:

- provide users with the information necessary to acquire the knowledge of the structure and rules of the EMDN for consultation and use
- provide users with sufficient knowledge to make a valuable input to update the EMDN

FOR FURTHER INFORMATION
Ministry of Health website
Friuli Venezia Giulia autonomous Region website
Helpdesk

• The Helpdesk activity is aimed to respond to requests for information and clarification on nomenclature.

• A dedicated digital platform will be activated in Q4 2024.

• Through the platform:
  
  ✓ Users can submit questions about the structure of the EMDN (Categories, Groups and Types)

  ✓ Manufacturers are provided with all relevant information that will help them to choose the appropriate EMDN code for the MD/IVD
**WP5: EMDN Management**

*Procedure for the annual revision of EMDN - MDCG 2024-2*

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**Phase I**
- Collection of requests submitted through the platform and from NOM-WG members

**Phase II**
- Technical evaluation by the EMDN-TT of the requests submitted during Phase I and EMDN usage in EUDAMED.
- A first draft proposal for the update of the EMDN and the list of rejected requests are submitted to the NOM WG for review.
**Phase III**

- NOM WG reviews the proposal submitted and provides feedback on the proposed changes to the EMDN-TT, as necessary.
- A final draft is endorsed by the NOM WG.

**Phase IV**

- Endorsement of the final draft by the MDCG and publication of the officially endorsed update in EUDAMED and the EMDN browser
Thank you!

For information or questions regarding EMDN, contact us at: sante-med-dev@ec.europa.eu and sante-emdn@ec.europa.eu
GMDN INTRODUCTION FOR THE WHO WEBINAR “NOMENCLATURE OF MEDICAL DEVICES”, 08 JULY 2024

JOHN WILKINSON – CHAIR, BOARD OF TRUSTEES
DENIZ BRUCE – CEO
DR BARRY DANIELS – SENIOR CLINICAL LEAD
ED GLENN – SENIOR NOMENCLATURE DEVELOPER
CHINANISO MAJONI – SENIOR NOMENCLATURE DEVELOPER
LUÍS CARRAÇA – SENIOR NOMENCLATURE DEVELOPER

STANDARDISED NOMENCLATURE IS ESSENTIAL FOR MAINTAINING PATIENT SAFETY AND PROMOTING BETTER HEALTHCARE OUTCOMES.
AGENDA - GMDN INTRODUCTION

- What we do
- Governance
- GMDN Database
- GMDN Use Cases
- Access to GMDN
- UDI Implementation and Language Translation Guidance
- Q&A
GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)
A NON-PROFIT, CHARITY

GMDN’s history started in 1991 by the European Standards Organisations (CEN) and later supported by the Global Harmonisation Task Force (now the International Medical Device Regulators Forum - IMDRF)

Name and Group All Medical Devices

- ~25,000 GMDN Terms for all medical devices. All are systematically named to reduce duplication and ambiguity
- Representing the current innovation and supply of all medical devices. Dynamic nomenclature updated in real-time
- Term Enquiry service for all users

Access to GMDN

- Register to GMDN, become a Member
- Free access to the complete GMDN Database for all Regulators/Governments, Healthcare Providers/Hospitals, Academia, CABs; and public data sharing via free of charge licence agreement
- Access to all: Membership options (incl. free of charge) are available (https://www.gmdnagency.org)

Globally Recognised and Independent

- ~13,000 users: >70 Regulatory systems, users across the globe >145 countries (Medical Device Manufacturers, CABs, NGOs, Academia, others)
- UDID used since 2013 (FDA’s GUDID)
- Self-funded, independent and guided by Regulators

Do not duplicate or distribute without written permission from GMDN Agency.
THE GOVERNANCE OF GMDN
A NON-PROFIT, CHARITY

Management and maintenance of the GMDN Database is monitored and controlled by an ISO9001 Quality Management System. Our QMS is annually audited by a third-party Certification Body. The GMDN Agency has internal QMS and SOPs regarding Term development, management of GMDN Term Enquiries, translations, stakeholder/Regulator consultation and management of conflicts.

*All Advisory Groups are providing advice to the Board of Trustees, and all members are volunteers and are not funded for activity linked with GMDN Agency governance.

*GMDN Agency reserves the right to change the organisational structure as needed.
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Non-proprietary groups are defined by:

- **Name** – Unique and full-descriptive
- **Definition**
  - Scope of devices covered by name, including
    - Intended use
    - Technology/material
    - Form/components
    - Significant attributes (e.g., use-frequency, pharmaceutical inclusion, device power)
- **Code (ID)**
Wound-nonadherent dressing, absorbent, non-antimicrobial
46854
A wound covering typically in the form of a multi-layered pad having a material or substance on its skin-contact surface (e.g., silicone gel), or designed to be soaked in saline prior to application, to prevent adherence to the wound bed thereby decreasing wound trauma potential; it does not contain an antimicrobial agent. It is typically used to absorb wound blood/exudates while protecting the wound from external contamination and maintaining a moist internal environment. It may be used as a primary or secondary dressing to treat chronic and postoperative wounds, burns, ulcers, abrasions, cuts, or puncture sites; it is not a dedicated burn dressing. This is a single-use device.
GMDN* USE CASES

Traceability, Single Language

Safety signal detection and vigilance reports
Post-market surveillance

Regulators

Pre-market approval (Planning, Innovation)

Manufacturers

Clinical

Supply Chain

Inventory
Purchasing

Hospitals

Tendering
Market Analysis


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WHY GMDN IS IMPORTANT FOR GLOBAL PUBLIC HEALTH?

- >25 years of experience, reliable editorial rules, internal SOPs and QMS, guided by Regulators
- Embedded in the global regulatory framework
- Represents the current supply of all medical devices, captures innovation
- Complements UDI:
  - Traceability across jurisdictions
  - Early signal detection of medical device performance issues (Beyond single device issue detection, capturing proportional reporting ratio within the group of similar devices)
  - Enables data analysis - pooling data from pre-market and post-market surveillance programs
  - Enables to identify the right technology for the patient
- Linking medical device data across different health systems and stakeholders: Government (Regulatory/Customs, etc.) – Healthcare Providers – Supply Chain – Procurement/Tendering – Asset Management, etc.
- Supports “Global Harmonisation”, “Regulatory Convergence” and “Regulatory Reliance”
THE WHO AND THE GMDN COLLABORATION

- The collaboration/agreement scope includes the “Essential in vitro Diagnostic (EDL) list” and the “List of Priority Medical Devices”: Publications, electronic platforms, database management, database analysis and consultations

- The rights granted to the WHO include using 3,000 GMDN Codes, Terms and Definitions in the above-listed WHO publications and electronic platforms (Creative Commons Licence, Non-Commercial)
  - https://medevis.who-healthtechnologies.org/

- GMDN is willing to expand its collaboration with the WHO to support global harmonisation
HOW TO ACCESS GMDN

- Visit the GMDN website [www.gmdnagency.org](http://www.gmdnagency.org) and select the Register button on the top right of the website
- Complete the member registration form as a ‘Government Department’ and verify your e-mail address
- As a Regulator/Healthcare Provider/CAB member, you will have free access to the full GMDN Database
- The GMDN Agency uses a membership model for access to the GMDN to protect and maintain the integrity of the data, ensuring that any publicly available data is accurate, up to date and supports patient safety
SUPPORT FOR USING GMDN

- The GMDN website www.gmdnagency.org has an FAQ section, Training Videos and User Guides to help you use GMDN
- We also offer one-to-one training sessions for Regulators
- You can email us at admin@gmdnagency.org to request a session or for any queries
As a global organisation, the GMDN Agency supports several language translations of the GMDN Categories and Terms. Our supported languages are:

- **GMDN Categories Translations**: Arabic (in development), Brazilian Portuguese, Chinese (Simplified), Danish, Dutch, English, French, German, Italian, Japanese, Norwegian, Polish, Russian, Spanish, Swedish
- **GMDN Terms Translations**: Brazilian Portuguese, English, French, Russian, Spanish, and more
- They can be viewed on the Term Details and Explorer pages via the advanced search functionality. Complete available translation datasets for selected languages may also be obtained via our file-sharing FTP service. Please contact us for more information
- Additional languages: There are available historical translations for additional languages (EU languages, Traditional Chinese). Please contact us for more information

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REGISTER FOR OUR NEXT GMDN TRAINING WORKSHOP FOR REGULATORS

- Join our next GMDN Training and Q&A Workshop for Regulators:
  17 July 2024, 11:00 am (UTC + 01:00) - 75 minutes
- You can register your interest by emailing communications@gmdnagency.org.uk
- Or register directly with Zoom using the below link:
  https://us06web.zoom.us/webinar/register/WN_cA_ohu2mRHK6-znSRgF2qg

Agenda

- How to set up a GMDN Account
- How to manage your GMDN Account (users)
- How to search for a GMDN Term
- How to access the full GMDN Dataset
- Overview of different GMDN memberships
- Q&A Session
UDI IMPLEMENTATION & GMDN

- GMDN collaborates with:
  - FDA
  - MHRA
  - TGA
  - Health Canada
  - ANVISA
  - INVIMA

- Countries working on their UDI implementation, have access to the GMDN Database: Japan, Türkiye, Saudi Arabia, Singapore, South Korea, Switzerland, and others

- Some European countries still access and refer to GMDN in different capacities

- GMDN is willing to collaborate with all “Regulators” who wish to utilise GMDN Database
GMDN IS HERE FOR YOU
THANK YOU

Our Website: https://www.gmdnagency.org/
Email Us: admin@gmdnagency.org