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

World Health Organization

Information session 1 December 2022

World Health Organization

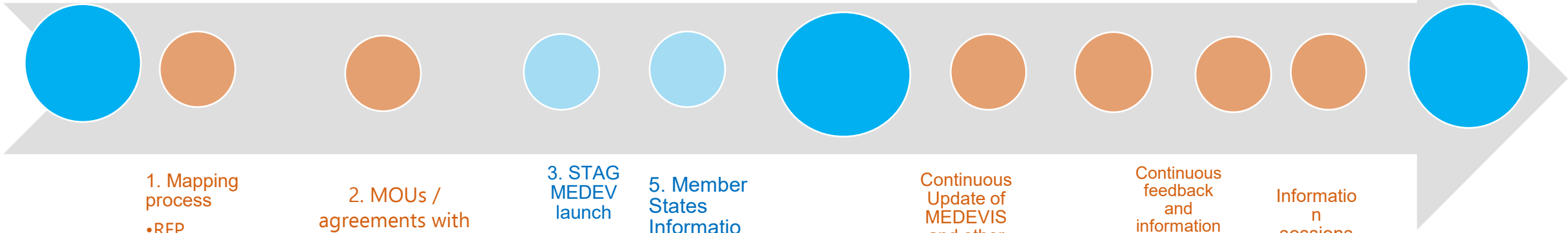
Actions following WHA75(25) decision

WHO May 2022

WHA75 (25) decision

WHO EB 152 January 2023

EB156 January 2025



1. Mapping process
   - RFP September
   - Vendor selection October
   - Mapping Dec 2022 to July 2023.

2. MOUs / agreements with nomenclature agencies and with other entities

3. STAG MEDEV launch

4. Global Atlas 2022

5. Member States Information session on 1 Dec 2022

Continuous Update of MEDEVIS and other WHO platforms

Continuous feedback and information sessions in 2023

Information sessions in 2024

0. Decision by WHA 75[1]
28 May 2022

On standardization of medical devices nomenclature… Decided to request the Director General:

(1) 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)4 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 156 in January 2025**

https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(25)-en.pdf

1. Publication of the Global Atlas of medical devices 2022, Including country profiles

https://apps.who.int/iris/handle/10665/364709

Global atlas of medical devices 2022 (who.int)

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.regjeringen.no/no/dokumenter/meld-st-10-20122013/id709025/
Language(s): —
Ministry of health responsible for health technology policy implementation: The Department of Specialiced Health Care Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, refer to the procurement of medical devices at national level section.

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: https://www.helsedirektoratet.no/tema/beredskap-og-krisehandtering

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[8] Yes
HTA unit/department includes the assessment of medical devices: Yes
Unit/department: Norwegian Knowledge Centre for the Health Services within Norwegian Institute of Public Health (NIH).
Website(s): https://www.fhi.no/en/qk/HTA/
https://helsedirektoratet.no/english
Contact: — Email: Folkehelseinstituttet@fhi.no
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The system has two levels; a national level where decisions based on HTAs are made by the four regional health authorities in concert, and a local/"hospital-level" where decisions are made based on the mini-HTAs performed locally in each hospital. Pharmaceutics have to pass always by the national level. The Norwegian Knowledge Centre for the Health Services (member of the NIPH since 2016) do HTAs on selected

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Norwegian Directorate of Health, Department of Medical Devices and Medicinal Products.
Website(s): http://www.helsedir.no
https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&#x2a
Contact: Ms. Marit Endresen Email: meddev-no@helsedir.no
Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Health: Department of M;edical Devices and Medicinal Products.
Other agency's website: https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&#x2a

National regulatory comments (...Annex 1):
The Directorate of Health, Department of medical devices and medicinal products is the Competent Authority for medical devices in Norway, it has the tasks of the competent authority as they are given in the European directives for medical devices. These tasks, however, are not identical with those listed under the corresponding ones of this survey.

Additional comments sent by member States

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Bosnia and Herzegovina	For the Republika Srpska: Regarding the procurement of various medical devices, the company that generally provides the medical device must ensure capable suppliers who can implement a proper assessment and who can carry out the certification of medical devices.	The nomenclature is based on GMDN and EDMA codes; the instructions request manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. This country have free access to the GMDN base, and found a new version of EDMA codes on the internet.	Responsible authority in both entities. Ministry of Health of Republika Srpska is responsible for the procurement of high-cost technologies while the Health Care Institutions can provide procurement of other medical equipment.	–	–
Botswana	There is a drug regulatory unit. It has a draft for an Act that will regulate medicines and medical devices.	–	–	There is the Medical Equipment Asset Register which was completed in December 2009. The Custom Solution is being implemented; the contract was signed on May 19th 2010.	Concerning the Infrastructure section: there are 800 clinics, healthposts and mobile clinics.
Brazil	–	Anvisa started working to internalize the GMDN. So far, 100 of Anvisa's technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, which was sent to the Public Consultation (2021).	In the given website search for the corresponding documents in procurement field. There are Lists of OPM, Procedures and Protocols.	Even though there is no standardized software for the medical equipment management in Brazil, some hospitals and other health facilities have developed and implemented their own. Besides that, the Post Market Surveillance of Medical Devices Unit of ANVISA, the Brazilian Regulatory Authority, intends to develop a software to address the main needs related to medical electrical equipment management (information related to the history of the medical equipment).	–

2. Update of the Global Model regulatory framework. Approved by ECBS to be published 2023

Including a section on nomenclature of medical devices.

2017 publication ,underwent update

https://cdn.who.int/media/docs/default-source/biologicals/bs-documents-(ecbs)/ecbs-oct-2022_executive-summary_13_nov_2022_ik.15_nov_2022.pdf?sfvrsn=beee3268_1&download=true

Expert Committee on Biological Standardization (who.int)

Main outcomes of the meeting of the Expert Committee on Biological Standardization held from 24 to 28 October 2022Approved and for later publication

WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices.

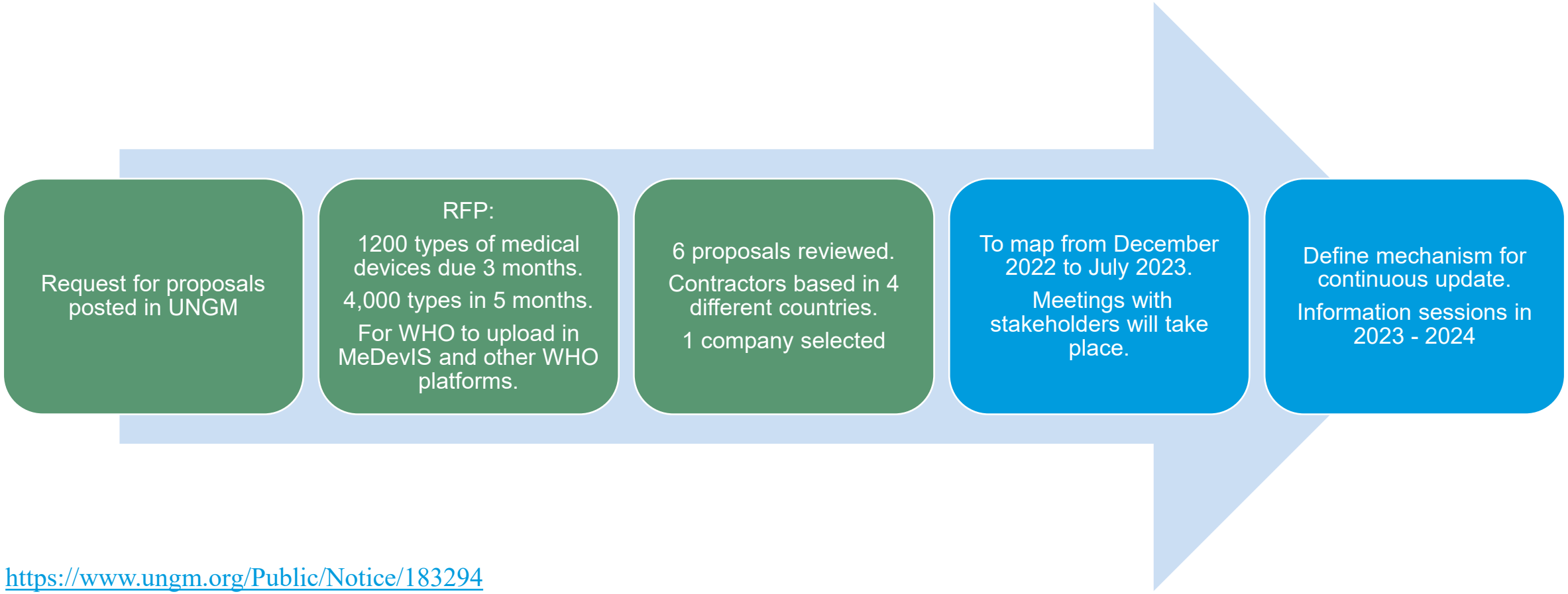
The effective regulation of all medical products has long been recognized by the World Health Assembly as an essential component of health system strengthening and improved public health.

The 2017 WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (IVDs) has provided guidance to countries on the regulatory control of such devices.

In light of subsequent technological advances, increasing product complexity, and a need to support new developers and regulators with only limited experience of new developments in the field, the framework has now been substantially revised and updated.

3. Mapping / cross reference of nomenclature terms and codes of medical devices

"Mapping of MD nomenclature data, for integration in WHO platforms"



https://www.ungm.org/Public/Notice/183294

4. Agreements for collaboration in process

To have a framework of cooperation and facilitation of data and integrate available information related to MD (code, terms and definitions) in WHO platforms.

Parties:

A) Nomenclature Agencies and data owners: EC, GMDN, ECRI (UMDNS), UNDP-GS1(UNSPSC):

   A) to provide access to the database

   B) ensure continuous access to updates

   C) and willingness to make publicly available the results in WHO platforms and under Creative Commons Attribution IGO License (CC BY 3.0 IGO).

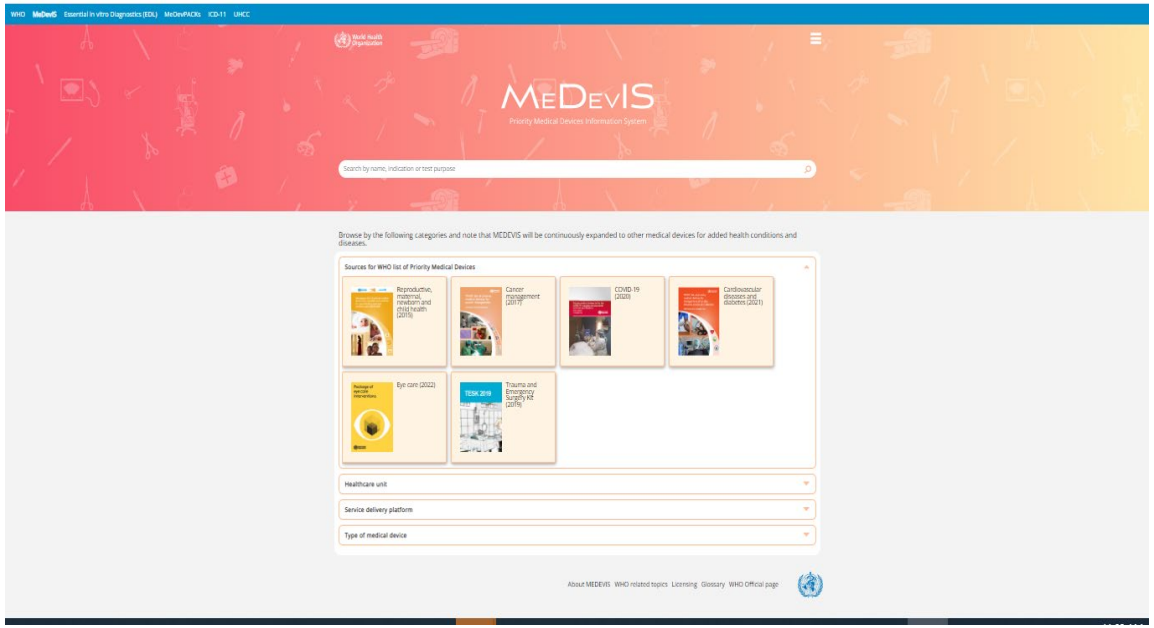
B) Other nomenclature sources:

- Ministries of Health
- National regulatory authorities
- UN Agencies
- NGOs with UDIDs or Product Lists, etc.

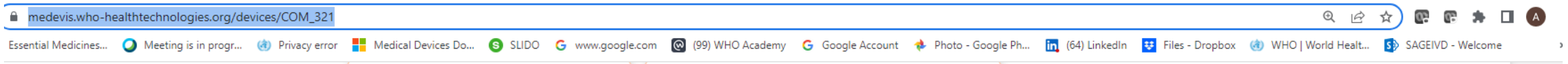
5. Update of MEDEVIS, including links to other WHO platforms

World Health Organization

WHO **MeDevIS** Essential in vitro Diagnostics (EDL) ICD-11 UHCC



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



Service delivery platforms	2. Community-based services 5. First referral level (District Hospital) 6. Second referral level and above (Regional or National hospital)
Healthcare unit	Emergency care General surgery Inpatient care Intensive care Long-term care Pre-hospital care Specialized surgery
Type of medical device	Medical gas equipment
EMDN related* code(s)	Z12159004 OXYGEN CONCENTRATORS https://webgate.ec.europa.eu/dyna2/emdn
GMDN related* code(s)	31321 Mobile/portable oxygen concentrator 12873 Stationary oxygen concentrator https://gmdnagency.org © GMDN Agency 2005-2021
UMDNS related* code(s)	12873 Oxygen Concentrators https://www.ecri.org/solutions/umdns © ECRI. All rights reserved
UNSPSC related* code(s)	42271702 Oxygen concentrators https://store.unspsc.org/collections/codeset-downloads

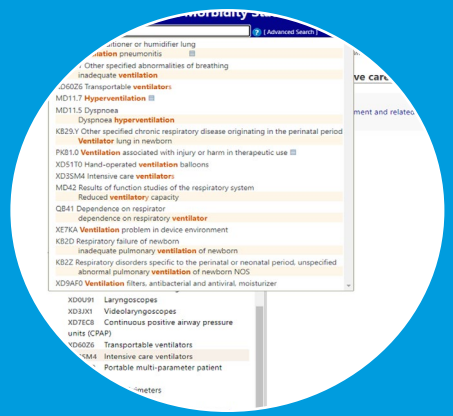
* The codes shown in this section were observed and retrieved from public databases and complemented with the input of Nomenclature Agencies. More information

Capital, reusable or single-use	Capital

Towards: Exchange of information on medical devices terms and codes, for regulation, assessment, management

Among WHO electronic platforms

MeDevIS &
eEDL



ICD-11 &
ICHI

UHCC &
Smart guidelines

6. STAG MEDEV Strategic and Technical Advisory Group on Medical Devices, to advise WHO on:

1. **Current and future challenges** relative to medical devices and related health technologies…

2. Global **policies and strategies** on medical devices and their linkages with other health systems elements, to support Universal Health Coverage and Global Public Health Security;

3. The adequacy of progress towards the achievement of Medical Devices related objectives set in the **World Health Assembly resolutions;**

4. Evaluation of the scientific technical and strategic aspects of access to good quality, affordable, appropriate, safe and efficacious medical devices;

5. The development, update and implementation of the **WHO Priority and Essential Medical Devices**

6. **S**trategies for investment on appropriate priority **medical technologies for primary health care**;

7. Strategies for **increased access** to medical devices for early diagnosis, effective treatment, continuous monitoring and protection.

8. Priorities within the Organization and/or relevant technical unit related to the field of work of STAG-MEDEV;

9. Strategic directions to be prioritized on all types of medical devices; and

10. P**olicies, naming, innovation, selection, regulation, management, safe use until decommissioning.**

Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) (who.int)

Areas of impact of the nomenclature of medical devices:

World Health Organization

Nomenclature

Policies

- Development of national policies

R&D

- Innovation

Regulations

- Lists of approved MD for marketing in country.

Assessment

- Health Technology Assessment
- Priority medical devices lists

Management

- Technical specifications, procurement and supply
- Installation, inventories, training, maintenance, operations
- Post market surveillance and adverse event report
- Decommissioning, Replacement
- Safe use

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Medical devices

Email: medicaldevices@who.int

website:https://www.who.int/health-topics/medical-devices#tab=tab_1