EB156 Item 11 Standardised nomenclature for medical devices

Contents

In focus

In accordance with decision WHA75(25) (2022) the Director-General has published a report (EB156/13) on the integration of terms, codes and definitions in the Priority Medical Devices Information System (MeDevIS) and their linkage with other WHO platforms. The Board will be invited to note the report and provide further guidance.

Background

EB156/13 provides an overview of the history of this complicated story. See also Tracker links to previous EB &/or WHA discussions of medical devices and the WHO summary of Executive Board decision making related to a standardized nomenclature for medical devices and its use in Priority Medical Devices Information System (MeDevIS).

A standardized international classification, coding and nomenclature for medical devices supports technology assessment, regulation (standard setting, marketing approval), patient safety (adverse event reporting), procurement (discoverability, ordering), and quality of health care (efficacy, cost-effectiveness).

A particular benefit of standardisation from WHO point of view is that it makes WHO's priority medical devices lists more useful by specifying the devices referred to more precisely. These lists presently include:

- reproductive, maternal, newborn and child health,
- cancer management,
- cardiovascular diseases and diabetes,
- eye care,
- emergency surgery, and
- in vitro diagnostics.

Most of these functions will still benefit from the new MeDevIS (including EMDN and GMDN systems) although research and evaluation across international borders will be somewhat more involved than if a single global system had been developed.

A further benefit of having a standardised nomenclature system is that it can be used to support mandated unique device identification (UDI) and the documentation of UDI in clinical records. This requirement can facilitate international collections and analyses for patient safety, clinical research and surveillance post marketing approval. (See TGA and FDA on UDI.)

While the International Medical Device Regulators' Forum originally recommended the development of a globally applicable mandatory UDI (here) this has been shelved for the time being. At the national level mandatory UDI, using either EMDN or GMDN, is still implementable.

PHM Comment

The Secretariat has accepted that a single universal open source, freely available nomenclature system which articulates with other WHO classifications, especially ICD11 is not practicable.

The reluctance of certain countries, currently committed to a particular system, to agree to moving towards international standardisation in accordance with the principles outlined by the Secretariat, is understandable in terms of avoiding disruption to their existing systems.

The medical device industry is huge and politicians are very sensitive to allegations regarding 'red tape'. Presumably governments have been under pressure from device manufacturers, hospital organisations, and private health insurance organisations all of whom have organised their systems around a particular classification.

The work the Secretariat has done in setting up MeDeIS1 is appreciated.

PHM urges member states to support the Secretariat's continued development of MeDeIS, expanding its range of guidance resources on priority medical devices, continuing to work towards interoperability with other classification systems (especially ICD, ICPM, and ICF).

Advice on the long term pathways directed to harmonising EMDN and GMDN would be useful.

Notes of discussion

Colombia

Panama

Republic of Moldova

Uruguay

Session 11

Canada (on behalf of UK and Australia): support progress towards standardisation of med dev nom. Critical for identifying med dev and resp to safety issues. Appreciate the report. Regulators require accurate and comprehensive data for post marketing surveillance. Agree that it is critical

to ensure that med dev nom is uptodate in WHO publications and databases. Appreciate the agreement between WHO and GMDN to publish codes in MeDivIS. Disagree that access via registration is a barrier; it is free and open to register and then gain access. GMDN remains a reliable and trusted resource that is consistent with WHO principles. Recognise that the mapping of GMDN to EMDN is complex and requires ongoing resource commitment. Rec continuing focus on updating data from original sources.

Poland (EU and memberstates etc, Norway): Thank Sect for the report. EU committed to global harmonisatoin and reg convergence for pt safety, reg compliance. Eu welcomes work of Sect in particular its inclusion of EMDN data in MeDevIS. EMDN is a clear publicly available nom system. Devd through open transparent collab process incl contribution from WHO. EMDN is freely available for use and downloading. EU has been developing data base on med devices. Will be mandatory to use. EU recall that EMDN clear free nom. global public good.

European Union

Ethiopia (Africa): ack progress made in Decision 75(25) integrating med systems and establishment of MeDevIS as clearing house. Welcome establishment of Africa med dev forum whjich will play important role. Several challenges: lack of uniformity, variable regulation, resource constraints, limited tech expertise, weak gov and oversight, limited access to high tech equip. Seek continued support from WHO in capacity building, support for developing standardiseed lists, tech ass in impln. Call for sustainable funding mechanism support implementation.,

China: Appreciates progress to harmonised nom. Will lead to safer high quality and more affordable. Mapping different nom systems highly time consuming. Closely following. 1. GMDN and EMDN systems are used in only some MS. Countries yet to adopt lack effective means of linking their products to WHO lists. Need to consider countries that use their own systems. 2. Standarisation is fundamental reqt.High qual data vital. Capacity building is essential, will improve feedback and improve quality. 3. UDI serves as id card for devices. Facilitates traceability, integrates and sharing of data. AT present WHO uses UDI in the context of mapping across different systems. Expanding its application and reserving dedicated fields in WHO's system for UDI would improve accuracy of product accessibility. China implied UDI in 2019 with 4m publicly accessible master data. China looks forwar to working with other member states to deepen cooperation with other countries and contribute to building a global community of shared health for mankind.

Session 12

Thailand: med dev fast growing industry. TL appreciates progress towards harmonising GMDN and EMDN. TL two suggestions: 1. sust maint and timely updates of MeDevIS 2. Stakeholder engagement to facilitate rapid implementation and continuing updating.TL supported

Moldova: welcomes report. ack progress. aligns with EU position presented by Poland. Importance of med dev nom. About Moldova system. Currently uses GMDN codes. Importance

of free access. Appreciate integration of EMDN and GMDN into WHO's MeDevIS. Strengthen accessibility and interoperability. Capacity building. Open access and sustainability.

Togo: Ass w statement fr Ethiopia. Commends sect on report. Should be applied and implemented. Appreciates the importance of medical devices in patient care. Welcomes progress in harmonisation of GMDNa nd EMDN. Invites MS to create national nom committees to ensure standardised nom systems in place.

Somalia (EMR) thank Sect for work on med dev nom. Reasons why important. v important in our region with diverse systems. WHO's priority device lists useful in various settings. standardised systems into MeDevIS is appreciated. this platform must continue to evolve. Integrate nom across WHO coding systems. Must be updated regularly. Need WHO support to countries in deploying priority lists and in capacity building. request WHO to promote integration between MeDevIS and global databases to promote seamless data sharing.

Morocco: Align with EMRO statement. Thank DG for continuedc work on standardiseaation of med dev nom. standardisation of med dev nom of strategic importance in terms of .Modernising rigorous reg framework for registering medical devices. Propose measures. Adopt standardised nom system. Str capacity. adopt reg capacity step up training. International and regional cooperation. share good practices and harmonise supply chains. Innovation and interoperability.

Colombia: Thank DG for report. Col backs WHO initiative. Need to consolidate nomenclature standardisation. Encourage updating and working with national systems. Importance of good system for traceability, emergency response,transparency. Fair access to priority med dev in all regions. Col uses EMDN. Col calls for further work on reg harmonisatoin, updating and integration. Impr capacity in use of EMDN. Enc interoperability. Support for WHO

Japan: App of WHO for its efforts. Med dev and med tech rapidly developing. Constantly being updated. App WHO role. Requests that WHO's platform is linked to global databases.

Russia: Thanks DG for report. Principles set out important. Despite the fact that the report mentions four systems the work program only addressing two systems, namely EMDN and GMDN. Both have pros and cons. Need to ensure transparency and avoid conflict of interest given the field is developing rapidly. Need to ensure balance between our requirements. Need to create a mech which links MeDevIS and other systems which do not necessarily comply with all of WHO's criteria. So look at local nom systems.

Panama: Welcomes report. Crucial step forward in ensuring patient safety. Standardised sysetm will facilitate traceability, and post marketing surveillance and international procurement. More efficient trade. WHO model list of priority med devices impt step forward. Contributes to regulation. capacity building of staff and stakeholders important. integration into national regulatory frameworks. Need to focus on interoperability across all database, avoid errors,m capa building, regulatory strentthening

Mexico: welcome integration of inf systems. including across ICD, person centred. Mexico will continue to promote reg str, cap building, procurement and use of med deve. Interoperability means that equipment and medicines are compatible,. Contextualise diseases in acc with local epidemiology. Need to be effective in local systems. Need to ensure progress (see full statement)

Mexico

Int Fed Int Ass for Med and Biomed Engineering. Appreciates progress. Need to update and increase the number of entries. RElatively few entries in MeDevIS as compared with 7,000 in EMDN and 20,000 in GMDN.

Dr Nakani: Thanks to MS to your report. Standardised naming contribute to a lot of benefits. Across databases. Have reached agreement with GMDN to use their definitions in MeDevIS. which includes both EMDN and GMDN. Second version of MeDevIS will be released shortly. We continue to populate and expand the list. China mentions UDI. We ack UDI is more accurate than naming systems. Continue to discuss with MS on how to improve usefulness. Expand. Look forward to working together with MS and other partners.

Board notes the report EB156/13