Overview of Nomenclature Systems for Medical Devices in WHO Member States

Draft Version 2

2021 Country Consultation and Desk Review

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Introduction

For a long time the need of a common Medical Devices nomenclature available for all WHO member countries has been acknowledged, and recently during the covid-19 pandemic its absence has been painfully felt. During the past WHO Executive Board 145 and 148 and World Health Assembly WHA74, WHO member states are exploring the current status of global medical device nomenclature systems and opportunities to harmonize approaches. The objective of this work is to present and summarize the information available concerning the existence and use of nomenclatures in the world.

Methodology

We collected and compared information about whether state members of the WHO had a nomenclature system in place and publicly available through the web, as well as the type and use of the nomenclature. There were three main sources of information:

- Country answers, comments and websites shared by the member countries within the BCSoMD 2021 (the Baseline Survey of Medical Devices that served to create the Global Atlas of Medical Devices or GAMD 21) and the subsequent nomenclature consultation
- Desk Review
    - Search for webpages
    - Search for studies such as journal articles, reports, and thesis using Medline and Google scholar

Global Atlas of Medical devices 2021 (or GAMD21) nomenclature consultation

Since the nomenclature data gathered from the BCSoMD 2021 was considered rather incomplete, it was decided to conduct an email consultation to ask the countries focal points to kindly confirm and complete the information we had from their countries. We sent the request on February 21 setting a first deadline of March 21st, and continued follow up receiving and updating answers up to the end of May.

In some cases it was discovered the contact person had changed and a follow up continued in order to find the information required. The information we acquired from this consultation was integrated into the GAMD 21 and used for this review.

Desk Review Search

The Desk Review search was made during the months of February, March and April 2021.

The following search string was used in Google and Medline search engines:

COUNTRY NAME AND (“NOMENCLATURE” OR “CLASSIFICATION” OR “REGULATION” OR “SYSTEM”) AND ("MEDICAL DEVICES" OR "MEDICAL EQUIPMENT")

If no relevant hits were found in English, a reviewer would translate to the country's official language. When reviewers did not yet find an answer, they tried synonyms, and then proceeded by searching and reading anything related to laws and commercial sites on medical devices in order to find the appropriate wording for the search terms in the target language and adjust the search accordingly. In many cases, they also looked for clues into the Ministry of Health website, searched for dedicated agencies and eventually for procedures regarding import of medical equipment.

Results

In the following sections we present the quantitative results for the nomenclature system of medical devices taking into account two sources of information: the Baseline Country Survey of Medical Devices 2021 update, the desk review 2021. Moreover, in this research we also made a comparative analysis between two sources in order to develop a more comprehensive account.

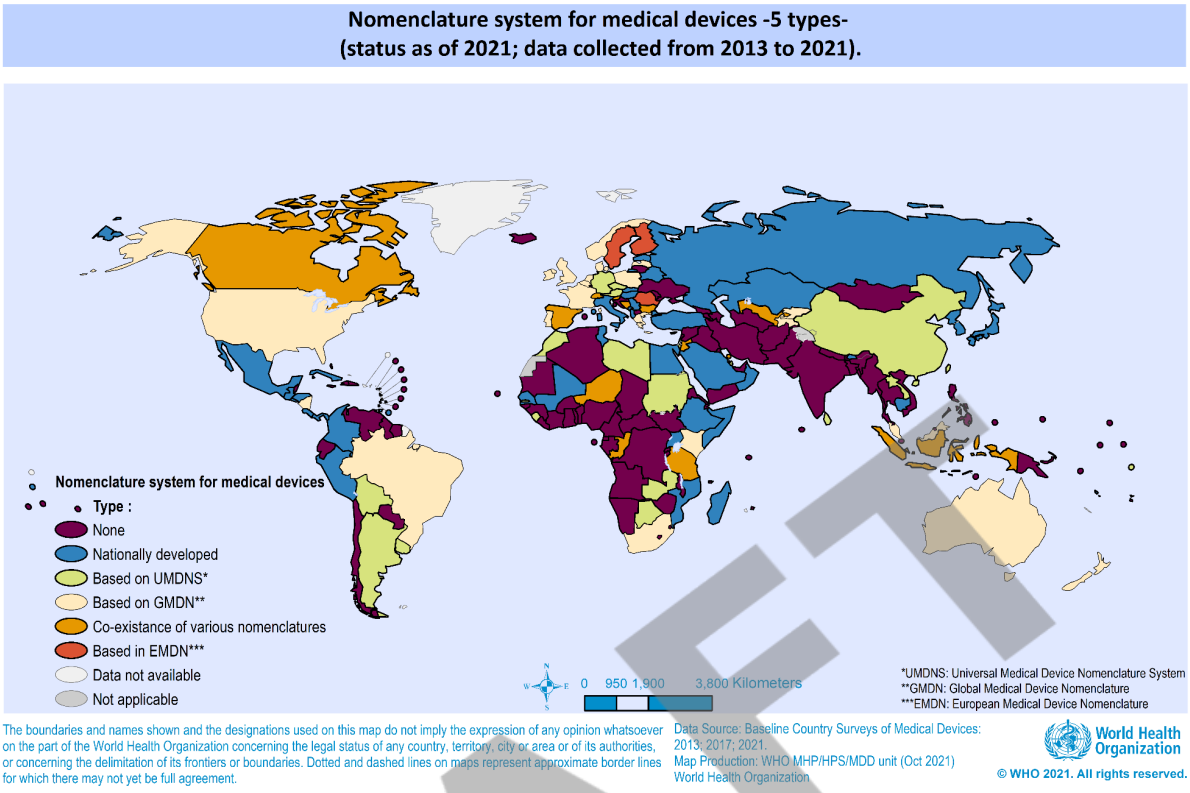
Baseline Country Survey of Medical Devices

The Baseline Country Survey of Medical Devices (BCSoMD) is of particular interest in the context of our research since BCSoMD covered several cross-cutting themes concerning medical devices and collected a significant amount of data during the following periods: 2010-2013, 2014-2017, 2020-2021.

The latest BCSoMD update, in which 179 countries took part, comprises data summarized in the Global Atlas of Medical Devices 2021 regarding the key points of our research that are listed as follows:

- countries that had a nomenclature system;
- type of a nomenclature system;
- nature of the use of a nomenclature system;
- variability of the mentioned above parameters by region.

An overview of the results of our analysis of BCSoMD data can be seen in Map 1.



Map 1.

Half of the responding member states, i.e., 98 (50%) had an official nomenclature, and 42% did not have an official one. A total of 15 countries (8%) did not participate in the survey (see Fig. 1).

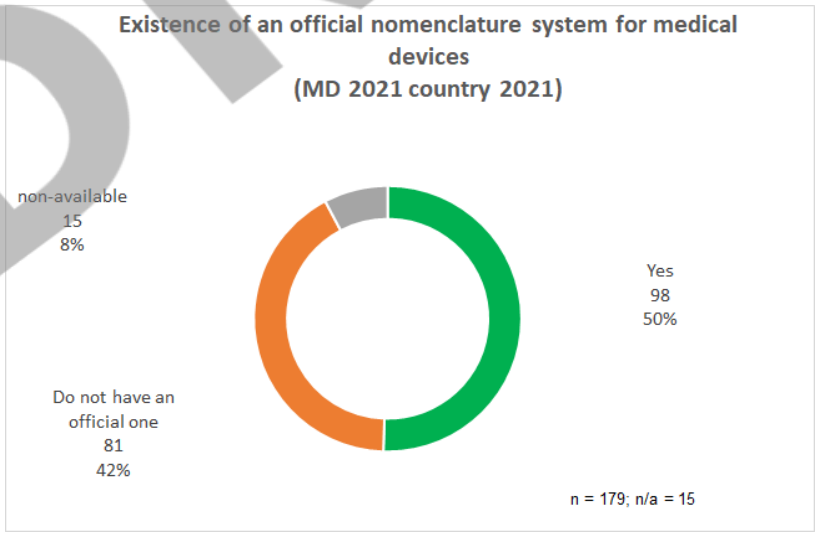


Figure 1.

Less than a half of the responding member states, i.e. 81 countries (45%) do not have an official system for medical devices. In contrast, 98 member states use, at least, one nomenclature system with the following types: 23% have developed a national nomenclature system, 11% use the Universal Medical Device Nomenclature System (UMDNS), 12% use the Global Medical Device Nomenclature (GMDN), 8% use more than one system and only 2% uses the Italian Classificazione Nazionale Dispositivi medici (CND) or the European Medical Device Nomenclature (EMDN) (see Fig. 2).

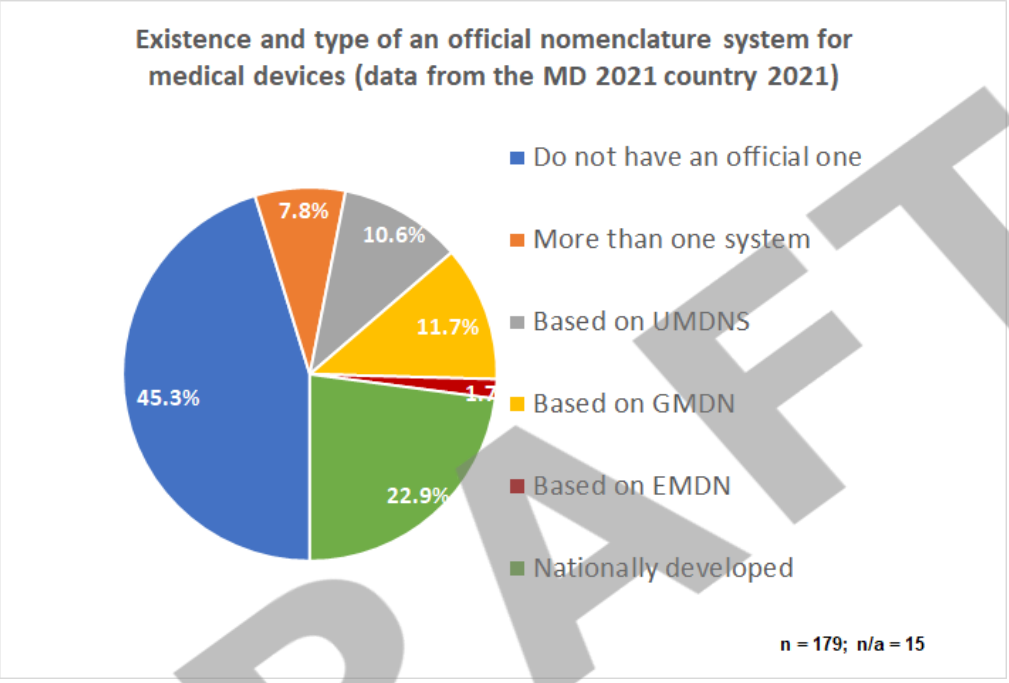


Figure 2.

In most of the regions — African (AFR), Region of the Americas (AMR), Eastern-Mediterranean (EMR), European (EUR), Western Pacific (WPR) — it was reported that the usage of medical device nomenclature systems comprises mainly regulatory, procurement, and a combination of both purposes. The countries of the South-East Asia Region (SEAR) did not indicate any specific use for their corresponding nomenclature systems (see Fig. 3).

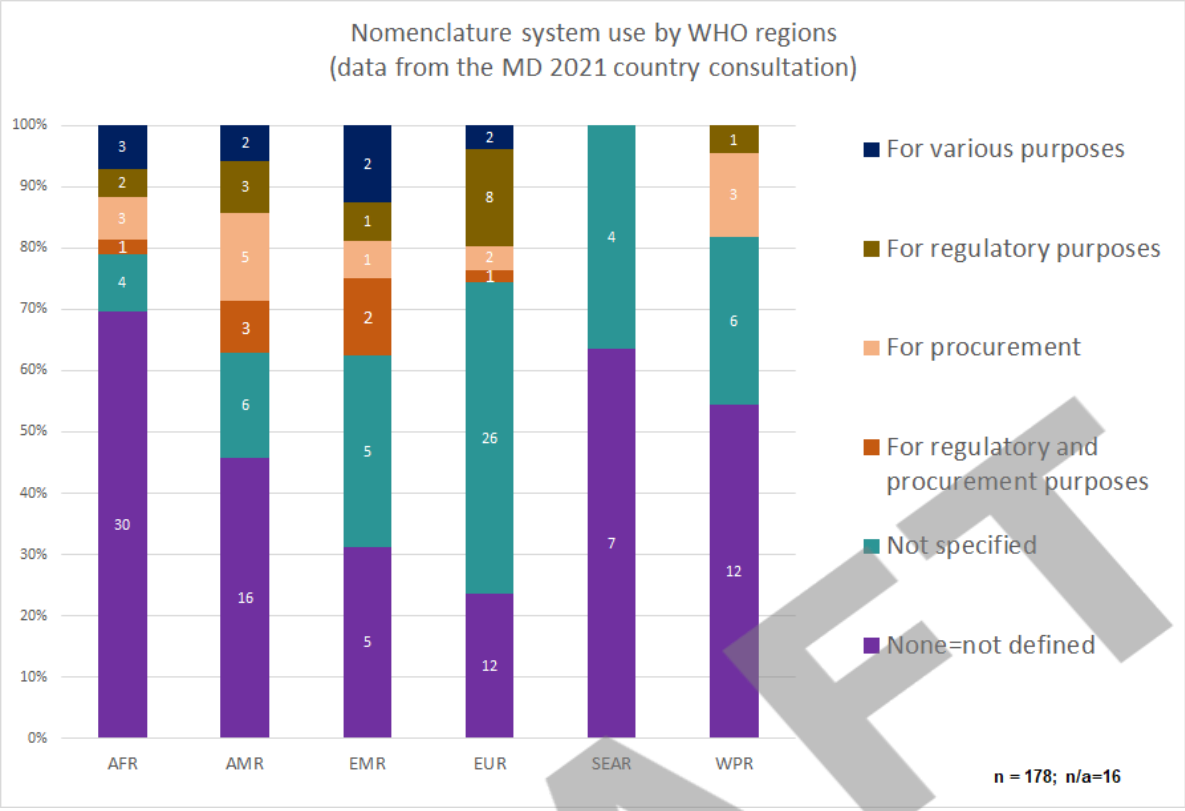
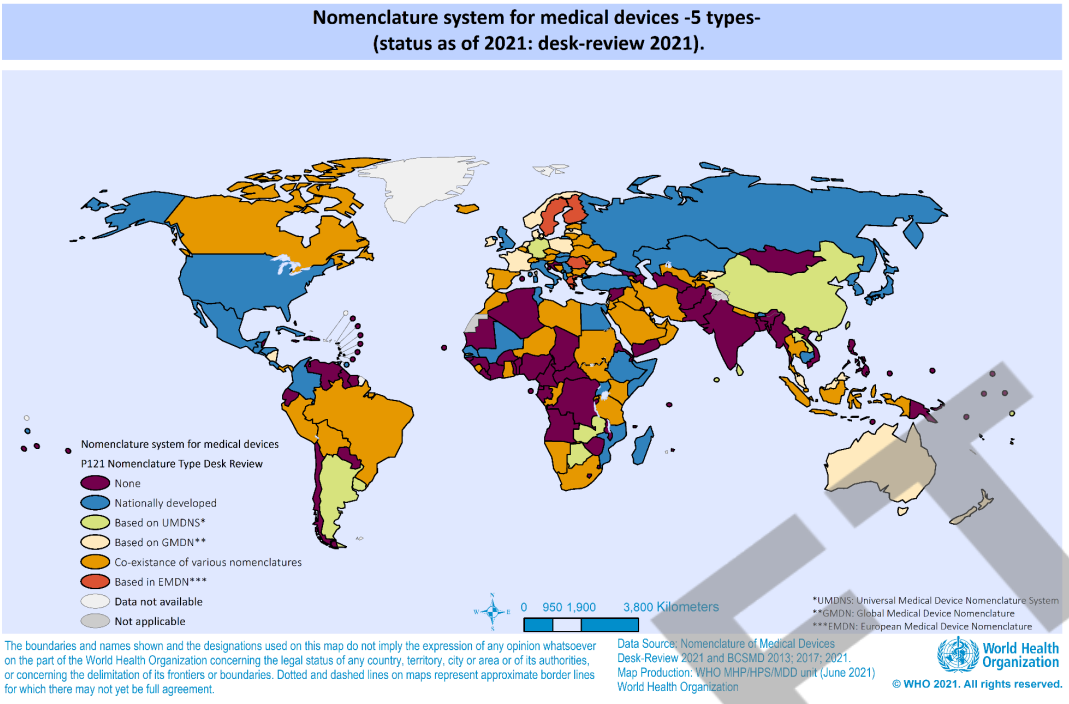


Figure 3.

Desk review

Regarding the scientific literature, we found five scholar sources (which we summarize in the Annex 1 - Relevant scholar sources) that covered regulatory requirements of Medical Devices in Southeast Asia and China, Africa, Europe, MENA countries and the Americas. These papers and master thesis contributed directly to the International Agreements section and some Countries data, and provided leads to continue the web search, such as the names of international agreements and institutions.

Most of the Desk review country findings come from publicly available web pages. Information from the web searches was found for a total of 184 countries. An overview of the country-results can be seen in Map 2.



Map 2.

The consultation stated that more than a half of the member states, i.e., 119 (61%) have an official nomenclature, 34% do not have an official one, and the data from 10 countries (5%) was not available (see Fig. 4).

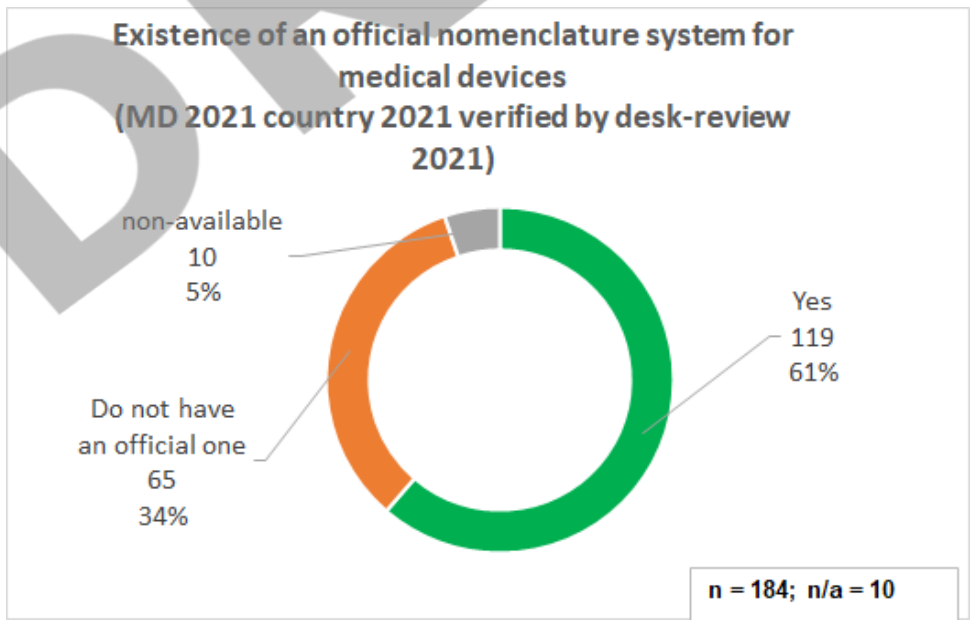


Figure 4.

Around one third of member states, i.e., 65 (35%) do not have an official nomenclature system for medical devices. In contrast, 119 (61%) who have an official nomenclature system are using the following types: 52 (28%) have more than one system, 37 (20%) have developed a national system nomenclature, 14 (8%) use a nomenclature based on Global Medical Device Nomenclature (GMDN), 12 (7%) use the Universal Medical Device Nomenclature System (UMDNS), and only 4 (2%) uses the Italian Classificazione Nazionale Dispositivi Medici (CND) or the European Medical Device Nomenclature (EMDN), (see Fig. 5).

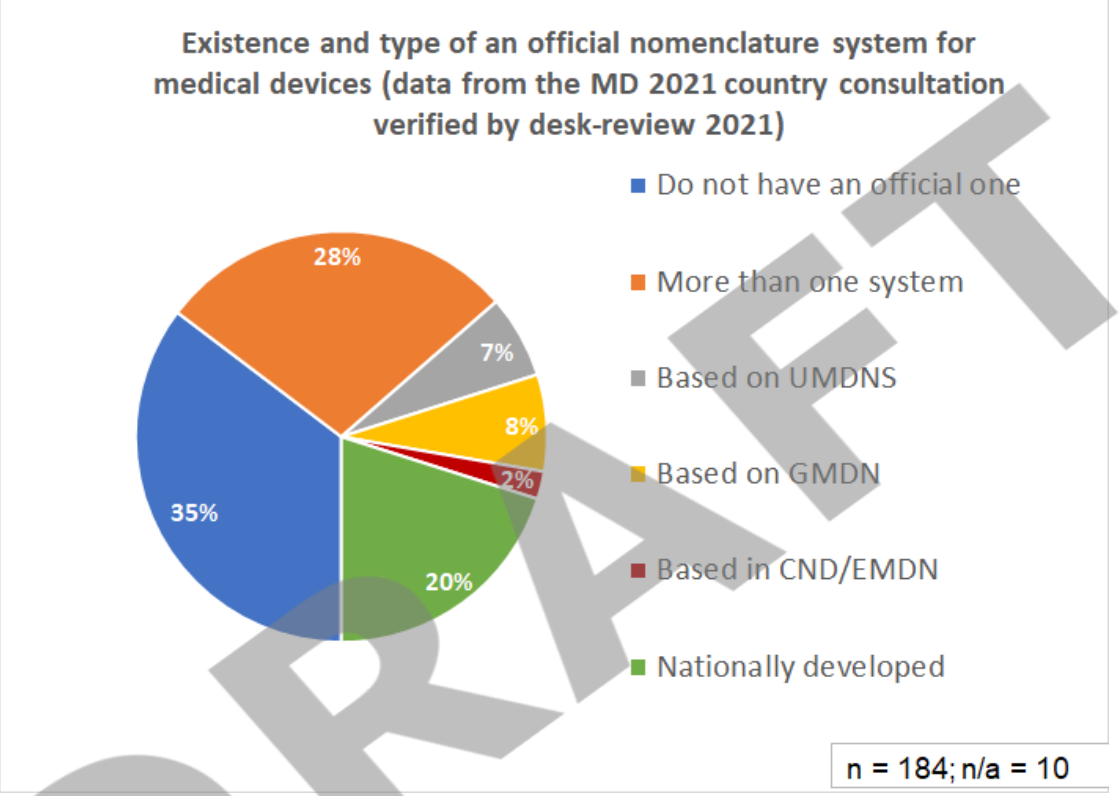


Figure 5.

In five regions —Africa (AFR), Americas (AMR),Eastern-Mediterranean (EMR), Europe (EUR) and the Western Pacific Region (WPR)— the usage of medical device nomenclature systems comprises several purposes such as regulatory, procurement, a combination of the both mentioned above and other purposes. In the South-East Asia Region (SEAR) only one country was found to use, for various purposes, a nomenclature system.

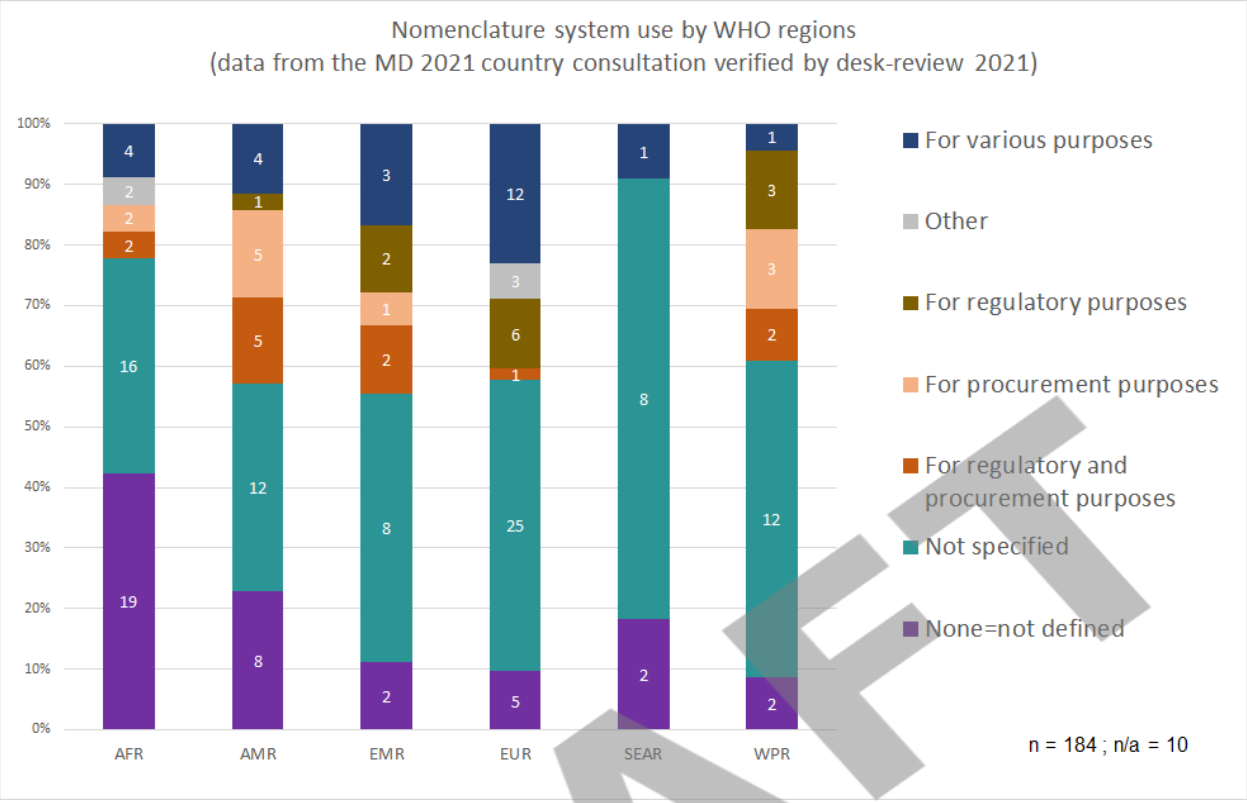


Figure 6

The majority of the country-specific findings of the desk review are shown as comments in Annex 2 - Findings by country, and supported by websites and literature. The full extraction sheet can be found in this spreadsheet.

International and regional agreements

In addition to country-by-country analysis we also examined the regulation of medical devices, in particular in terms of nomenclature systems, at the international and regional level.

Various countries as well as corporations use the United Nations Standard Products and Services Code (UNSPSC) alongside the Harmonized Commodity Description and Coding Systems (HS) to trade products, including medical devices.

European Union

The member states of the European Union use different nomenclature systems of medical devices (for more detailed information,please, consult Annex 2 - Findings by country), however, the EU is currently making efforts to develop a common nomenclature system - the European Medical Device Nomenclature - (FAQ on EMDN) that will be based primarily on Classificazione Nazionale Dispositivi medici (CND).

Recent EU regulation updates dating from April 2017 (Regulation (EU) 745/2017 on medical devices and Regulation and (EU) 746/2017 on In Vitro diagnostic medical devices) introduce the use of an EU identification system for medical devices based on a Unique Device Identifier (UDI). For more information, please, see the following link:

- Unique Device Identification (UDI) System.

Eurasian Economic Union (EEU)

In March, 2019 the Eurasian Economic Commission (EEC), whose members are Armenia, Belarus, Kazakhstan, the Kyrgyz Republic, the Russian Federation, and the Global Medical Device Nomenclature Agency (GMDNA) signed the Memorandum of Understanding with a primary goal to start harmonizing Eurasian Economic Union's nomenclature system with the one developed by the Agency.

The common market of medical products within the Eurasian Economic Union begins to function in full from 2022. In order to implement the Agreement on common principles and rules for the circulation of medical devices (medical products and medical equipment), more than 20 general regulatory documents have been developed; two of them are devoted to the creation and maintenance of the medical device nomenclature of the Union (link).

The Southern Common Market (MERCOSUR)

MERCOSUR has developed the Mercosur Common Nomenclature (MCN) that is based on the Harmonized Commodity Description and Coding System developed by the World Customs Organization (WCO). The MCN provides information concerning a wide range of products including medical devices.

The member countries of MERCOSUR agreed to use the MCN in terms of importing and exporting commodities, however, some of the countries use nationally developed or other types of nomenclature systems, for more detailed information about each member of MERCOSUR, please, consult Annex 2 - Findings by country.

Association of SouthEast Asian Nations (ASEAN)

One of the key documents that addresses several issues concerning medical devices regulation within ASEAN is the ASEAN Medical Device Directive (AMDD). The AMDD includes provisions under which the member states committed themselves to harmonize the sphere of medical devices regulation to facilitate trade and cooperation. Today, ASEAN is working on the development of a common nomenclature. For further information, please, consult the Medical Device Guidance and The 1st Asian Medical Device Committee Meeting and Related Events.

United States-Mexico-Canada Agreement (USMCA)

Although the USA, Canada, Mexico within the United States-Mexico-Canada Agreement (USMCA) are advancing towards more integrated environment in terms of regulatory framework convergence (the USITC document), in particular developing the same risk-based classification of medical devices, countries do not use a common nomenclature system of medical devices yet.

African Medical Devices Forum (AMDF)

The African Medical Devices Forum (AMDF), under the auspices of the African Union, serves as a platform for enhancing integration and regulatory framework convergence in the context of medical devices. The issue of a common nomenclature system has not been addressed yet.

Asian Harmonization Working Party (AHWP)

Global Harmonization Working Party (formerly known as the Asian harmonization working party: the AHWP) with members from Asia, Africa, Middle East and South America facilitates the process of regulatory framework convergence, encouraging its member states to use GMDN, although no common nomenclature has been adopted yet.
Related links below:

- Playbook for Implementation of a Medical Device Regulatory Framework
- Requirements of Medical Devices Nomenclature for the AHWP
- Asian Harmonization Working Party (AHWP)

The Global Harmonization Task Force on Medical Devices (GHTF) and the International Medical Device Regulators Forum (IMDRF)

The Global Harmonization Task Force on Medical Devices (GHTF) established the International Medical Device Regulators Forum (IMDRF) in order to accelerate international medical device regulatory harmonization and convergence. The IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence

IMDRF Adverse Events Working Group developed a nomenclature for the adverse events reporting, including terminology and codes (see the IMDRF Terminologies for Categorized Adverse Event Reporting). IMDRF strategic plan for 2021-2025 can be found here.

Comparison of desk review and BCSoMD

The BCSoMD collected data about 179 countries and the desk review gathered information about 5 more, bringing the total number of countries that we have information about to 184. Nevertheless, the nomenclature system status of 9 countries remains unknown. Although some gaps in the data provided by the member states on the BCSoMD21 were covered through the web and literature search of the desk review, the difference between both data sets can also provide some insight about the accessibility of such information, either public or through the country itself.

For example, there is a 10% difference between countries that answered that they do not have any official nomenclature system for their medical devices and the data found via desk review i.e., 81 countries (45.3%) versus 65 countries (35.3%), respectively. Concerning the use of more than one system, there is a difference of 21% between what countries indicated through their responses, i.e., 13 countries (7.3%) and what was found through the desk review 52 countries (28.3%).

Either the BCSoMD21 or the desk review showed that at least a third of the member states do not have an official nomenclature coding structure for the proper management of their medical devices.

For specific types of nomenclature, the percentage differences were less than 5%. The UMDNS showed a usage difference of 4% (BCSoMD21: 10.6% versus desk review: 6.5%, corresponding to 19 and 14 countries, respectively); the nomenclature developed at a national level showed a difference of 4.5% (BCSoMD21: 24.6% vs. desk review: 20.1%, corresponding to 44 and 37 countries, respectively); a percentage difference of 4.5% was found between the countries that use the CND/EMDN nomenclature, i.e., 3 respondent countries (1.68%) versus 4 countries (6.2%) whose information was found through the desk review.

Finally, the countries whose nomenclature was based on GMDN showed a 3% difference between the data from the survey, i.e., 19 countries (10.61%) versus the data collected through desk review, i.e., 14 countries (7.6%).

Many of the differences can be explained by the following:

- Existence of a nomenclature system, type and use is a continuous and rapidly evolving area of medical devices.

- Important to note that around *a third* of the country's answers from the BCSoMD da*ted back from the period 2010-2013*, another third from the period 2013-2017, and the last third were recently collected in 2021. Thus, it is expected to see the changes in the three studied parameters: existence, type and use of the nomenclature system.
- Nomenclature system of medical devices is a cross-cutting subject that depends on many factors such as legislation, commerce, management, political will, economy etc.

Regarding the nomenclature system use, and comparing the results between the data obtained through the BCSoMD21 and the desk review 2021, we obtain the following:

The summed set of two country answers —'not defined' and 'nor specified'— had the largest number of countries by region. This can be explained by the difficulty to specify the various uses of the nomenclature system of medical devices within a country's health system.

In addition, the sum of answers, at least in four regions, was rather similar, with a difference no greater than 3 countries between the responding countries and the information collected from the desk review. For example, AFR-BCSoMD21: 34 countries versus the AFR-desk review: 35 countries; AMR-BCSoMD21: 22 countries versus the AMR-desk review: 20; EMR-BCSoMD21: 10 countries vs. the EMR-desk review: 10 countries; SEAR-BCSoMD21: 11 countries vs. the SEAR-desk review: 10 countries.

In contrast, in the European region the results were as the following: EUR-BCSoMD21: 38 countries versus the EUR-desk review: 30 countries and, for the WPR-BCSoMD21: 18 countries versus the WPR-desk review: 14 countries showed a difference of 8 and 4 countries, respectively.

- Concerning other specific purposes of use of nomenclature systems: In all WHO regions the desk review found more countries using their nomenclature for various purposes than countries using their nomenclature only for regulatory, procurement or both purposes. This was not the case for the BCSoMD21, where less countries declared using their nomenclature for various purposes rather than only regulatory, procurement or both.
- Concerning the set of countries found to use nomenclatures for specific purposes, (be them regulatory, procurement or both), the WHO regions presented several patterns: i.e. EUR-BCSoMD21: 11 countries and the EUR-desk review: 7 countries, AMR-BCSoMD21: 6 countries and the AMR-desk review: 4 countries; the WPR-BCSoMD21: 4 countries and the WPR-desk review: 8 countries; the AFR-BCSoMD21: 6 countries and the AFR-desk review: 4 countries; and, the EMR-BCSoMD21: 4 countries versus the EMR-desk review: 5 countries.
- Concerning South-East Asia, SEAR-BCSoMD21 did not find evidence about any of the nomenclature specific purposes specified above, and SEAR-desk review just found about one country using their nomenclature for various purposes.

As previously shown the specific purposes for the use of the nomenclature system, if any, are rarely mentioned such as the following: For reimbursement purposes; For in-vitro diagnostics Lists/Inventory; For inventory systems in healthcare facilities.

Conclusion

As presented in this report there are various nomenclature systems (national developed, UMDNS, GMDN, EMDN, etc.) used around the world for different purposes (regulation, procurement, reimbursements, lists, healthcare facilities, inventories). Around one third of the world does not have yet an official nomenclature to manage medical devices, one third uses various systems simultaneously, and another third either national developed nomenclature or EMDN, GMDN or UMDNS. This situation has been continuously evolving in the past ten years with promising signals of more countries acquiring an official(s) nomenclature(s) and also signals of multiple nomenclatures used for different purposes around the world. Several efforts are currently in place to harmonize not only the heterogenous regulatory framework worldwide, but more specifically universal nomenclature system. Until now these efforts have not been achieved due mainly to lack of agreement between the main stakeholders and member states. As indicated before, the nomenclature system of medical devices is a cross-cutting issue that interrelates the national health system with other areas such as economy, commerce, politics within a country, as well as with other countries due to globalization and regional agreements between countries. Thus the actors, and interrelations multiply, the chances of agreement seem to diminish.

However, we observe a positive trend of countries strengthening their regulatory frameworks, harmonization of procedures, and adoption of an official nomenclature of medical devices. In the measure that the health system is strengthened it will facilitate the service delivery in order to achieve faster Universal Health Coverage.

Other limitations: More often than not, several regulations and agreements may be in use in a country for different purposes, but also for a single purpose. For instance, it is possible to have more than one agreement regarding imports and exports depending on the destination or origin of merchandise. In consequence sometimes there may be more than one answer to the questions we ask.

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Annex 1 - Relevant scholar sources

Regulatory requirements of Medical Devices in MENA Countries

In this 2015 master thesis the author attempts to define the regulatory environment for Medical Devices in the Middle East and the North African countries (MENA) and to show their limits and their prospects.

After a brief overview of the medical devices market and healthcare market of MENA-countries the author examines the history of medical devices regulation and focuses on the work of International Medical Devices Regulators Forum (IMDRF) paying particular attention to the technical documents, definitions and classification systems, which IMDRF produced and elaborated through the activities of the Global Harmonization Task Force (GHTF).

Drawing comparisons between MENA-countries' standards of medical devices regulation and IMDRF standards the author scrutinizes concepts of medical devices regulation in GCC countries, states of Western Asia and North Africa providing information concerning medical device definitions and required documentation for import or export of medical devices to the countries of the region (Samadi) (Samadi) (Samadi).

Some of the conclusions that the author makes follow:

- Despite the overall positive economic development in most of the MENA countries the regulatory environment can be challenging. Publicly accessible written legislations are limited in these countries, sometimes only available in the local language (mostly Arabic) and leave room for interpretation.
- Often websites and local regulations are only available in the local language (mostly Arabic) that is why in the majority of cases only local agents can benefit from participation in local regulatory or industry networks.
- As the requirements for Medical Devices are not homogeneous throughout the MENA countries, different types of dossiers will have to be prepared. The technical documentation will cover the requirements of the majority of countries, however not internationally named as 'design dossier' or STED. Beside the technical documentation, the main requirements are usually GMP or QM-System certificates, a Free Sales Certificate (FSC) from the Country of Origin, a Letter of Authorization, EC certificates, and Declaration of Conformity, a Certificate of Analysis the finished product, a statement about the status of Devices distribution, a local application form and country specific declarations.
- The FSC is a key document in the registration process of Medical Devices in most MENA countries, which must be legalized by the chamber of commerce and the embassy of the foreign importing country in C.O.O.
- Medical Devices in general usually are divided into three groups as in the USA or four groups as in the EU or according to the GHTF guidelines. Some MENA countries accept both EU and FDA definitions.
- In vitro diagnostic Devices are seen as a separate group and the classification of these products vary a lot.

- Good manufacturing practice is required in all countries. An ISO 13485 certificate is in most countries the way to demonstrate compliance with the quality system requirements. In some countries like Egypt, an ISO 13485 certificate - issued by EU notified bodies or USA/Australian bodies - might be enough to demonstrate compliance with the quality requirements but it must be approved by the local certification body.

This thesis contributed data for Jordan, Israel, Lebanon and Yemen.

Regulatory requirements of Medical Devices in Southeast Asia and China

This 2010 master thesis presents the regulatory requirements for medical devices in the ASEAN countries as well as Hong Kong SAR and China at the time of the research. ASEAN represents the following Southeast Asian countries: Singapore, Malaysia, Indonesia, Thailand, the Philippines, Vietnam, Laos, Brunei, Cambodia and Myanmar.

To place a medical device on the market in any of these countries, highly diverse regulatory requirements have to be met at the present time: Out of the 10 ASEAN member states only five have medical device laws (Singapore, Indonesia, Thailand, the Philippines, Vietnam), while one maintains a voluntary registration system using administrative guidelines (Malaysia). The remaining four countries do not have laws or guidelines specifically aimed at medical devices at all. Similar to Malaysia, Hong Kong SAR utilizes a voluntary registration system based on guidelines, while China has its own medical devices law.

Currently, there is no common definition of the term medical device in these countries, which leads to the fact that certain products may be subject to medical devices law in some countries, but not in others. Products for veterinary use, for example, have to fulfil national medical device requirements in Thailand and the Philippines at the moment, but not in any of the other countries.

Classification will also often follow specific national rules. The requirements for registration differ widely with mandatory registration for all classes of devices and licensing requirements for manufacturers, importers and distributors in some countries, while in other countries, there are no requirements at all due to the lack of relevant legislation or administrative guidelines. The standard of adverse event reporting also varies and does not always form a part of the existing regulations. Therefore, it is the explicit aim of the ASEAN member countries to develop and harmonise regulatory control of medical devices in all its member countries with the introduction of the ASEAN medical device directive (AMDD). The AMDD will introduce a common set of rules in all member countries and is mainly based on the recommendations of the Global Harmonisation Task Force (GHTF), a voluntary international group of medical device regulatory authorities and medical device trade associations from the European Union, the United States of America, Canada, Japan and Australia. The ASEAN member countries will be required to pass national laws implementing theAMDD over the next years. Singapore is the first country to finalize this process in 2011, but the other countries will follow on their own time depending mainly on the resources available at the national level.

Hong Kong SAR also relies on the GHTF guidelines for its own national regulations: The GHTF recommendations were completely transposed into the administrative guidelines, building a voluntary registration system. However, there is currently no defined point in time, when the change from voluntary to mandatory registration will take place. In contrast to this, China has developed its own medical device legislation independently from GHTF recommendations and is still in the process of further ·developing some aspects, like for example adverse event reporting, special requirements for IVD medical devices or GMP for medical devices.

A complete harmonisation of requirements for medical devices for the whole region is not to be expected in the near future, but major steps are already being taken in that direction. Until this goal is accomplished, companies intending to market products, which are considered to be medical devices in Europe, in these countries, have to verify for every single country, if and what specific requirements have to be met.

Regulation of Medical Devices in the Americas

In this 2016 original research in spanish, the authors describe and analyze the regulation of medical devices in the Americas. They also present the results of the Regional mapping made by the Regional working group and show the advancement in indicators buit for evaluation and creation of regulatory profiles.

Regulation of medical devices outside the European Union

In this 2012 paper, the author presents and compares medical devices regulations for USA, Russia, AHWP, ASEAN, APEC, China, Hong Kong, India, Iran, Saudi Arabia, Israel, Jordan, UAE, Africa, Mexico, South America, and Cuba.

Safe innovation: On medical device legislation in Europe and Africa

This 2018 study aims at comparing the certification route that manufactures have to respect for marketing a medical device in some African Countries and in the European Union.

African medical device regulations have an affinity to European directives, despite the fact that the latter are particularly strict. Several states have also implemented or harmonized directives to medical device regulation, or have expressed interest in establishing them in their legislation. Open Source Medical Devices hold a great promise to reduce costs but do need a high level of supervision, to control their quality and to guarantee their respect for safety standards. Harmonization across the two continents could be leveraged to optimize the costs of device manufacture and sale. Regulated open design strategies can enhance economically sustainable innovation.

Annex 2 - Findings by country

The desk review findings by country concern qualitative national information. Concerning regional nomenclature agreements, the information can be found in the dedicated International Agreements section. For binary and quantitative data, check the full findings in this spreadsheet.

Countries without comments

No qualitative information was found during the desk review (nor sent during the GAMD survey) about the nomenclature use of the following countries:

Afghanistan
Antigua and Barbuda
Bahamas
Barbados
Belize
Burkina Faso
Burundi
Cameroon
Cape Verde
Central African Republic
Chad
Chile
Comoros
Congo
Côte d'Ivoire
Cyprus
Democratic People's Republic of Korea
Democratic Republic of the Congo
Ecuador
Gabon
Guinea-Bissau
Haiti
Liberia
Malawi
Malta*
Marshall Islands
Mauritania
Mauritius
Micronesia (Federated States of)
Mongolia
Mozambique
Myanmar
Nauru
Pakistan
Papua New Guinea
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
San Marino
Seychelles
Solomon Islands
Somalia
Suriname
Swaziland (Eswatini)
Tonga
Vanuatu
Vietnam
Algeria
Andorra
Kuwait
Lesotho
Niue
Palau
Turkmenistan
Tuvalu

*Note on the European Union

Members of the European Union such as Malta may not have information available on the web or GAMD survey but from the EU regulations 745 and 746 they are required to implement EMDN.

Albania

GAMD 2021

This Italian nomenclature system CIVAB comes with the Inventory system called CLINGO.

Desk review

The registration list for medical devices in Albania and the codes that appeared belong to CIVAB nomenclature. Nomenclature is used mainly for registration and inventory purposes.
https://www.tga.gov.au/sme-assist/what-classification-my-medical-device#109

Angola

Desk review

Access to the information is restricted since user accounts and passwords are required to access the website of the Ministry of Health.

Argentina

Desk review

Medical equipment research in the national inventory revealed that identification codes and technical names of medical equipment are similar to the ones that are used in UMDNS.

[When searching for medical equipment in the national inventory, identification codes and technical names are UMDNS.]

https://helena.anmat.gob.ar/uploads/pdfs/dc_17612_30714838411_8533.pdf?rnd=ade6bf84-fed4-48cb-b11f-c7b913a302ea

Armenia

Desk review

Armenia uses a nomenclature that was developed within the Eurasian Economic Union (see first link, paragraph 8, an official website). The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union's (EAEU) medical device nomenclature with the GMDN. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022. From 2022 an EAEU nomenclature will be developed and based on the GMDN for various purposes mentioned in the purpose of use question. By now, some enterprises use GMDN for procurement in the country.
https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx
http://www.eurasiancommission.org/en/nae/news/Pages/19-03-2019-3V.aspx
https://www.e-draft.am/projects/222/about
http://www.pharm.am/index.php/ru/2015-06-03-16-27-43/3571-2017-11-28-13-33-46

Australia

Desk review

The Therapeutic Goods Administration site (Australian Regulatory Agency) states the use of GMDN. Also, for IVDs the GMDN is recommended.
https://www.tga.gov.au/global-medical-device-nomenclature-gmdn
https://www.tga.gov.au/sites/default/files/ivd-gmdncodes.pdf

Austria

GAMD 2021

The Austrian Medical Devices Register uses the UMDNS and the EDMA Code.
https://goeg.at/Medizinprodukteregister

Desk review

The Austrian Medical Devices Register uses the UMDNS, GMDN and EDMA Code for IVDs. In the future, the CND/EMDN will be used as part of the European Commission Standard.
https://goeg.at/Medizinprodukteregister
https://medizinprodukteregister.at/Nomenklaturen

Azerbaijan

Desk review

State registration of medical devices is not carried out by the government. For import of medical products and medical equipment, it is necessary to obtain a confirmation letter regarding the classification of an imported product, and then obtain a hygienic certificate from the Republican Center for Hygiene and Epidemiology of the Republic of Azerbaijan.
http://www.pharma.az/

Bahrain

GAMD 2021

It is needed the GMDN code for registration of medical devices, as well as the HS code.
https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Device%20Registration_%20Ver%206.0.pdf
https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Registration%20Form%20%2020%20Dec%202020.pdf
https://www.gmdnagency.org/Services/Members#N

Desk review

According to the 19 sub-section of the Registration Guideline for medical devices (from the National Health Regulatory Authority), it is needed the GMDN code for registration of medical devices; for registration purposes, it is needed the GMND and the HS code. In some cases, it might be required to fulfil the classification criteria issued by the NHRA Medical Devices Regulations department (it should be provided). The National Health Regulatory Authority has been found as a member of the GMND agency.

Bangladesh

Desk review

A medical equipment price list can be found on the website of the Directorate General of Drug Administration, but naming systems are not provided.
https://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list

Belarus

GAMD 2021

State register of medical equipment and medical supplies of Belarus.
https://www.rceth.by/Documents/3mz3prN132420141216.pdf

Desk review

Country uses the EEU's nomenclature system alongside the nationally developed one. The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union's (EAEU) medical device nomenclature with the GMDN.
https://www.rceth.by/Documents/3mz3prN132420141216.pdf
https://pravo.by/document/?guid=3871&p0=F91800087
http://www.eurasiancommission.org/en/nae/news/Pages/19-03-2019-3V.aspx

Belgium

GAMD 2021

The GMDN code is used during the notification of the placing on the market of class I medical devices, it is also used in the form for the transmission of material vigilance incidents. This code is also used for the registration of diagnostic medical devices in vitro in the European database Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.
(Original in French) *Le code GMDN est utilisé lors de la notification de mise sur le marché des dispositifs médicaux de classe I, il est également utilisé dans le formulaire de transmission des incidents en matériovigilance.Ce code est également utilisé pour l'enregistrement des dispositifs médicaux de diagnostique in vitro dans la base de données européennes Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.*
https://kce.fgov.be/en
https://www.famhp.be/en

Desk review

The country uses the GMDN, and as it is a member of the EU it will be used in parallel with CND/EMDN.
https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Benin

GAMD 2021

The CNEH nomenclature is used informally in some of the country's hospitals.
(Original in French) *La nomenclature CNEH est utilisée de façon informelle dans certains de nos hôpitaux.*
http://www.sante.gouv.bj/

Desk review

The adoption of national and / or international nomenclatures for the identification of infrastructure, biomedical equipment and care structures is an important prerequisite for the establishment of harmonized management of health assets across the country.
(Original in French) L'adoption de nomenclatures nationales et/ou internationales pour l'identification des infrastructures, des équipements biomédicaux et des structures de soins est un préalable important pour la mise en place d'une gestion harmonisée du patrimoine sanitaire à travers le pays
http://www.sante.gouv.bj/
https://www.jhia-online.org/index.php/jhia/article/download/179/110/664

Bhutan

Desk review

There is a national medical devices list that is based on the nationally developed nomenclature.
http://www.moh.gov.bt/national-medical-devices-list/

Bolivia (Plurinational State of)

Desk review

Country uses the UMDNS as well as the Mercosur Common Nomenclature (MCN).
http://www.agemed.gob.bo/
https://www.mercosur.int/bolivia-ingresa-al-mercosur/

Bosnia and Herzegovina

GAMD 2021

Our nomenclature is based on GMDN and EDMA codes; In our instructions we ask for our manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. We have free access to the GMDN base, and we found a new version of EDMA codes on the internet.

Internal comment Desk review

The country's law on medicines and health products was revised; it does not contain information on the use of nomenclature.

Desk review

Our nomenclature is based on the GMDN and the EDMA codes.
http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-i-medicinskim-sredstvima

Botswana

Desk review

Country uses the UMDNS.
https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals

Brazil

GAMD 2021

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 should be sent to the Public Consultation later this year (2021).
https://www.anvisa.gov.br/datavisa/nomestecnicosggtps/consulta_ggtps.asp

Desk review

Brazil's regulatory agency uses the GMDN system. For importation the Mercosur Common Nomenclature is used.
https://www.gov.br/anvisa/pt-br

Brunei Darussalam

Desk review

The UMDNS is used for regulatory purposes (see second link). Country is a Member of the Asian Harmonization Working Party (AHWP). Within the AHWP efforts are being made to start developing a unified medical devices nomenclature system for regulatory purposes.
http://www.ahwp.info/index.php/node/57
https://www.dgra.de/media/pdf/studium/masterthesis/master_matthies_c.pdf

Bulgaria

GAMD 2021

Use of GMDN and UMDNS.
https://www.mh.government.bg/en/
https://www.bda.bg/en/information-for-companies/122-medical-devices-announcements-category

Desk review

It uses the GMDN and the UMDNS, and as a member of the EU it will use the CND/EMDN.
https://www.mh.government.bg/en/
https://www.bda.bg/en/information-for-companies/122-medical-devices-announcements-category

Cambodia

GAMD 2021

The Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.

Canada

GAMD 2021

Not publically available. Used internally for coding products in the database. Prefix Name Codes are based on US FDA Panel Codes.
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

Desk review

Health Canada is initiating the transition from its current medical device categorization method to the Global Medical Device Nomenclature (GMDN) to improve the availability, access to, and quality of information available on medical devices in Canada (see first link). However, it is planned to develop a national nomenclature that can be used alongside the UMDNS.
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-global-medical-device-nomenclature.html

China

Desk review

Based on the UMDNS (China has plans to develop a uniquely identifiable database for medical equipment).
http://english.nmpa.gov.cn/2019-12/10/c_456290.htm

Colombia

GAMD 2021
Nationally developed. It is in the phase of implementation.
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-2535-de-2013.pdf
Desk review
Currently, the country is in resolutions to generate a new nomenclature.
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/analisis-estandar-semantico-dispositivos-medicos.pdf

Democratic Republic of the Congo

GAMD 2021
The official nomenclature does not exist. We use what can be at hand depending on the circumstances.

Cook Islands

Desk review
Regulated by MOH
https://www.health.gov.ck/policies-guidelines/

Costa Rica

GAMD 2021
The GMDN has been adapted to the national needs.
Desk review
Costa Rica has a national nomenclature system for classifying medical equipment.
http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=62959&nValor3=99850&strTipM=TC

Croatia

Desk review
Croatia uses the GMDN nomenclature for the national registration of medical equipment. As an EU member, it will adopt the use of CND/EMDN too.
https://www.halmed.hr/Medicinski-proizvodi/Upute-za-podnositelje-zahtjeva-41/Proizvodnja-medicinskih-proizvoda/

Cuba

GAMD 2021
SUCNEM based on the UMDNS code. It also use the GMDN.
https://www.cecmed.cu/, http://www.electromedicina.sld.cu
Desk review
Cuba has its system for classifying medical equipment: SUCNEM, which is based on the UMDNS. Additionally, the country uses the GMDN.
https://www.cecmed.cu/registro/equipos-medicos
http://cencomed.sld.cu/socbio2007/trabajos/pdf/conferencias/aguiar/viernes/mesa2/dulce.pdf

Czech Republic

GAMD 2021

The GMDN and UMDNS remain the historically used nomenclatures. Three national specific systems (categorizations) of medical devices are used for reimbursement and statistical purposes. The GMDN remains a comprehensively recognized system for the registration and notification of medical devices in the Czech Republic. GMDN codes are used in the Register of Medical Devices (RZPRO) administered by the State Institute for Drug Control (SUKL) for regulatory purposes, adverse events reporting, safety corrective measures, and information on clinical trials.

Desk review

It is used by the UMDNS for registration, and other types of medical device nomenclature for reimbursement purposes. As a EU member it will adopt the use of CND/EMDN too.
https://www.niszp.cz/en/registration-and-notification

Denmark

Desk review

The use of the GMDN system is in the law, but soon it will be used in alongside the CND/EMDN, as the EU nomenclature.
https://laegemiddelstyrelsen.dk/en/devices/

Djibouti

Desk review

Regulated by MOH
https://sante.gouv.dj/reglements

Dominica

Desk review

No change. Neither in the web portal of the government nor the Ministry of Health, Wellness and New Health Investment (the latest is in development) there's no information about nomenclature of medical devices.
http://health.gov.dm/

Dominican Republic

GAMD 2021

There is no official nomenclature. However, there is a proposal dating from 2006 that responded to a project for preventive maintenance of medical equipment.

(Original in Spanish) *No existe una nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos.*

Desk review

There is no official nomenclature system. The access to the Dirección General de Medicamentos, Alimentos y Productos Sanitarios have only three windows of information about the process and certification of medical devices, medicines and cosmetics; none of them is available for public navigation as a supplier registration and password are needed; the only available classification (but not nomenclature system) of medical devices is in the Oficial Decret No. 246-06, Book 2, chapter 1, articles 11 to 20.

https://digemaps.msp.gob.do/menu/

Egypt

GAMD 2021

Used in the database of geographical information system health.

https://www.edaegypt.gov.eg/

Desk review

Medical devices registration requires use of a nomenclature (not specified, link 2).

https://www.edaegypt.gov.eg/

https://www.wikiprocedure.com/index.php/Egypt_-_Register_with_Central_Administration_of_Pharmaceutical_Affairs_(CAPA)

El Salvador

GAMD 2021

The catalog developed is for medical equipment in general and is for purchase purposes only. There is no distinction or classification of medical technology equipment based on its application or impact on the health of the patient

(Original in Spanish) *El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.*

Desk review

In the Dirección Nacional de Medicamentos is available the guide for medical devices registration. It includes the classification of medical devices (see link).

https://www.transparencia.gob.sv/institutions/h-zacamil/documents/207883/download

Equatorial Guinea

Desk review
Regulated by MOH

Eritrea

GAMD 2021
Official nomenclature system for medical devices is currently in the process of development.
https://shabait.com/

Estonia

Desk review
It uses the MSA code (nationally developed) although it also uses the GMDN, both for various purposes such as regulation and procurement.
https://msa.sm.ee/eng/search/
https://msa.sm.ee/ctrl/en/Fail/laadi_alla_mall/96968
https://haigekassa.ee/en/people/medical-devices
https://www.terviseamet.ee/en/medical-devices-2/regulatory-controls-medical-devices

Ethiopia

GAMD 2021
Nationally developed and based on both the UMDN and the GMDN. This nomenclature is developed by EPSA, ESDA and FMoH in collaboration with stakeholders. The nomenclature is mainly used for procurement and regulatory purposes. The Established Public Infrastructure Directorate is now starting an inventory to identify the type, source and status of the devices.
www.fmhaca.gov.et
https://epsa.gov.et/featured-services/procurement-list/

Desk review
The Guideline for Registration of Medical Devices includes the medical devices' essential safety and performance requirements, and risk classification I to IV. As well as a nationally developed nomenclature as stated in the Ethiopian Food and Drug Administration (first link and third link). The second link shows the registration form for medical devices.
http://www.fmhaca.gov.et/publication/guidelines-for-registration-of-medical-devices-or-supplies/
https://www.eris.efda.gov.et/public/registration

Fiji

Desk review

There is no specific nomenclature system. The procurement, management, inventory and registration use the generic name or the trade name of the product (according to the 2013 policy).
http://www.health.gov.fj/wp-content/uploads/2018/02/Fiji-National-Medicinal-Products-Policy-2013.pdf

Finland

GAMD 2021

Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.
https://www.fimea.fi/web/en/medical-devices

Desk review

The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.
https://www.fimea.fi/web/en/medical-devices
https://www.fimea.fi/documents/160140/764068/english_Publications_Forms_IVDD_manufacturers_formulaire.pdf/0d7e0ec9-072e-c61b-934d-2fa178875ddf?t=1577451373998

France

GAMD 2021

The classification of the provisions of medical devices is provided for in Article R. 5211-7 of the Public Health Code. The rules are specified in the order of March 15, 2010 amending the order of April 20, 2006 setting the classification rules for medical devices.
(Original in French) *La classification des dispositions des dispositifs médicaux est prévue à l'article R. 5211-7 du code de la santé publique. Les règles sont précisées dans l'arrêté du 15 mars 2010 modifiant l'arrêté du 20 avril 2006 fixant les règles de classification des dispositifs médicaux.*
http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E555F0AB933E0B91227088DB46C.tpdjo04v_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330
https://www.gmdnagency.org/

Desk review

It is used as a nomenclature based on the GMDN (for procurement and commercialization), and as it is in the EU it will be used in parallel with the EMDN (for different purposes such as regulation, registration, procurement, surveillance, etc.).
https://www.legifrance.gouv.fr/codes/id/LEGISCTA000006190738/
https://www.ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/DM-classes-IIa-IIb-III-et-DMIA-Communication-et-liste/(offset)/6#paragraph_25854

The Republic of The Gambia

GAMD 2021

The Medical Research Council (UK) in Gambia (refer to specific link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.
http://www.mrc.gm/

Georgia

GAMD 2021

According to Georgian legislation, Georgia recognises international or national (according to a list of certain countries) certificates of medical devices there.

https://matsne.gov.ge/ru

Desk review

The Law of Medicines and Pharmaceutical Activities (which includes the regulation of medical goods or medical devices) proposes three groups on the classification of pharmaceutical products (article 11, superindex 2) for advertising and retailing purposes. But there is no nomenclature system for medical devices.

https://matsne.gov.ge/ru/document/download/29836/21/en/pdf

Germany

GAMD 2021

At the German Institute for Medical Documentation and Information (DIMDI) German manufacturers or an authorised representative of non-EU manufacturers have to register their products themselves. The database is served by DIMDI and today uses UMDNS.

http://www.dimdi.de

Desk review

According to the information of the regulatory agency of Medical devices (BfARM) and the Ministry of Health two systems are used: UMDS (for medical devices in general) and EMDN for IVD. Although it is announced that both of them will be replaced (in May 2021) with the EMDN (European Nomenclature system for medical devices) which itself is based on the Italian CND system.

https://www.dimdi.de/dynamic/de/medizinprodukte/bezeichnungssysteme/

Ghana

Desk review

According to the "Guideline for registration of medical devices", the GMDN will be required for registration just in case it is previously coded. The nomenclature is used for registration purposes.

https://fdaghana.gov.gh/images/stories/pdfs/downloads/GUIDELINES%20FOR%20THE%20REGISTRATION%20OF%20MEDICAL%20DEVICES-REVIEWED.pdf

Greece

GAMD 2021

A specific technical committee is responsible for the correlation of Nomenclature, Classification and Codification of Medical Devices. The final deliverable is expected in 2014.

https://www.gmdnagency.org/

Desk review

A specific technical committee is responsible for the correlation of the nomenclature, the classification and codification of medical devices. The final deliverable is expected in 2014. The novel EMDN which is based on CND nomenclature will be introduced soon as the official EU's system. The National regulatory authority is the National Organization for Medicines in charge of medical products and devices.

https://www.eunethta.eu/eof/

Grenada

GAMD 2021

A system was developed but was not supported by management. There is no URL because this software was locally developed.

Desk review

The Ministry of Health website is not available for this country, nor the "Biomedical unit", which is responsible for the identification, procurement and maintenance of the medical equipment at the Hospitals and the Community Health facilities; nevertheless, the Strategic Plan for Health 2016-2025 is available and provides an in in which it is mentioned the lack of material and human resources.
http://www.gov.gd/moh/ced/mofa/sites/moh/files/grenada_health_sector_strategic_plan_2016-2015_approved.pdf

Guatemala

GAMD 2021

La Clasificación se encuentra contemplada en el Anexo de la Norma Técnica No. 37. In Vivo y según clase.
(Original in Spanish) *The Classification is contemplated in the Annex of Technical Standard No. 37. In Vivo and According to class.*
https://www.mspas.gob.gt/
https://medicamentos.mspas.gob.gt/

Desk review

In accordance to the "Norma Técnica 37 versión 5-2016 Para la inscripción sanitaria de dispositivos médicos" the nomenclature system use for regulation, surveillance and control of medical devices has been nationally developed.
https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/normas-tecnicas?download=262%3Ainscripcion-sanitaria-de-dispositivos-medicos&start=40

Guinea

Desk review

In the Medicines and Cosmetics Regulation 2002 Act it is indicated that medicinal products for importation, manufacture, processing or packing should be done with the generic, official or approved non-proprietary name found in official pharmacopoeias or formularies alongside the brand name.
https://wipolex.wipo.int/en/text/199156

Guyana

Desk review

There is no official nomenclature for medical devices. The Regulation Agency (GAFDD) is in charge of the registration of devices.
https://gafdd.gy/inspectorate/#

Honduras

GAMD 2021

El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.
(Original in Spanish) *The Regulation for the Sanitary Control of Products, Services and Establishments of Sanitary Interest, establishes a nomenclature for registration purposes.*
http://www.salud.gob.hn/site/

Desk review

The 'Reglamento de control sanitario 2005' proposes a nomenclature system for sanitary license (art. 133/ unidad III) and for registration (art. 159, unidad V).
https://arsa.gob.hn/public/archivos/Reglamentocontrolsanitario62005.pdf

Hungary

GAMD 2021

The coding is not available on the Internet.

Desk review

A national nomenclature system (and classification) has been developed for medical devices on "4/2009. (III. 17.) Decree"; also the acceptance of another nomenclature system such as the "Global device name" for registration of products (see: "Annex II"). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.
https://net.jogtar.hu/jogszabaly?docid=A0900004.EUM&celpara=#xcelparam
https://net.jogtar.hu/jogszabaly?docid=a0300008.esc

Iceland

Desk review

It uses a nomenclature system for registration (see link). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.
https://www.ima.is/medical_devices/about_medical_devices/

India

Desk review

Regulated by the Central Drugs Standard Control Organization: CDSCO. The GMDN nomenclature system is used for regulation in the private sector.
https://cdsco.gov.in/opencms/opencms/en/Home/

Indonesia

GAMD 2021

It uses a Harmonization System code (HS) at the moment. After harmonization, GMDN will be used.

Desk review

There are classification guidelines and a policy for the distribution of medical devices and IVDs. The nomenclature systems mentioned in the regulation documents are the Harmonization System code (HS) and the GMDN (see two links).

http://regalkes.kemkes.go.id/informasi_alkes/Pedoman%20Klasifikasi.pdf

http://regalkes.kemkes.go.id/informasi_alkes/PMK_No_62.pdf

Iran (Islamic Republic of)

Desk review

Regulated by IMDR (first link). For its registration, any medical device needs a declaration of conformity as stated in GHTF STED which is accepted in the report in one of the following nomenclatures: National developed classification (IRC Code: Iran Registration Code); EU classification or US-FDA classification. However, in order to fulfil the whole documentation, the UMDNS classification is used.

http://imed.ir/

http://www.imed.ir/uploads/forms/documents/73a82691-3330-4eef-a1d1-36c769376672.pdf

http://imed.ir/ExtendedModules/Document/UI/DownloadFile.aspx?FileCode=a2ab141c-cd93-4904-8108-56f912e9e6bb&fileid=411

Iraq

GAMD 2021

The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

https://kimadia.iq/en

Desk review

No official nomenclature system, but several such as UMDNS are accepted. The State Company for Provision of Medicines and Medical Appliances (KIMADIA) oversees imported medical devices. oversees imported medical devices. Tecmoh registers all medical devices in Iraq.

https://kimadia.iq/assets/files/1613646335_67-2021-2-%D8%A7%D8%B3%D8%B9%D8%A7%D8%B1-%D8%A7%D9%84%D9%85%D9%81%D8%A7%D8%AA%D8%AD%D8%A9-%D8%A7%D9%84%D9%85%D8%B1%D9%82%D9%85%D8%A9_1613646335.pdf

https://www.facebook.com/Iraqi-Pharmacovigilance-Center-IPhvC-159782860751953-المركز-العراقي-للرصد-الدوائي/?hc_ref=ARSHWx4DaLIQXMMMAOzGGWzuyBIjp90GRSRgwilptidc_P7hppyjNAGTkdxXOsm7KlQ&fref=nf&__tn__=kC-R

Ireland

Desk review

For registration of medical devices, it is recommended to use the GMND nomenclature system (see link 1), even if other nomenclatures are also accepted. Although as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0054-guide-to-registration-of-persons-responsible-for-placing-medical-devices-on-the-market-v2.pdf?sfvrsn=10

Israel

Desk review

There is no official nomenclature, but the use of several nomenclatures is accepted, such as UMDNS, for the registration of medical technologies (regulated by the Division of Medical Equipment (see first link)). Risk Classification often uses the same as EC states. As in agreement with EC states, it may use the EMDN (European Nomenclature system for medical devices) too. The risk classification for medical devices used is divided into the following classes: I, IIa, IIb, and III (Decreto Legislativo 24 febbraio 1997, Art. 8). [From (Samadi)]

https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx
https://medicaldevices.health.gov.il/

Italy

GAMD 2021

As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to ongoing maintenance even today at the request of manufacturers. This map was introduced at the beginning because the GMDN code was originally the mandatory registration key in the Italian system. Subsequently, the mandatory use of the GMND code was removed at the request of the manufacturers, due to the difficulty of using it and, in many cases, due to its unavailability. In any case, the possibility of using the GMDN code and its connection with the CND is still allowed, but it appears that, despite this possibility of use, the GMDN code is rarely used in the registration in the Italian system.

http://www.salute.gov.it/imgs/C_17_paginaree_328_listaFile_itemName_15_file.pdf
http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

Desk review

The Italian classification system (CND Classificazione Nazionale dei Dispositivi Medici) has been correlated to the GMDN nomenclature, as well as it will be the basis for the future EMDN (European Nomenclature system for medical devices) too, that will be the one used soon for EC states.

http://www.salute.gov.it/imgs/C_17_paginaree_328_listaFile_itemName_15_file.pdf
http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

Jamaica

Desk review

There is the Standards & Regulations Division within the MoH. However, there is not mentioned a specific nomenclature for registration of medical devices, nor for risk classification.

https://www.moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/guidelines-forms-lists/
https://moh.gov.jm/wp-content/uploads/2015/12/Ven-List-2015.pdf

Japan

GAMD 2021

Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.
https://www.pmda.go.jp/english/index.html

Desk review

It uses a national nomenclature system called Japanese Medical device nomenclature (JMDN) - see PMDA regulatory agency link for more details
https://www.std.pmda.go.jp/stdDB/index_en.html
https://www.std.pmda.go.jp/stdDB/Data_en/InfData/Infetc/JMDN_en.pdf
https://www.pmda.go.jp/english/index.html

Jordan

GAMD 2021

We support the WHO to adopt a standard nomenclature for medical devices. We used a nomenclature based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.
http://www.jfda.jo/Default.aspx

Desk review

Jordan relies on the EU directives to classify its devices, namely, the Medical Devices Directives 93/42/EEC and the Active Implantable MDD 90/385/EEC and the Medical Devices Importation Directives, Art. 2.
http://www.jfda.jo/Pages/viewpage.aspx?pageID=153

Kazakhstan

GAMD 2021

Medical State Register of lekarstennyh.
https://www.ndda.kz/category/nomenklatura_men_izd

Desk review

It uses a nationally developed nomenclature system that is harmonized with the GMDN.
https://www.ndda.kz/category/nomenklatura_men_izd
http://nmirk.dari.kz/

Kenya

GAMD 2021

The GMDN is used for regulatory purposes.
https://www.gmdnagency.org

Desk review

The nomenclature is used for registration purposes. The following systems are allowed for registration purposes: nationally developed, GMDN, UDI and UMDNS; as stated in the guidelines, at least, one system must be used for registration of medical devices or IVDs (see link 1) alongside the risk classification for medical devices A-D (see link 2).
https://pharmacyboardkenya.org/files/?file=Final%20Guidelines%20for%20Medical%20Devices%20and%20IVDs.pdf
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Kiribati

Desk review

The Medical Equipment Management Committee within the MoH is in charge of the registration of medical equipment. There is no specific nomenclature used nor a risk classification system.

Kyrgyzstan

GAMD 2021

The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.

http://cbd.minjust.gov.kg/act/view/ru-ru/1197
http://cbd.minjust.gov.kg/act/view/ru-ru/111673
http://www.pharm.kg/ru/about

Lao People's Democratic Republic

Desk review

No change as no nomenclature system is mentioned on any guidelines, policy, rules or acts; in this country, it is used the generic name of medical products or the active ingredients officially recognized by the World Health Organization which are used worldwide and have no copyright owner, according to "Law on drugs and medical products (Amended)(2011); Medical Devices risk classification A- D (law on Drugs and Medical Products, Art. 11.).

http://www.fdd.gov.la/download/contents_documents/2019-07-05_100305am_Law%20on%20Medical%20Products%20(Eng).pdf

Latvia

Desk review

t. 119,3. from the "Procedimientos de registro, evaluación de la conformidad, distribución, operación y supervisión técnica de dispositivos médicos" regulation it is used a nomenclature system for the registration of medical devices and it is also accepted the GMDN for registration purposes (see link 1)

https://likumi.lv/ta/id/295401-medicinisko-iericu-registracijas-atbilstibas-novertesanas-izplatisanas-ekspluatacijas-un-tehniskas-uzraudzibas-kartiba

Lebanon

GAMD 2021

The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.

https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Medical%20Technology/Laws%20and%20Regulations/karar%201506-2014.pdf

Desk review

There is no official nomenclature for medical devices, but GMND is accepted as stated in the "Minister Decision No. 1506 date 1/9/2014" page 1 (see link).

https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Medical%20Technology/Laws%20and%20Regulations/karar%201506-2014.pdf

Libya

GAMD 2021

For the medical equipment list it uses a nomenclature based on UMDNS. Nomenclature is used for inventory systems in healthcare facilities and lists.

http://www.mhtc.ly

https://seha.ly/en

Desk review

It is accepted the use of various nomenclature systems of medical devices for procurement and donations (see link 2).

http://seha.ly/en/laws-regulations

https://mhtc.ly/docs/GeneralConditions/Generalcondition.pdf

Lithuania

Desk review

Medical devices are divided into classes I-III according to their risk (MS 102, 17-19). The State Health Care Accreditation Agency, MoH, is in charge of regulation. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too (see link 2).

https://vaspvt.gov.lt/node/78

http://vaspvt.taduliz.lt/node/44

https://vaspvt.gov.lt/node/1166

Luxembourg

Desk review

Although as part of the EC they will use the (European Nomenclature system for medical devices) too.

https://sante.public.lu/fr/support/recherche/index.php?~=do&from=search&s=desc%28score%29&r%5B0%5D=f%2Fsection%2Flegislation&res_length=20&q=dispositifs+m%C3%A9dicaux#main

Madagascar

GAMD 2021

Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique).

(Original in French) *National nomenclature for the material accounting of State assets (codification for the technical inventory).*

http://www.agmed.mg/

Desk review

There is a nationally developed nomenclature. The regulation is in charge of L'Agence du Médicament de Madagascar (AGMED).

http://www.agmed.mg/PDF/SI/doss/ARRETE-14993_2013_MSANP-modalit%C3%A9s_fabrication_information_au_public_vente_dispositifs_m%C3%A9dicaux.pdf

Malaysia

Desk review

For medical devices registration it is used the HS Code (Harmonized Tariff Nomenclature and Coding System) as well as the GMDN code (see link).
https://portal.mda.gov.my/documents/guideline-documents/30-guidelines-on-medical-device-registration-under-act-737-mda-gl-md-01-june-2014-2nd-edition/file.html

Maldives

Desk review
There is a project to develop a national nomenclature system based on the UMDNS (see: Situation analysis report, Link 3).
http://health.gov.mv/
https://www.facebook.com/mfdamv-102808298333472/
https://www.researchgate.net/publication/260766912_Situation_Analysis_on_medical_equipment_in_Maldives#fullTextFileContent

Mali

GAMD 2021
Il existe dans le document de la comptabilité matière une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c'est un domaine très important qui mérite une action.
(Original in French) *There is a summary nomenclature section in the stock accounting document where the different products are classified by categories, but this is a very important area that deserves action.*
Desk review
http://www.cnop.sante.gov.ml/docs/LISTE%20AMO%20DANS%20LE%20SECTEUR%20%20PHARMACEUTIQUE%20PRIVE%20-%20%20Edition%202018.pdf

Mexico

GAMD 2021

The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized now as a compendium and it is in the process of depuration.

https://www.gob.mx/cms/uploads/attachment/file/512087/NOM-241-SSA1-2012.pdf
http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_II_EQUIPO_MEDICO_-_link.pdf
http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_I_INSTRUMENTAL_-_link.pdf
http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_ANEXO_SET_QUIRURGICOS.pdf
http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/aux_diag/catalogo/2017/EDICION_2017_CByC-AUX_DE_DIAGNOST.pdf
http://www.csg.gob.mx/images/priorizacion/cuadro-basico/osteo-endo/catalogos/EDICION_2017_MATERIAL_DE_OSTESxNTESIS_Y_ENDOPRxTESIS.pdf
https://www.gob.mx/cms/uploads/attachment/file/512083/NOM-229-SSA1-2002.pdf
https://www.gob.mx/cms/uploads/attachment/file/512207/NOM-137-SSA1-2008.pdf
https://www.dof.gob.mx/nota_detalle.php?codigo=5562796&fecha=14/06/2019&print=true

Desk review

https://www.gob.mx/cofepris
http://www.csg.gob.mx/contenidos/priorizacion/cuadro-basico.html

Monaco

GAMD 2021

Directive 93/42/CEE.
https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

Desk review

There is a nationally developed nomenclature for medical devices. Medical devices and IVDs are grouped by risk category: class I-III (arrêté ministériel n. 2003-581, Sec. I, Art. 1er). The Direction de l`Action Sanitaire et Sociale within the MoH is in charge of the regulation of medical devices.
https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

Montenegro

GAMD 2021

“Register (notification) of medical devices” that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will have information what is on Montenegrin market as well.
https://www.calims.me/Portal/faces/dinamickeStrane?_afrLoop=4618826366059702&paramPut=+%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

Desk review

It has recently developed a nomenclature system of medical devices based on GMDN.
https://www.calims.me/Portal/faces/dinamickeStrane?_afrLoop=4618826366059702&paramPut=+%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

Morocco

GAMD 2021

Nomenclature basée sur l'ECRI et le CNEH.
(Original in French) *Nomenclature based on ECRI and CNEH.*
http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

Desk review

It is based on the UMDNS.
http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

Namibia

Desk review

Many nomenclatures are accepted as stated in the second link
https://www.rrfa.co.za/wp-content/uploads/2012/11/NAM-Medicines-Registration-Guidelines.pdf
http://www.nmrc.com.na/

Nepal

Desk review

A national nomenclature system is based on the GMDN and the UMDNS.
https://www.dda.gov.np/
https://www.dda.gov.np/content/health-technology-product-an-medical-device-directive-2074

Netherlands

Desk review

There is a national nomenclature system based on the GMDN. Although, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.
https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport
https://www.igj.nl/
https://www.rivm.nl/medische-hulpmiddelen
http://www.igz.nl/english/medical_devices/

New Zealand

Desk review

New Zealand uses a nomenclature based on the GMDN. The Global Medical Device Nomenclature (GMDN) codes are required to identify types of medical devices notified to the WAND database.
https://www.medsafe.govt.nz/regulatory/DevicesNew/1Definition.asp

Nicaragua

GAMD 2021

Although we do have an official nomenclature system for medical devices, it is not used for various reasons.

Desk review

Nicaragua has its own nomenclature system based on the GMDN.
http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/

Niger

GAMD 2021

There are several types of codification tested. The first were inspired by the French CNEH code (national code for hospital equipment). There is no single codification adopted at the national level.
(Original in French) *Il y a plusieurs types de codification testés. Les premières se sont inspirées du code CNEH (code national pour l'équipement hospitalier) français. Il n'y a pas de codification unique retenue au niveau national.*

Nigeria

Desk review

There is no official nomenclature system. Medical devices are regulated by the National Agency for Food and Drug, Administration and Control (NAFDAC). Compliance with the classification of the country where the device is manufactured (link 2).
https://www.nafdac.gov.ng/drugs/
https://www.sciencedirect.com/science/article/pii/S2211883718300303#tbl0010
https://www.nafdac.gov.ng/

North Macedonia

GAMD 2021

No, but we are recognising the GMDN code.

Desk review

There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures such as GMDN.

https://lekovi.zdravstvo.gov.mk/medicaldevices

http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-lekovi-i-medicinski-pomagala.pdf

Norway

GAMD 2021

The use of GMDN is not imposed by law.

https://www.gmdnagency.org/

Desk review

Norway uses a nomenclature system based on the GMDN. However, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://legemiddelverket.no/English

Oman

Desk review

The GMDN is used for regulatory purposes. However, UMDNS and GMDN are both accepted nomenclature systems.

https://www.moh.gov.om/documents/16539/0/11%2B5++Listing+Guidance.pdf/9a6f51f7-b7b1-f209-2015-b3fd56d37b2c

Panama

GAMD 2021

The UMDNS system has been adopted into legislation. Its implementation is still in process.

(Original in Spanish) *El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.*

http://www.minsa.gob.pa/

http://minsa.b-cdn.net/sites/default/files/normatividad/decreto_468_de_2007_para_publicar_en_gaceta_2.pdf

Desk review

Panama is now in the process of adopting both the GMDN and the UMDNS for regulation purposes.

http://www.minsa.gob.pa/direccion/direccion-nacional-de-farmacia-y-drogas

Paraguay

GAMD 2021

A plan is being developed to proceed with the installation of a naming system.
(Original in Spanish) *Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.*

Desk review

The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social.
https://www.mspbs.gov.py/monitoreo-insumos-medicamentos.html

Peru

GAMD 2021

Ley Nº29459-D.S and the D.S. Nº 016-2011-SA.
http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/DocumentosConsulta/P08_234-2017-05-04.PDF;
http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Normatividad/2020/DS_036-2020-SA.pdf
https://www.gmdnagency.org/

Desk review

According to the form DMEB-002 published on the official website, Peru uses the GMDN in the private sector, although the use of UMDNS or other systems is legally accepted (Ley Nº29459-D.S and the D.S. Nº 016-2011-SA). The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social. Advance Scientific del Perú.
http://www.digemid.minsa.gob.pe

Philippines

GAMD 2021

The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.

Desk review

The national regulatory authority is the Bureau of Health Devices and Technology (BHDT), Department of Health.
https://doh.gov.ph/node/266

Poland

GAMD 2021

The GMDN code is mentioned as a basic medical device nomenclature system in Polish legislation: Act of 20 May 2010 on Medical Devices; however, the use of other nomenclatures is allowed. Poland is part of the EU medical device regulatory framework so a new obligation from the European Commission in the area of medical device nomenclature and Eudamed will be implemented, e.g. adopting the European Medical Device Nomenclature (EMDN) when available.

Nevertheless, according to the EC statement, this nomenclature will still share some features with the GMDN code.

https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Desk review

In the private sector, Poland uses a nomenclature system of medical devices based on the GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products.

http://www.urpl.gov.pl/en/office

https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Portugal

Desk review

In the private sector Portugal uses a nomenclature system of medical devices based on GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the National Authority of Medicines and Health Products (INFARMEDC, IP).

https://www.infarmed.pt/

Qatar

GAMD 2021

This is used for planning medical equipment for new / upcoming projects.

https://www.ecri.org/solutions/umdns/

Desk review

Medical devices are regulated by the MOHP but registered by the Ministry of Economy and Commerce (MEC). It uses the UMDNS for planning for new/upcoming projects, but the GMDN is also accepted. The national regulatory authority is the Medical Device Registration Unit, Pharmacy & Drug Control, Supreme Council of Health.

https://www.mfds.go.kr/eng/index.do

Republic of Korea

Desk review

Undefined nomenclature but uses medical devices classification and medical devices are regulated by the Korean Food and Drug Administration (KFDA).

https://www.mfds.go.kr/eng/wpge/m_39/denofile.do

https://www.mfds.go.kr/eng/index.do

https://www.mfds.go.kr/eng/brd/m_61/view.do?seq=74

Republic of Moldova

Desk review

It uses its own developed nomenclature that, nevertheless, is harmonized with the EU's regulation. The nomenclature is based on the GMDN (as seen in the second link, second page point 3c) but the use of other nomenclature is accepted too. The national regulatory authority is the AGENŢIA MEDICAMENTULUI ŞI DISPOZITIVELOR MEDICALE.
http://nomenclator.amdm.gov.md
https://amdm.gov.md/ro

Romania

Desk review

There is the European regulatory provision on medical devices Regulated by ANM (see first link) and a national database of medical devices. There is also an own nomenclature system. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.
https://www.anm.ro/en/
https://www.anm.ro/nomenclator-dm/
https://www.anm.ro/en/dispozitive-medicale/regulamentele-europene-privind-dispozitivele-medicale/

Russian Federation

Desk review

There is an own developed nomenclature system but according to the fact that the state is a member of the EEU, which signed an agreement with the GMDN about nomenclature systems harmonization. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022. From 2022 an EAEU nomenclature will be done based on the GMDN for various purposes mentioned in this question. The national regulatory authority is Roszdravnadzor.
https://roszdravnadzor.gov.ru/services/mi_reesetr

Rwanda

Desk review

It uses the GMDN to register medical devices (see first link page 24).
http://www.rwandafda.gov.rw/web/guidelines/Guidelines_for_Regsitration_of_Medical_Devices.pdf

Sao Tome and Principe

Desk review

Regulated by the Central de Aprovisionamiento de Medicamentos:CAME (see link).
http://ms.gov.st/?p=57

Saudi Arabia

GAMD 2021

A committee inside NUPCO has been established for that purpose and the work is in progress.
http://www.nupco.com

Desk review

Medical devices are regulated by the MOH (first link) via the unit NUPCO (second link) which manages tenders for medical devices. Medical devices are Regulated by the Saudi Food and Drug Authority (third link). Private industry uses the GMDN.
https://www.moh.gov.sa/
https://www.nupco.com/
https://udi.sfda.gov.sa

Senegal

Desk review

Private industry uses the GMDN. The national regulatory authority is the Direction des Infrastructures, d'équipement et de la Maintenance.
https://sante.sec.gouv.sn/les-directions/la-direction-des-infrastructures-des-equipements-et-de-la-maintenance

Serbia

GAMD 2021

National nomenclature is in the process of updating and amendment.
http://www.zdravlje.gov.rs

Desk review

The national regulatory authority is the Medicines and Medical Devices Agency (ALIMS) which assures the use of the official nomenclature.
https://www.zdravlje.gov.rs/tekst/335365/medicinska-sredstva.php

Sierra Leone

Desk review

Medical devices are regulated by a national regulatory authority which is the Pharmacy Board (PBSL). The GMDN is used for registration of medical devices, and it is regularly used by the private industry.
http://www.pharmacyboard.gov.sl/

Singapore

GAMD 2021

There is a Global Medical Device Nomenclature (GMDN) which we only use as an internal reference. It is not required for medical device product registration in Singapore.

Desk review

The GMDN is used for internal reference but not for the registration of medical products. In addition, since the country is a member of ASEAN, other nomenclature systems are also used. The national regulatory authority is the Health Science Authority.

https://www.hsa.gov.sg/medical-devices

Slovakia

Desk review

Regulated by the MoH, it uses the SNOMED system. The national regulatory authority is the Ministry of Health.

https://www.health.gov.sk/Titulka

Slovenia

GAMD 2021

When medical devices are being produced by the manufacturers of medical devices with their registered place of business in the Republic of Slovenia, are notified to the national competent authority, GMDN code should be submitted, if available.

http://www.jazmp.si

https://simap.ted.europa.eu/cpv

Desk review

No changes. The official information is regulated by the JAZMP. The private industry uses the GMDN. The national regulatory authority is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

https://www.jazmp.si/

South Africa

GAMD 2021

The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.

Desk review

There are many co-existent nomenclatures. In many hospitals UMDNS is used. According to the country's legislature the GMDN can be used for special equipment, and IVDs (see first/second link). For medium and high-risk devices it is obligatory to use the GMDN for manufacturing, importing, exporting and distribution (see first/second link). South Africa, for example, regulates medical devices according to 3 distinct pieces of legislation and guidelines most closely resembling those of the IMDRF founding members (see link 3). The national regulatory authority is the South African Health Products Regulatory Authority.

https://www.sahpra.org.za/wp-content/uploads/2019/09/20180201_SAHPRA-Registration_Medical-Devices_Call-up-plan_v1.pdf

https://www.sahpra.org.za/wp-content/uploads/2020/01/Classification_Medical_Devices_IVDs_Nov19_v2.pdf

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

South Sudan

Desk review

There is no official nomenclature system in South Sudan (first link 1st paragraph from the beginning of page 6: The South Sudanese Drug and Food Control Authority Act, 2012). One of the nomenclatures that may be used for the registration of medical devices is the one developed by US-FDA (second link: registration requirement's section).

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

https://www.wikiprocedure.com/index.php/Sudan_-_Registration_of_medical_device_and_In_Vitro_devices_(IVDs)

Spain

GAMD 2021

The code UMDNS has been used, but will be replaced by GMDN when the Spanish version is available. (Original in Spanish) *Se ha utilizado el código UMDNS, pero se sustituirá por GMDN cuando esté disponible la versión en español.*

Desk review

It uses the UMDNS as the main nomenclature system. The GMDN is used for the regulation of medical devices in the private sector. Both GMDN and UMDNS are proposed on the official website (AEMPS). Uses the CIMA for medicine (see 2nd link). Regularly, private industry uses the GMDN system. The national regulatory authority is the Agencia Española de medicamentos y productos sanitarios.

https://www.aemps.gob.es/

https://cima.aemps.es/cima/publico/home.html

Sri Lanka

Desk review

Medical devices are regulated by the National Medicines Regulatory Authority (NMRA).

https://nmra.gov.lk/index.php?lang=en

Sudan

Desk review

It uses the UMDNS system, and since 2011 it has officially recommended the use of the GMDN. There is a risk-based classification system (link 4).

https://fmoh.gov.sd/

https://fmoh.gov.sd/Health-policy/Sudan%20HTA&M%20Policy_final.pdf

https://fmoh.gov.sd/index.php/files/index/93

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Syrian Arab Republic

Desk review

Medical devices are regulated by the MOH (see link). There is no specific information about the nomenclature system used.

http://www.moh.gov.sy/

Sweden

GAMD 2021

The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.

Desk review

For medical substances registration use SNOMED CT

https://www.lakemedelsverket.se/en/e-tjanster-och-hjalpmedel/substans-och-produktregister/national-substance-register-for-medicinal-products-nsl#hmainbody1

Switzerland

GAMD 2021

Swissmedic uses GMDN (no country specific nomenclature); if manufacturers do not know the GMDN number, a UMDNS code may be given.

Desk review

Both UMDNS and GMDN are used (the preference is given to GMDN, however, if manufacturers do not know GMDN, then UMDNS is used). Currently, there is a transition to EMDN (based on CND), as well as the corresponding mapping with the GMDN. The national regulatory authority is the Swiss Agency for Therapeutic Products, Swissmedic.

https://www.bag.admin.ch/dam/bag/en/dokumente/biomed/forschung-am-menschen/mdr-eu-berichterstattung/mdr-eu-berichterstattung-feb-20.pdf.download.pdf/20200217%20MDR%20IVDR%20Reporting%20BAG%20February.pdf

https://www.bag.admin.ch/bag/en/home.html

Tajikistan

GAMD 2021

https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx

Desk review

It uses the EAEU nomenclature, and the GMDN nomenclature, as well as others. The nomenclature of the manufactured drugs and medical products is determined by the manufacturers themselves as the official website states. The national regulatory authority is the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan.

https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx

https://www.wipo.int/edocs/lexdocs/laws/ru/tj/tj036ru.pdf

Thailand

Desk review

In Thailand, the sphere of medical devices is regulated by the Thai-FDA in cooperation with the Association of Southeast Asian Nations (ASEAN) that works together with the AHWP Asian on the harmonization of medical devices regulation. The GMDN is used for the regulation of medical devices in the private industry.

https://www.fda.moph.go.th/sites/fda_en/SitePages/Medical.aspx?IDitem=index

https://asiaactual.com/blog/thailand-implements-new-medical-device-regulations/

Timor-Leste

Desk review

There is an ongoing project for a nomenclature for MD, however there is scarce information.
http://timor-leste.gov.tl/?lang=en

Togo

GAMD 2021

The level of the sub-service responsible for the equipment is too low to be read. The hierarchical superiors do not show the necessary interest for the implementation of the management which is essential for medical devices.

Desk review

https://www.wahooas.org/web-ooas/

Trinidad and Tobago

GAMD 2021

Developed and in use as "Fixed Asset Inventory and Facilities Management". TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes).

Tunisia

GAMD 2021

The nomenclature of medical devices is an integral part of the Manual of biomedical and hospital maintenance management procedures drawn up in 1996 and improved in 2007 by the Ministry of Public Health, which was the subject of an order.
(Original in French) *La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l'objet d'un arrêté.*

Desk review

It uses a nationally developed nomenclature system, as well as the GMDN for the regulation of medical devices in the private sector.
http://www.dpm.tn/

Turkey

GAMD 2021

Huab (see second link) is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.

https://www.saglik.gov.tr/?_Dil=2

http://www.huap.org.tr/ubb/

Desk review

It uses a nomenclature system that is based on the UNSPSC and GMDN, however, they are adapted to national needs. Turkey is in the process of using the EU regulation. The national regulatory authority is the Turkey Medicines and Medical Devices Agency, Ministry of Health.

https://www.gs1.org/docs/healthcare/events/220610/8_Turkey_Goksin.pdf

https://www.ispartaeo.org.tr/haber-9

https://www.saglik.gov.tr/TR/

Uganda

GAMD 2021

See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.

www.health.go.ug

Desk review

There exists a regulatory framework for medical devices registration, importation and use (link 3). However, Risk-based classification does not exist, and the application of the MD regulation is still limited (link 4).

https://www.health.go.ug/download-attachment/ivZtalade9SPz4To_dbsBqwckPflb2S57yGgoi0lTo8

https://www.health.go.ug/download-attachment/wxVPCk1sDLk3NnNJiYkpYY-ohGwUXSeQMm7srliHbMM

https://www.nda.or.ug/medical-devices/#1603100276960-871cf845-bab3

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Ukraine

GAMD 2021

https://zakon.rada.gov.ua/rada/show/v0331282-01#Text

https://moz.gov.ua/article/ministry-mandates/nakaz-moz-ukraini-vid-28122019--2711-pro-zatverdzhennja-nomenklaturi-likarskih-zasobiv-ta-medichnih-virobiv-scho-zakupovuvatimutsja-za-naprjamami-vikoristannja-bjudzhetnih-koshtiv-u-2020-roci-za-bjudzhetnimi-programami-kpkvk-2301400

Desk review

The incorporation of the GMDN is in progress. The national regulatory authority is the State Administration of Ukraine on Medicinal Products (SMDC).

https://www.dls.gov.ua/en/state-service-of-ukraine-on-medicines-and-drugs-control/regulation/

United Kingdom of Great Britain and Northern Ireland

GAMD 2021

The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the “Official Journal of the European Union” (OJEU) CPV codes. The NHS also has a national system known as “e-class” which is a classification system for products and services.

http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/index.htm

www.nhseclass.nhs.uk

Desk review

The MHRA will be moving forward to solely use the GMDN with its previous system being phased out. The nomenclature used by the NHS is for the procurement of medical devices that are used by the “Official Journal of the European Union” (OJEU) CPV codes. Also, the NHS has a national system known as “e-class” which is a classification system for products and services. The national regulatory authority is the Medicines & Healthcare products Regulatory Agency (MHRA).

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#history

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949074/Device_Registration_Reference_Guide_January_2021_Migrated_and_Re-registered_and_New_accounts_Final_v1.pdf

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

United Republic of Tanzania

GAMD 2021

TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.

http://www.gmdnagency.org

Desk review

It has been used by the GMDN since 2015, but there is no access to the nomenclature code from the official website. It is obligatory to use a nomenclature system as it has been stated in the guidelines for the registration of medical devices.

https://www.tmda.go.tz/publications/24

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

United Arab Emirates

Desk review

There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures (often suggested by the importer -see first two links-). Regulated by the MOH (see links).

https://www.mohap.gov.ae/Files/MOH_OpenData/562/MoH-UAE-Registred-MD-2-2-2014.pdf

https://www.mohap.gov.ae/Files/MOH_Service/373/09%20Classification%20of%20a%20ProductEN.pdf

https://www.mohap.gov.ae/en/services/issuing-a-permission-to-import-medical-equipment

United States of America

GAMD 2021

1. Product Code. FDA- The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode.The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 Code of Federal Regulations (CFR) Parts 862-892.2. Problem code FDA-CDRH also has a nomenclature for CDRH Event Problem Codes for Medical Devices used in reporting adverse device events. The adverse event vocabulary codes were developed in cooperation with the National Cancer Institute Enterprise Vocabulary Service (NCI-EVS); see the second link.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

Desk review

https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Uruguay

Desk review

The nomenclature commonly used in the Mercosur bloc is used.
https://www.gub.uy/ministerio-salud-publica/home

Uzbekistan

Desk review

It uses its own nomenclature system (see first link). Used nomenclature correlates with one used by the EU (second link).
https://data.gov.uz/uz/datasets/3514?dp-1-sort=G1

Venezuela (Bolivarian Republic of)

GAMD 2021

There is no specific nomenclature. The nomenclature used for the certification of medical devices is the FDA product classification.
https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Yemen

Desk review

Regulated by the Supreme Board for Medicines & Medical Appliances (SBDMA)/ MoPHP.
www.sbd-ye.org

Zambia

Desk review
Regulated by the Zambia Medicines Regulatory Authority (ZAMRA).
https://www.zamra.co.zm

Zimbabwe

Desk review
Regulated by the Medicines Control Authority of Zimbabwe (MCAZ).
https://www.mcaz.co.zw

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