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MINISTRY OF HEALTH-ETHIOPIA
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ETHIOPIAN FOOD & DRUG AUTHORITY

Adopting Standard Nomenclature for Medical Devices in Ethiopia

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Addis Ababa, Ethiopia

FORWARD

The Ethiopian ministry of health (MOH) and Ethiopian Food and Drug Authority (EFDA) have been working to ensure everyone in the community has access to affordable, equitable, quality and safe healthcare service. The national health policy, medicines and medical devices policy, health sector transformation plan, Ethiopian hospital service transformation guidelines, Ethiopian health center reform implementation guidelines, and other strategies by the two organizations place a strong emphasis on the accessibility of safe and quality-assured medicines and medical devices.

For effective communication in the medical device assessment, regulation and overall management and therefore achieve effective health care delivery, a standardized medical device nomenclature system is vital. The presence and use of internationally recognized medical device nomenclature supports consistent and accurate identification of medical devices with similar characteristics by a variety of stakeholders, including policymakers, regulators, manufacturers, trade and customs officials, insurance companies, the health care sector and users.

We understood that different stakeholders who get involved in the manufacturing, distribution, sales, procurement, utilization, assessment, and regulation of medical devices- use different names to refer to similar generic devices. These practices have been leading to- miscommunication during procurement process, use of inappropriate devices during health service provision (ultimately causing medical error), error during exchange of information on adverse events and incidents reporting and analysis, and difficulty to locate unsafe devices during recall. By recognizing the aforementioned problems and therefore urgent importance of a harmonized nomenclature system, we established a task force to evaluate and select one of existing internationally recognized medical device nomenclatures (EMDN, GMDN and UMDNS). Based on a series of evaluation activities, Global Medical Device Nomenclature (GMDN) is hereby officially approved and recognized to be used in Ethiopia throughout the medical device's lifecycle.

We believe that adoption/recognition and use of the GMDN will facilitate the consistent identification of medical devices in the

Procurement process, Inventory management, Premarket regulatory assessment, Clinical Investigation/performance study, post-market surveillance and Vigilance, Adverse event reporting, and any other information exchange that involves medical devices among relevant stakeholders.

MOH and EFDA want to give deserved credits to many individuals who have contributed to this work of evaluation and selection. We would like to thank all members of the task force and specifically extend our especial gratitude and appreciation to- Mr. Regassa Baysa, Mr. Mahdi Abdella, Ms. Bethel Haile, Mr. Keneni Benti, Ms. Rediet Desalegn, Ms. Lemlem Tiruneh, Mr. Samuel Tadesse, Mr. Alemu Abibi, Ms. Mulumebet Fikadu, Mr. Eyob Adugnaw, Mr. Matiwos Tekalign, Mr. Yonas Kebede, Mr. Andualem Wube, Mr. Demeke Bitew, Dr. Fahmi Mohammed, Mr. Jia Uga, Mr. Ayeru Fikadu, Mr. Sisay Kebed, Mr. Tadesse Yadete, S/r Yeshalem Bekele, Ms. Selamawit Asfaw who were active members of the TF and highly contributed to this work from its initial phases until its output.

Mrs. Frehiwot Abebe
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BACKGROUND

Access to safe, effective and quality-assured medical devices is the key elements of quality healthcare system. Safety, performance and quality of the devices are ensured through an effective regulatory system that is established on a sound legal basis. Accurate identification of medical devices from their manufacturing time throughout their supply chain to their point of use at the healthcare facilities until their decommissioning and disposal is crucial to reduce issues related to- miscommunication during procurement, distribution, premarket regulatory assessment, adverse events reporting, post-market surveillance and others.

The Ethiopian ministry of health (MOH) and Ethiopian FDA (EFDA) are committed to facilitate, promote and enforce common naming and coding of generic medical devices including In vitro Diagnostic Devices (IVDs) throughout their lifecycle. They recognize the urgency of moving towards having harmonized medical device nomenclature. Nomenclature is a classification, naming and coding system designed to identify and categorize medical devices and related health products, aiding in communication and regulatory processes. The Ministry and the Authority believe that- use of harmonized nomenclature will promote quality health system by ensuring effective procurement, inventory management, premarket assessment, post-market regulatory activities and information exchange. To achieve this goal, the MOH established a Task Force (TF) in 2023 with members pooled from the ministry itself, the Agencies

under it including Ethiopian Food and Drug Authority (EFDA), Ethiopian Pharmaceutical Supply Service (EPSS), as well as academic institutions and healthcare facilities to work on national medical device nomenclature system. The plan was to systematically analyze existing resources and capacities to do one of the following-

- Creating national medical device nomenclature system/database
- Adopting/adapting one of internationally recognized nomenclatures

After assessing all existing opportunities, the TF finally decided to adopt or recognize one of the existing nomenclatures based on predetermined criteria. Following a series of workshops that used nomenclature selection criteria recommended in the World Health Organization's (WHO) Global Model Regulatory Framework for Medical devices including In vitro diagnostic medical devices (GMRF) document, the TF did the evaluation and forwarded the recommendation to higher officials of the Ministry and the Authority for endorsement. The selection criteria used were: Harmonization, Accessibility and ease of Use, Governance, Inclusion of Medical devices range, Timely updates, Used in source jurisdictions, Language, Transferability and interoperability. Using these criteria, the TF looked for the existing internationally recognized Medical device nomenclature systems and identified three nomenclatures to evaluate and select from. These are- Global Medical Device Nomenclature (GMDN), European Medical Device Nomenclature (EMDN) and Universal Medical Device Nomenclature System (UMDNS). The

evaluation reports and recommendation of these nomenclatures by the task force were accepted and endorsed by the two organizations. Following this, relevant medical device documents will be updated to include this decision and enforce the use of this nomenclature for all medical devices to be marketed in the country.

TERMS DEFINITION

Medical Device: - Refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,

Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Post Market Surveillance: - is a systematic process of collecting, analyzing, and testing samples of medical devices that have been placed on the market as well as collecting relevant information through market surveillance and measures taken to ensure the devices compliance with the requirements set out in the relevant legislation.

Vigilance: - is a system of manufacturer awareness and reporting of any incidents involving medical devices that is part of its post-market surveillance activities.

Medical Device Nomenclature: - is a coding and naming system used to generically classify and identify all medical devices and related health products.

PURPOSE

The purpose of this document is to publicize the decisions made by the MOH and EFDA regarding the recognition of one of the existing internationally recognized medical device nomenclatures. This will ultimately facilitate accurate communication and information exchange during-procurement, inventory management, premarket regulatory assessment, post-market surveillance, adverse events reporting and investigation, and minimize medical errors caused by use of inappropriate devices.

WHY SHOULD ETHIOPIA USE AN HARMONIZED MEDICAL DEVICE NOMENCLATURE?

Medical device nomenclature is vital to establish a standardized, consistent and universally recognized framework for identifying and classifying medical devices across healthcare systems. It benefits patients, healthcare providers, regulatory bodies, manufacturers, and other stakeholders, enhancing various aspects of the healthcare ecosystem, including:

Patient Safety

The nomenclature plays a crucial role in ensuring patient safety and improving treatment outcomes by facilitating appropriate identification of medical devices for patient treatment.

This reduces the risk of medical errors and improper application that could compromise patient care.

Standardization and Communication

Medical device terminology offers a common structured language with unified terminologies, recognized across systems and reduce errors and misidentification by various healthcare system stakeholders. It reduces errors, misidentification and classification, misunderstandings, subsequently ensuring clear communication, and streamlines the collaboration process.

Regulatory Compliance Assessment and Post market surveillance

Nomenclature helps EFDA for appropriate naming and risk classification of medical devices during premarket assessment and post-market surveillance. It used for correct/accurate identification of the concerned devices during adverse event reporting, investigations, recalls, and etc. It will also be integrated with the Unique Device Identification (UDI) system to enable traceability throughout the supply chain that will ultimately support in reducing the prevalence of substandard and falsified medical devices.

Supply Chain Efficiency and Data Integration

Standardized nomenclature is used to improve procurement, inventory management, logistics and accurate reporting and analytics. In addition, it enhances interoperability between electronic health records and hospital systems, leading to better data documentation and healthcare outcomes.

International harmonization and facilitation of trade

A globally accepted system serves to harmonize regulatory and trading procedures. Alignment with GMDN, and ISO 15225 provides regulatory consistency, improved access to markets, and a more standardized global medical device market.

Research and Innovation

Enables easy comparison between different models, facilitating accurate data analysis and supporting collaboration among global researchers. Offers a clear and structured system, it helps identify market gaps and emerging technological trends, driving the development of new devices. It clarifies intellectual property boundaries, reducing potential conflicts over patents and fostering a more secure innovation environment.

EVALUATION AND SELECTION CRITERIA USED

The Ministry of health including Regional Health Bureaus, healthcare facilities, EPSS, AHRI, Academic institutions, and development partners. The task force identified available nomenclature systems and established selection criteria based on WHO's GMRF document. The major evaluation criteria were harmonization, accessibility and ease of use, governance, medical device covered, timely update, used in imported devices country of origin, language, transferability and interoperability.

The existing recognized medical device nomenclatures were carefully assessed for selection to be used in the country throughout the medical devices lifecycle. The following table shows the summary of the evaluation findings.

	EMDN	GMDN	UMDNS
Harmonization	Utilized currently in 30 countries (EU Member States (27), Liechtenstein, Norway and Turkey (3). In addition, the 9 accession candidate countries to the EU will be expected to align their regulations to the EU MDR. Used by WHO's MeDevIS platform.	Approximately 12,000 registered users under different categories 70 of which are regulators. Used in more than 140 countries. Twelve countries have the 'mandated use' of the GMDN three of which are African countries. Used by US FDA's GUDID and WHO's MeDevIS platforms.	According to WHO's GAMD, 21 countries use UMDNS.
Accessibility and ease of Use	Accessible through the website no subscription required, and database is downloadable for offline use. The database is easy to use through simple search.	Free for online and offline use for various stakeholders, including regulators, researchers and healthcare providers. All users can have access to codes, names and definitions.	It is not freely accessible. It requires subscription fees. Accessing the database is complex and does not appear on search engines with simple searches.
Governance	Transparently governed by Medical Device Coordination Group (MDCG) under European Commission.	The database is transparently governed by the GMDN Agency.	It is developed and managed by ECRI. It does not have a transparent review and feedback mechanism for

	Involve more public consultation and stakeholder. Has transparent feedback and review process		defining codes and names. Some feedback is taken from users who have paid for licenses to use other ECRI products.
Medical devices covered	6,500+	25,000+	18,000+
Timely updates	A structured annual revision process. There are also ad-hoc updates to address urgent needs, particularly those initiated by competent authorities and notified bodies within EU.	Addition of new terms and modification of existing terms are transparently proposed and reviewed by all registered users. Dynamic, with updates occurring on a continuous basis.	The periodicity of updates is dynamic and does not take place in a pre-set manner; however, updates are known to only the users of the UMDNS.
Used in Imported devices Country of Origin	All devices imported from EU member states use EMDN.	Devices imported from US, UK, Australia, Turkiye, Russia, Ukraine and others use GMDN.	Imported devices from China (one of the most predominantly importing country alongside India) uses UMDNS.
Language	Available in all official languages of the European Union including English.	GMDN Terms are available in 6 languages and Categories are available in 15 languages including English.	Available in English language.
Transferability and interoperability	Primarily focused on the European regulatory	Transferable and interoperable with other	It is less interoperable
	framework, which may limit its transferability and interoperability outside the EU.	systems and databases including inventory, regulatory control outputs, procurement and others.	with limited adoption.

WHEN SHALL THE NOMENCLATURE BE USED?

Manufacturers, Suppliers, Importers, Wholesalers/local distributors, donors, healthcare providers, government organizations including regulators, diagnostic centers, research and academic institutions, users and any other person or organization who is engaged in manufacturing, distribution, or use of medical devices shall use this officially recognized GMDN Term code, Term name and Term definition in their information exchange or any related activities including, but not limited to-

- Procurement process
- Inventory management
- Premarket regulatory assessment
- Clinical Investigation/performance study
- Post-market surveillance and Vigilance
- Adverse event reporting
- Any other information exchange that involves medical devices.

All the relevant regulatory documents by EFDA and medical device related documents by the MOH should be revised to accommodate this decision of recognizing GMDN for all medical devices to be marketed and used in the territory.

Summary of features of GMDN

Harmonization: As of today, approximately 12,000 users have registered to use the GMDN worldwide by different user categories 70 of which are regulators. These registered users are from more than 140 countries. The US FDA has been using GMDN in its GUDID (Global Unique Device Identification Database) since 2013. WHO also uses this nomenclature in its MeDevIS (Medical Device Information System) platform. Twelve countries have the 'mandated use' of the GMDN three of which are African countries.

Accessibility and ease of Use:

The GMDN database is freely available to government organizations including regulators as well as public health providers. GMDN term codes, term names and term definitions are also freely available to all users including manufacturers and distributors. It can be referenced and used by regulators, procurers, managers and all users of medical devices (hospitals/health care workers and patients).

In addition, it supports unique device identifier system; accessible through simple and intuitive search and available for use in all health-related database systems.

Governance and Periodic Updating

GMDN system is managed in a transparent manner with a process for obtaining feedback from all stakeholders, and a quality system for managing changes to terminology. The registered users can propose changes through “Term Enquiry” for adding new or modifying existing devices in the database. In addition, if any changes are proposed, users can comment on the proposed changes. This makes the GMDN a very transparent medical devices nomenclature. The update does not need to wait for a preset timeframe as long as there is a need to update. This makes it to accommodate innovation in new generic types of medical devices and allow for the clear and consistent implementation of new terms by all stakeholders.

Language: The GMDN Terms are available with 6 languages including English and Categories are translated into 15 languages. This promotes the harmonization of this nomenclature.

Comprehensiveness and structure: The GMDN is the most complete nomenclature covering more than 25,000 generic medical devices in it as of today. The devices hierarchies are grouped into categories and subcategories to meet stakeholder needs. The terms are mutually exclusive.