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REGULATORY FRAMEWORK FOR MEDICAL DEVICES REGULATION IN ETHIOPIA: A REVIEW

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ABSTRACT

Medical devices are used for the diagnosis, monitoring and treatment of virtually every disease or condition, and include familiar objects such as simple bandages to high-end MRI scanners. The demand for regulation medical devices is raised as its market is growing fast across different countries around the world. The present review discussed the current regulatory framework for medical devices in Ethiopia and it similarity with USA and EU. Although the approach for regulation of medical device is differ between USA and EU, the requirements for registration to ensure safety and efficacy of device before markets are almost similar in it composition. Ethiopia adopted an EU and GHTF based classification system for registration of medical device in order to ensure its safety and efficacy before marketing.

KEYWORDS: Medical device, instrument, regulation, registration, harmonization.

1. INTRODUCTIONS

Medical devices are used for the diagnosis, monitoring and treatment of virtually every disease or condition, and include familiar objects such as simple bandages to high-end MRI scanners. Estimates suggest that from 2011 to 2016, the world market for medical devices is forecast to expand at a compound annual growth rate of 5%. The US, the EU, Japan, Australia, and Canada are extremely large and lucrative medical device markets. India, China, Brazil, and South Africa are emerging markets, which presently contribute around 9% of the global market for medical devices. Global harmonization of standards and regulatory requirements should help facilitate overall market growth.[1]

According to GHTF harmonized definition, a ‘‘medical device’’ is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article that is intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purposes; and. does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but that may be assisted in its intended function by such means.[2]

Despite growth of global market of medical device over decades, the issue of ensuring safety and its efficacy has become a problem for effective medical device regulation across a globe due to new devices still pose substantial risks to patients, with high-profile recalls in recent years affecting breast implants, specific types of artificial hips, devices for lung surgery, and implantable cardioverter-defibrillator leads. These occurrences have led experts to call for greater premarket testing for the safety and effectiveness of new devices and monitoring of their performance after approval.[3] The United States (US) and the European Union (EU), two of the most important world markets for medical devices, present vastly different approaches to approving devices for use in patients.[3]

The aim of this review is to provide informative review of medical device regulation in Ethiopia.

2. OVERVIEW OF REGULATORY PROCESS OF DIFFERENT COUNTRIES

2.1. Medical Device Regulation in USA

2.1.1. Regulatory framework

Medical devices are regulated by the US Food and Drug Administration (FDA) within the Center for Devices and Radiological Health is responsible for protecting and promoting the public health by ensuring the safety, effectiveness, and quality of medical devices, ensuring the safety of radiation-emitting products, fostering innovation, and providing the public with accurate, science-based information about the products to oversee, throughout the total product life cycle by the Federal Food Drug and Cosmetic Act of 1938.

In accordance with the Act, medical devices are classified into 3 classes, class I, II, and III, based on the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device as the classification increases, the risk to the patient and FDA regulatory control increases.[4]

Class I provides the lowest level of regulatory control and is intended for devices for which there is sufficient information to conclude that safety and effectiveness can reasonably be ensured by General Controls alone. General Controls are defined in the Medical Device Amendments and include enforcement authority for misbranding, adulteration, registration and listing, device banning, consumer notification and recall, product reporting, premarket notification, and good manufacturing practices. Class I devices present minimal potential harm to the user and are typically simple in design and have a history of safe use. Examples of Class I devices include manual surgical instruments such as clamps and retractors, hand-operated urological tables, and manual biopsy forceps. Most Class I devices are exempt from the requirement for premarket notification (more commonly referred to as the "510(k)" submission; described further in the next section) and may also be exempt from compliance with the good manufacturing practice requirements of the quality system regulation.[4]

Medical devices designated as Class II are devices for which General Controls alone are not sufficient to reasonably ensure safety and effectiveness, but for which there is sufficient information to establish Special Controls to provide this assurance. Therefore, in addition to General Controls, these devices are subject to one or more Special Controls. Special Controls include the following:

- special labeling requirements,
- mandatory performance standards, both International and United States,
- post market surveillance, and
- FDA guidance documents.

Although Class II devices typically require FDA review and clearance of a 510(k) submission before marketing, a few of them are exempt from the 510(k). Information on Class II exempt devices is located within the device regulations, 21 Code of Federal Regulations 862 through 892. Examples of Class II devices include urinary catheters, cryotherapy systems, x-ray systems, brachytherapy seed implants, and computer-assisted (robotic) surgical systems.

Class III medical devices pose the most risk, and, therefore, are subject to the most stringent regulatory controls. For Class III medical devices, sufficient information is not available to ensure safety and effectiveness through the application of General and Special Controls. Instead, in addition to General Controls, these devices require FDA review and approval of a premarket approval (PMA) application before marketing. Class III devices support or sustain

human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient.[5]

Additionally, as previously noted, devices that are not substantially equivalent to a predicate through the 510(k) process are automatically Class III by statute until re classified by FDA through a risk-based review process. Examples of Class III devices that require a PMA are transurethral microwave thermotherapy (TUMT) systems for the benign prostatic hyperplasia (BPH), inflatable penile implants for erectile dysfunction, and high-intensity focused ultrasound systems for uterine fibroid ablation.[5]

2.1.2. Registration of medical devices

In USA, before marketing any medical device the following procedures and requirements for registration is followed. These are[6]:

A 510(k) Notification: is a premarket submission made to the FDA to demonstrate that the device to be marketed is safe and effective and it must demonstrate that the device is substantially equivalent to a legally marketed device that is not subject to PMA.[6] Documentation required with the 510(k) submission includes: description of the device; labelling information including draft promotional material; identification of predicate devices with narrative and tabular comparisons, and intended use indications; technical characteristics and principles of operation; software documentation; biocompatibility information; sterility information; statement or declarations of conformance to applicable standards and guidance documents; summaries of any performance testing.

A legally marketed device to which substantial equivalence is drawn is commonly known as a predicate and a device is substantially equivalent if, in comparison to a predicate, it has the same intended use as the predicate; the same technological characteristics as the predicate; and has different technological characteristics, and the information submitted to the FDA does not raise new questions of safety and effectiveness, and demonstrates that the device is at least as safe and effective as the legally marketed device.[7]

Premarket approval (PMA): a process of scientific and regulatory review to evaluate the safety and effectiveness is required for all class III devices.[7] It demonstrates the safety and effectiveness of the device through, for example, technical documents, preclinical laboratory studies, and clinical data.

Quality System management: The US Quality System Regulation (QSR) for medical devices is based on Title 21, part 820 of CFR (21 CFR 820). The US FDA requires manufacturers to implement Good Manufacturing Practice (GMP) to ensure that medical devices meet the requirements of QSR, except for a few Class I devices that are not supplied sterile. However, manufacturers of devices exempted from the GMP by the US FDA are still requested to maintain complaint files (21 CFR 820.198) and general requirements regarding records (21 CFR 820.180). The quality system regulations include requirements related to all aspects of device design, manufacturing, labelling, control, packaging and servicing.[8]

2.1.3. Post market surveillances

To safeguard public health once a device is on the market, the FDA requires a range of post market surveillance activities, including adverse event reporting by manufacturers and user facilities (via the Medical Device Reporting [MDR] program) and post market studies to ascertain and monitor the device's safety and effectiveness.[9] The agency also supports a number of surveillance data networks, such as MedWatch, the Medical Device Surveillance Network (MedSun), and the Medical Device Epidemiology Network Initiative (MDEpiNET), to identify and address safety problems and advance epidemiological methods for device surveillance.[9]

2.2. Medical devices regulation in EU

2.2.1. Regulatory framework

Medical Device Directive (MDD) regulates the safety and marketing of medical devices in Europe since 1990s and this core legal framework consists of three directives that regulate the safety and marketing of medical devices in Europe. These three directives include:

- Active Implantable Medical Device Directive (AIMDD 90/385/EE);
- Medical Device Directive (MDD 93/42/EEC);
- In Vitro Diagnostic Medical Device Directive (IVDMDD 98/79/EC).

Until the 1990s, each country had its own approach to evaluate medical devices. To regulate this uneven and complex market, in 1990, the medical device directives (MDDs) became the set of EU legislative texts that cover the European regulatory requirements for medical devices; regulate the standards of safety, quality, and efficiency of medical devices; and harmonize safety requirements and specify the measures that need to be met to place a device on the European market.[10]

Medical devices in Europe are divided into classes I, IIa, IIb, and III, employing a series of 18 classification rules detailed in Directive 93/42/EEC Annex IX. Class III are ranked as the highest and higher the classification the greater the level of scrutiny (**Table 1**).[11]

Table 1
Examples of product classification

Classification	Risk	Description	Examples
General controls			Hospital beds, bed pans
I Sterile (Is)	Low	Most non-invasive devices that do not interact with the body.	Sterile plasters
Measuring (Im)			Thermometers, weighing scales.
IIa Special controls required: may include special labelling, mandatory performance standards & post-market surveillance	Medium	Exchange energy with a patient in a therapeutic manner or are used to diagnose or monitor medical conditions. Generally invasive but limited to natural orifices, if hazardous to a patient then it becomes a class IIb	Powered wheelchairs, hearing aids, ultrasonic diagnostic equipment
IIb Special controls (as IIa)	Medium	Most surgically invasive/active devices partially or totally implantable in the body. May modify composition of body fluids.	Infusion pumps, ventilators, surgical lasers
III Pre-market approval is the required process of scientific review to ensure the safety and effectiveness of these	High	Support or sustain human life and are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Device that connects directly with the Central Circulatory System or CNS, or contains a medicinal product.	Many implants: vascular & neurological, replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators

2.2.2. Registration requirements

Before any medical device is to be marketed in Europe the following requirements should be fulfilled. These requirements are[12]:

CE marking: a legal requirement for all medical devices to be sold in the EU. CE marking affixed on the product represents its compliance with relevant Directives. To obtain CE certification, manufacturers must decide an appropriate conformity assessment route based on the classification of their devices. For class I medical devices without a measuring function or those not supplied sterile, only the declaration of conformity is required prior to affixing the CE marking. All other devices need to be verified and certified by notified bodies.

Although the rules will adequately classify the vast majority of existing devices, a small number of products may be more difficult to classify. If a manufacturer is unsure how its devices should be classified, it should first consult a NB. If doubts remain or there is a disagreement with the NB, the relevant CA should be approached in accordance with Article 9 of Directive 93/42/ EEC.[12] Exemptions from CE marking include:

- Custom-made devices;
- Devices intended for clinical investigation;
- Health protection – urgent unusual circumstances, humanitarian use;
- In-house use.

Competent Authorities (CA), Notified Bodies (NB) and authorized representatives are all involved in the CE marking process. CA's exist in each European Member State and are nominated by each government to monitor and ensure compliance with its provisions of the MDD. The CA designates a NB to ensure that conformity assessment procedures are completed according to the relevant criteria. The authorized representative, designated by the manufacturers, is legally responsible for compliance with the regulations and acts as the first point of contact for the EU authorities. It is up to the manufacturer to ensure that their product complies with the essential requirements of the relevant EU legislation.

Conformity assessment procedure: demonstrates that the device complies with the requirements of Directive 93/42/EEC.[12] Compliance is stated by establishing a Conformity Declaration. The classification of the device dictates the appropriate conformity assessment procedure. The higher the classification the greater the level of assessment required by NBs. It is the intended purpose of the device that determines the classification and not the particular technical characteristics. Considerations for classification include the duration of contact with the body, degree of invasiveness and local versus systemic effect. **The highest possible class applies if a device can be classified according to several rule**s. Active implantable medical devices (AIMD) and in vitro diagnostic medical devices (IVD) are also subject to conformity procedures.

The declaration of conformity should have the name and address of manufacturer, identification of the product allowing traceability, list of relevant directives, declaration statement, name and position/job title of person signing. This should be someone with enough responsibility to ensure the declaration is true which is affirmed by their signature and date.

2.2.3. Post market surveillances

The competent authorities of each member state in Europe are responsible for the post market surveillance, including adverse event reporting, vigilance reporting, and post market clinical follow-up. In order to enhance the transparency of market surveillance, the European

Databank on Medical Devices (EUDAMED) was established for exchanging legal information. In addition to vigilance information, EUDAMED contains data such as manufacturer registration, certificates issued, and clinical investigations.

Table 2: summary of medical device regulation in USA and EU.

	USA	EU
Regulatory Framework	The Federal Food Drug and Cosmetic Act	Medical Device Directive (MDD)
Regulatory Authority	Within FDA, the Center for Devices and Radiological Health (CDRH) is primarily accountable	The NBs are autonomous private enterprise to enact regulatory control over medical devices. NBs have the authority to grant the CE mark.
Risk Classification	Three-tiered system (Class I-lowest risk; Class II-intermediate risk; Class III highest risk)	Four-class scheme (Class I (including Is and Im), IIa, IIb, and III)
Registration Requirement	Class I device: general controls Class II devices : premarket notification 510(k) process class III devices need premarket approval (PMA)	Medical device manufacturers need to exhibit CE marking on their products in order to ensure that devices are safe and fit for their intended use

2.3. Medical devices regulation in Ethiopia[13]

2.3.1. Regulatory framework

In Ethiopia, the Food, Medicine and Health Care Administration and Control Authority (FMHACA) is responsible for medical devices regulation to ensure that manufacturers of medical devices follow specified procedures during the design, manufacture, and marketing as described in Proclamation No. 661/2009 for the regulation of medicines and healthcare products.

Under this Proclamation defined “medical instrument” means any instrument or supply that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in human, and includes various diagnostic, laboratory, surgery, dental medical instruments and suturing materials, syringes and needles.

In Ethiopia, devices are categorized into four classes, namely Classes I, II, III, and IV for medical devices other than IVDs, and Classes A, B, C, and D for IVD medical devices to easily distinguish between the two types of devices. For medical device other than IVD medical devices is risk based classification: class I (Lowest risk), class III (highest risk) and for IVD devices are also classified similarly Class A as the lowest risk and Class D as the

highest. The classification rules are based on various criteria, such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device, intended purpose, and duration.

2.3.2. Registration procedure

Medical devices and IVD are subject to the registration process. For representing the manufacturer to the regulatory authority, a local representative should be appointed. The appointed local representative should have permit (issued by Ministy of Trade) and certificate of proficiency (issued by FMHACA) at the time importation of product.

Conformity assessments, conducted before and after a medical device is placed on the market, and post-market surveillance of devices in actual use are complementary elements of the medical device global regulatory system. Medical device conformity assessments are intended to provide the objective evidence of safety, performance, and benefits and risks to maintain public confidence in the product.

Conformity assessment is primarily the responsibility of the medical device manufacturer; however, it is done in the context of the established requirements stated in this Guideline, and both the process and conclusions are subject to further review and approval by the Authority prior to its implementation. In general, the degree of requirement of conformity assessment is proportional to the risks associated with a particular category of devices.

The conformity assessment elements that should be provided with the registration dossier and/or after marketing of the device when requested by the Authority should include: a quality management system, a system for post-market surveillance, summary technical documentation, a declaration of conformity, and the registration of manufacturers and their medical devices. All five conformity assessment elements are required for each of the device classes. Where there are alternatives within a conformity assessment element, the manufacturer may choose the one that it believes to be the most suitable and provide justification for its suitability.

2.3.3. Post-marketing surveillance

Prior to and after placing the product on the market, the manufacturer should put a process in place, as part of its quality management system, to assess the continued conformity of the device to the essential principles of safety and performance through the post-marketing

phase. This process will include complaint handling, post-market vigilance reporting, and corrective and preventive actions. The manufacturer and/or local representative should provide annual post-marketing vigilance and post-marketing reports of Class II and higher devices.

3. GLOBAL HARMONIZATION FOR REGULATION OF MEDICAL DEVICES

Medical devices, like drugs, are used worldwide. With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to minimize regulatory barriers, facilitate trade and improve access to new technologies.[14] Harmonization also reduces the cost of implementing regulations for governments and local industry.[14-15] The Global Harmonization Task Force (GHTF) was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America to address these issues.[15]

The purpose of the GHTF is to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. The GHTF also promotes technological innovation and facilitates international trade. The primary means by which its goals are accomplished is via the publication and dissemination of harmonized guidance documents for basic regulatory practices. These documents, which are developed by four different GHTF Study Groups, can then be adopted/implemented by member national regulatory authorities or others. Technical committee members include representatives from national medical device regulatory authorities and the regulated industry.

3.1 Scope of the four GHTF study groups

Study Group 1: is charged with comparing operational medical device regulatory systems around the world and from that comparison, isolating the elements/principles that are suitable for harmonization and those that may present obstacles to uniform regulations. In addition, the group is also responsible for developing a standardized format for premarket submissions and harmonized product labelling requirements.

Study Group 2: examines the requirements for:

- the reporting of adverse events involving medical devices,
- post-market surveillance and other forms of vigilance

In addition, it is responsible for recommending ways of harmonizing the requirements, and for providing a discussion forum for harmonization initiatives.

Study Group 3: is responsible for examining existing quality system requirements in countries that already have well-developed device regulatory systems and identifying areas suitable for harmonization.

Study Group 4: is charged with the task of examining quality system auditing practices (initially among the founding members of the GHTF) and developing guidance documents that lay out harmonized principles for medical device auditing. It may be helpful to relate the roles of these four groups to the medical device life span.

With the exception of commercial activities including advertising and sales, which give freedom to local variations, the GHTF Study Groups are involved in all aspects that have direct impact on the safety and performance of medical devices. Therefore, recommendations from the GHTF Task Forces can provide excellent reference or guidance for countries that are establishing medical devices regulation programmes.

3.2 Benefits of the GHTF

- By following recommendations from the GHTF, countries can ensure that their regulatory controls are not in significant conflict with global harmonization recommendations. The GHTF is directing and converging the harmonized guidance documents.
- Critical issues such as safety and performance requirements, quality systems, standards and procedures of post-market surveillance are studied in-depth by experts from different countries to reach consensual recommendations and these are incorporated into the GHTF final guidance documents.
- Global harmonization and cooperation in post-market surveillance will facilitate an international devices data bank that allows rapid, global access to device information, alerts or recalls. This will promote the safety and effectiveness of medical devices.
- Where a country's programme is harmonized with the programmes of other countries, regulatory burdens and costs for local government and industry will be significantly reduced, while regulatory cooperation, commerce and international trade will be enhanced.
- Other emerging issues of international significance can be put to the GHTF for a common solution.

- GHTF provides an opportunity for countries to participate and observe regulatory developments that they could adopt. The current trend towards a regional harmonization will be useful for countries and can be supported by WHO's parallel regional structure.

For example, at the 1998 GHTF Meeting in Australia, the Asian Harmonisation Working Party (AHWP) held its first formal meeting and at the 1999 GHTF meeting in the United States, medical device regulators of the Americas launched a regional GHTF group.
(For simplification, the solid line arrows indicate the primary focuses of work, although each group has a continuum of influence throughout all phases.)

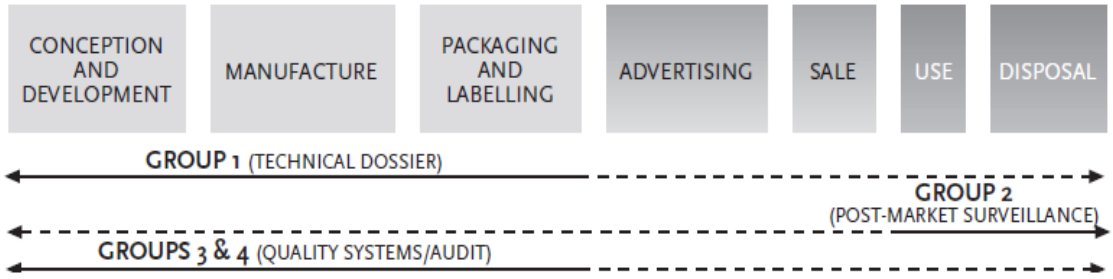

Figure 1. Current focus of work of the GHTF study groups.

As at June 2003, 19 final guidance documents supported by consensus of the regulators and industry representatives of the GHTF founding members have been published. These are listed in Annex 2 with an indication of how they relate to the common framework developed in this Guide. Each document is identified by study group (SG) and document numbers.

3.3 Global Medical Device Nomenclature (GMDN)

The Global Harmonization Task Force described further down has developed a recommended classification system where medical devices are divided into class A, B, C and D where class D represents the highest risk. This system is however a recommendation to regulatory authorities and not to companies. Information on the GHTF recommended classification system is found in the GHTF document Principles of Medical Devices Classification.

A nomenclature is usually given to a medical device when it is classified. There are two international nomenclatures that are very common:

- ✓ The Emergency Care Research Institute (ECRI) nomenclature called the Universal Medical Device Nomenclature System (UMDNS). The UMDNS terms are harmonized with the classification system of the USA and exist in ten languages.[16]

- ✓ The Global Medical Device Nomenclature (GMDN) codes. The GMND code is built according to EN ISO 15225 and is collaboration between the EU, EFTA, USA and Canada.[17] The GMDN terms only exist in English but can be translated with special software. This nomenclature system is required for registering a medical device within the EU.[18]

Both systems consist of defined terms that describe a group of products with similar characteristics. The GMDN system is developed from 6 different nomenclature systems and the UMDNS system is one of them. GMDN and UMDNS harmonize with each other but GMDN has more terms and is therefore preferred.[19]

The GMDN, endorsed by the GHTF as the global nomenclature to be used by regulators for the classification and registration of medical devices, is intended:

- ➢ to give a common generic description for every general term that describes characteristics of a medical device. This is to be used for identifying similar devices to those involved in an adverse incident report;
- ➢ to identify a device, using the generic term, for having been awarded a specific design or other certificate;
- ➢ to serve as a basis for E-commerce – to provide a generic basis for purchasing individual types of manufactured devices, by establishing a heading for comparison of products from different manufacturers.

4. CONCLUSION

The regulatory process of medical device in EU, USA and Ethiopia are discussed above. Although the approach for regulation of medical device is differ between USA and EU, the requirements for registration to ensure safety and efficacy of device before markets are almost similar in it composition.

Ethiopia adopted an EU and GHTF based classification system for registration of medical device in order to ensure its safety and efficacy before marketing.

GHTF is working toward harmonizing the regulatory requirements for registration of medical device in order to promote fast market access, reducing time and cost for approval and better quality and safety assurance of medical device.

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