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A REVIEW ON MEDICAL DEVICE REGULATION BY VARIOUS REGULATORY AGENCIES

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ABSTRACT

Today lot's of patients depends on medical device based treatment for the diagnosis and cure the several diseases. Medical Device plays an important role in healthcare by monitoring of various medical conditions. The quality and safety depends upon the regulatory guidelines. In 1992 by five members: European Union, United States, Canada, Australia and Japan invent the Global Harmonization Task Force (GHTF) to achieve regularity between the national medical device regulatory system. This study conducts a comprehensive analysis of medical device regulation by various regulatory agencies like India, European Union (EU), United States (US), Australia and Africa.

KEYWORDS: The quality and safety depends upon the regulatory guidelines.

INTRODUCTION

The term “medical device” includes a broad category of products ranging from therapeutic medical devices with local applications, such as tissue cutting, wound covering or propping open clogged arteries to highly sophisticated computerized medical equipment and diagnostic medical devices. Because these devices vary widely in type and are highly essential for patient’s care, their manufacture, distribution, and sale must be regulated to ensure their quality, safety, and efficacy.[1] A medical device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or related article used for a specific medical purpose.[2] To ensure the safety, efficacy and effectiveness and useful medical technologies and to also increase the uniformity between the national medical device regulatory system, the Global Harmonization Task Force (GHTF) was developed in 1992

by five members mainly: European Union, Unites States, Australia, Japan and Canadawhere surveillance was between the study groups.[3]

The medical devices are used to sustain the life of the individual, support the anatomy or replacement of any kind of process, control of the conception and disinfection of medical devices in hospitals and other places, provide the information regarding the sample kits, reagents, chemical used for cleansing, calibrators and software data by means of in vitro examination of particular specimens derived from the human body and which does not achieve its action intended action by pharmacological, metabolic or immunological means but which may be used in such ways.[3] Instruments has been used to address medical issues throughout history. The complexity and sophistication of medical equipment have increased from the time of the first stone blades and saws. With new tools made of bronze, the Greeks and Romans established the patterns for contemporary surgical instruments. Spectacles were created in the Middle Ages to improve vision. In the 20th century, lasers were used for surgery, kidney stone treatment, ophthalmoscopy, and cosmetic skin treatments. Electronic devices were also developed to monitor fetal heart rate. Computer technology is being employed to do robotic surgery, manage medical records, and operate tools.[4] Device efficacy primarily has been the most important element of medical device design, but now there is an increased understanding of human factors in designing and developing medical devices. Human factors engineering (HFE)-based design provides optimum results such as increased safety, reduced errors, decreased training time, and improved task performance.[5,6] The development of complex medical devices is more difficult because of the requirements from the regulatory environment it has to work in that need specific processes and testing to illustrate both the safety and efficacy of the device.[7]

Regulatory Authority

- **India**

In the Indian regulatory system, medical devices are considered as drugs by the Ministry of Health and Family Welfare.[8] Medical devices have emerged as a key aspect in the healthcare sector of any developing healthcare sensitive nation. These are used for various functions in the field of healthcare, as but not limited to, screening and diagnosis, treatment/care, restoration, and monitoring. The medical device market in India is one of the top 20 medical device markets globally. It is growing at a fast pace of 15% annual growth rate and is expected to touch $50 billion by 2025.[9,10]

- **European Union (EU)**

The European Union (EU) has an innovative medical device sector in which small and medium-sized enterprises (SMEs) are at the forefront. The regulatory framework for medical devices enables a well-functioning European single market. The medical device regulations aim to ensure a high level of health protection for patients and users.[11] Each EU countryhas its national authority that supervises the regulatory compliance of medical devices and operators.[12] MDR plays an important role in ensuring the safety of medical device users and should not be seen as an obstacle to the birth of healthcare innovations, but as an enabler.[13]

- **United States (US)**

The United States (US) is the largest consumer of medical devices in the world.[14] Responsible for assuring the "safety and effectiveness" of all medical devices, the Food and Drug Administration (FDA) regulates device manufacturers' ability to market devices within the US.[15] The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.[15]

- **Australia**

Medical device regulation is a complex and evolving area. Recently, a range of reports and reform proposals relevant to the Australian Therapeutic Goods Administration (TGA) have been put forward. A health technology assessment (HTA) tabled by the Department of Health and Ageing in December 2009 addressed "the regulatory burden on business that results from HTA processes".[16] The ARTG provides information on therapeutic goods that may legally be supplied in Australia. Each entry in the ARTG may provide information on one or more medical devices, with variants of a device included in a single entry. For example, two different-sized hip replacement prostheses may appear under the one entry. Each entry listed on the ARTG is classified by manufacturers and the TGA into one of several risk categories based on a series of algorithms.[17]

- **Africa**

The medical device regulatory processes in many African countries are not well-defined,and countries may rely on clearance from the European Medicines Agency[18] or the U.S. Food and Drug Administration (FDA).[19] In 1993, the Global Harmonization Task Force (GHTF), now known as the International Medical Device Regulators Forum (IMDRF), was founded in association with multiple national regulatory authorities. The IMDRF encourages convergence of regulatory standards for medical devices and facilitates information access for countries in the development phase of their regulatory process.[20] Despite these efforts, very few African countries have established regulatory systems. A 2017 World Health Organization (WHO) report found that 40% of countries in the WHO-defined African region have no regulations for medical devices, 32% have some regulations, and the remaining 28% have no available data. In contrast, medical device regulation is present in 58% of all WHO member countries.[21]

Classes

Medical devices are categorized on the basis of their medical uses or technical modeland manufacturing point. But medical devices have been classified by the regulatory authorities according to their safety and efficacy and quality standards to be set around the world. Different criteria are used to determine the risk, affected body system, effectiveness, and other local and systemic effects. The classification of medical devices differs fromcountry to country.

- **India**

The central drug standard control organization (CDSCO) divided medical device in four classes in India.

CLASS A:- These medical devices are subjected to general controls and referred as low risk devices. In this category mainly it contains the banned devices, replacement, refund, good manufacturing practices, repair, and notification. Class 1 devices are not used in preventing any impairment to the human health. Examples - surgical instrument, toothbrush, examination gloves, elastic bandages.

CLASS B:- This class mainly includes the general control and specific controls. It requires more regulatory control than class 1. These are referred as the low medium risk devices. These need certification by the notified body. Examples - sterile items surgical gloves,

urinary catheters, stomach tubes, needles, tracheal tubes etc.

CLASS C:- These devices are referred as the medium high risk devices, they need certification by the notified body for the design and manufacturing of medical devices. Examples - blood bags, condoms, non absorbable sutures, anesthesia machine, contact lens care products.

CLASS D:- General controls and specific control with premarket approval. These are referred as the high risk medical devices. These devices required premarket approval to ensure the device effectiveness and safety. Examples - pacemakers, vascular grafts, angioplasty catheters. Heart valves, implantable defibrillator.[22]

- **European Union (EU)**

The Medical Device Regulation (MDR) divides medical devices into four main categories: Class I, II a, II b and III. A Class III device is considered a high-risk device and therefore has the most stringent requirements.

CLASS I:- These devices are referred as low/medium risk devices. They further divided into two subclasses

1) Non-sterile/Non-measuring. Example - Corrective glasses.
2) sterile/measuring. Examples - Simple bandages or wound care products.

CLASS II a:- These devices are referred as medium risk devices. Examples - Syringes for pump infusion, ultrasound equipment, hearing aids.

CLASS II b:- These devices are referred as medium/high risk devices. Examples - Anesthesia machines, surgical lasers.

CLASS III:- These devices are referred as high risk devices. Examples - Stents-grafts, prosthetic joints.[23,24]

- **United States (US)**

The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.

Class I:– These devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages.47% of medical devices fall under this category and 95% of these are exempt from the regulatory process. Examples- adhesive bandages, hospital beds.

Class II:– Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. 43% of medical devices fall under this category. Examples- blood pressure cuffs, sutures.

Class III:– These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants. 10% of medical devices fall under this category. Examples- pacemakers, vascular grafts.[25]

- **Australia**

The TGA has classified medical devices into four classes on the basis of set of four classification rules: noninvasive, invasive, active, and special type of devices, which are:

Class I:- These devices are referred as low risk devices. Examples - examination lights and surgical microscopes.

Class II a:- These devices are referred as low/medium risk devices. Examples - warming blankets and electrical acupuncture.

Class II b:- These devices are referred as medium/high risk devices. Examples - infant incubators and external defibrillators.

Class III:- These devices are referred as high risk devices. Examples - heparin-coated catheters and biological heart valves.[26]

- **Africa**

A classification scheme was developed to categorize the level of medical device regulation.

Level 1:- It was designated for countries with the most well-established regulatory processes. These may closely resemble those of the FDA or European Medicines Agency in both complexity and level of establishment. Example - South Africa.

Level 2:- It was designated for countries with developing regulatory processes where such processes are not yet well-established or implemented. Examples - Sudan, Kenya, Uganda, Zimbabwe.

Level 3:- It was designated for countries with no defined regulatory approval process for

medical devices. This included countries that have legislation mandating the regulation of medical devices but have no defined system for pursuing implementation. It also included countries that use informal systems of regulation or regulate medical devices according to the same policies that govern the import of all commercial goods. Examples - Botswana, Namibia, Malawi, Burundi.[21]

Rules and regulations

- **India**

In India, the Federation of Indian Chambers of Commerce and Industry (FICCI) is being recognized as the focal point for regulations of medical device. It has been working closely with the Central Drug Standard Control Organization (CDSCO) and Indian medical regulators (both importer and native manufacturers) to increase access to medical device, promoting its manufacturing and streamlining the regulatory process toward global harmonization.[27]

In October 2005, the manufacturing of devices came under the control of the Central Licensing Approving Authority. It declared 10 devices, such as cardiac stents, drug-eluting stents, catheters, intraocular lenses, bone cements, heart valves, scalp vein sets, and so on, to be considered drugs and included another 19 sterile medical devices (on March 20, 2009) such as extension tubes, arterial venous fistulas and spinal needles, volume measuring sets, heart lung packs, and so on, under the provisions as such.[28] Medical Devices and Diagnostics Division of Central Drug Standard Control Organisation (CDSCO) has developed structured regulations for medical devices, IMDR which was released in January 2017 and came into force from January 2018.[29] IMDR was amended in February 2020 as "Medical Devices (Amendment) Rules, 2020"and came into force in April 2020. The 2020 amendment was released with an addition of "registration of certain medical devices".[30]

- **European Union (EU)**

The Medical Device Regulation, MDR 2017/745 (hereinafter referred to as "the MDR") came into force on 25 April 2017 and into application on 26 May 2021. The MDR replaced the Medical Device Directive, MDD 93/42/EEC, as well as the Council Directive 90/385/EEC on Active Implantable Medical Devices, AIMD.[31] The EUDAMED database European Database on Medical Devices – provides information about the lifecycle of medical devices available in the EU. The database has been developed by the European

Commission and contains information about economic operators such as manufacturers, authorised representatives and importers.[32] In the EU, medical devices require a CE marking, which proves that the product meets the essential requirements and has been evaluated under the requirements. The product's manufacturer or authorized representative declares that the product meets the standards regarding safety, health and environmental protection and consumer protection.[33]

- **United States (US)**

The regulatory limbo involving all-metal hips resulted from the Medical Device Amendments of 1976. The law set differing test requirements for various devices, depending on the perceived risk of using them or the role they played in sustaining a patient's life and health. Producers of devices considered high risk, like implanted heart defibrillators, had to perform clinical trials to obtain F.D.A. approval for new products. But makers of devices considered less risky, like hospital pumps, had to show only that a new product resembled one already on the market.[34] The FDA publishes three months for 510(k) clearance andnine months for PMA approval.[35]

- **Australia**

A manufacturer has to prove that both the device and manufacturing process used to make the device adhere to the requirement of the therapeutic good legislation under conformity assessment of medical device. The certificate granted by the regulatory body proving that a manufacturer has been assessed and has the proper system in place tomanufacture the device is known as conformity assessment evidence. A conformity assessment certificate, a Declaration of Conformity and an application to include the medical device in the ARTG are the three documents essential to register a medical device in Australia.[35,36]

- **Africa**

In Kenya, the regulation of medical devices is the responsibility of the Pharmacy andPoisons Board which is a regulatory authority established under the Pharmacy and Poisons Act, Chapter 244.[37] In Nigeria, the regulation of medical devices is the responsibility of the National Agency for Food and Drug Administration and Control under the provisions of Act CAP F33 LFN 2004 and the accompanying guidelines[38] With regard to Egypt, the registration and approval of medical devices require compliance with the Central Administration of Pharmaceutical Affairs, a division of the Egyptian Ministry of Health that oversees the country's medical device market.[39] In Sudan, the regulation of medical devices

is undertaken by the National Medicines and Poisons Board.[37]

The importation and registration of medical devices in Morocco is the responsibility of the Moroccan Ministry of Health through the Medical Devices Advisory Committee.[40] Angola has developed regulations for medicines and other pharmaceutical products which apply across the public and private sector, but the country does not have a comprehensive regulatory system that is specific to medical devices.[40] Medical devices in Algeria are regulated by the Directorate of Pharmacy in collaboration with the National Laboratory for the Control of Pharmaceutical Products, which falls under the supervision of the Ministry of Health and Population.[40] In Tanzania, the Food and Drugs Authority regulates the quality, safety and performance of medical device.[42] Medical devices in Ethiopia are regulated by the Food, Medicineand Healthcare Administration and Control Authority of Ethiopia.[43] In South Africa, medical devices are regulated by the newly enacted Medicines and Related Substances Amendment Act, 14 of 2015.[44]

Market Condition

The global connected medical devices market has grown rapidly as a result of rising government initiatives to promote automation in healthcare, a growing need for cost-cutting in the healthcare system, and a growing emphasis on active patient engagement and improving patient outcomes.

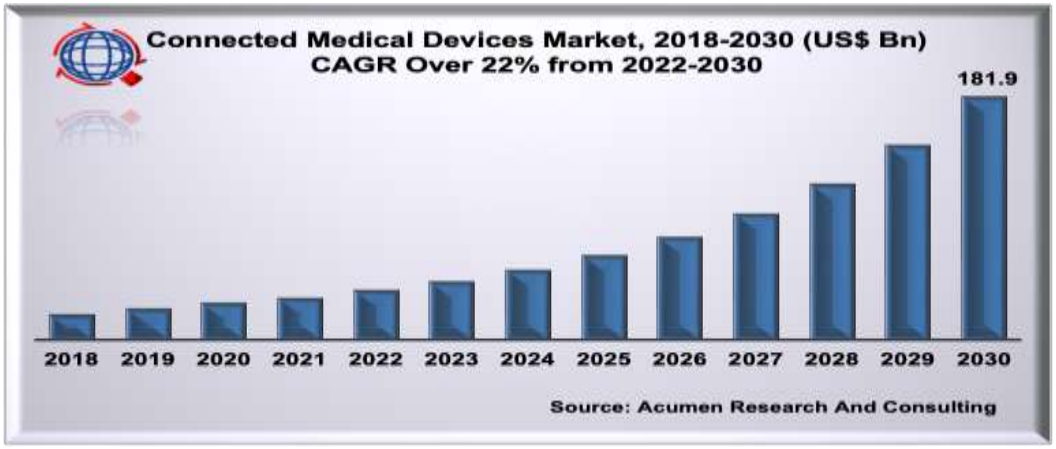

Fig. 1:- Connected medical divices market, 2018 – 2030.

- **India**

Approximately 70% of medical devices in India are imported.[9] This gap in import vs. manufacturing provides a big opportunity to medical device manufacturers to fulfill this gap by indigenous manufacture and sales. Currently, the medical device development process is

very complex and is time-consuming. Its approval is one of the most structured processes, which is highly regulated and governed by Indian Medical Device Rules (IMDR) 20179[29] and Medical Devices (Amendment) Rules, 2020.[30] Healthcare sector in India has undergone significant upgrades in the 21st century. Over the years, India has attained a 10% growth rate in this sector and by 2025 it is expected to reach $280 billion.[10] The devices distributed in various segments differ in terms of market share in India. Largest segment is of the medical instruments and appliances (34%), followed by diagnostic imaging devices (31%), consumables and implants (19%), and patient aids and others (16%).[10]

- **European Union (EU)**

The medical device sector is important for the European economy and there are over 500,000 medical devices on the EU market.[11] It is estimated that the global market has a total of two million medical devices and the devices are categorised into around 7000 device groups.[45] The MDR was introduced to ensure that all medical devices licensed in European market meet high safety and quality standards equally, thus minimizing the health risks for patients. In addition to the overarching goal of ensuring a high level of patient protection, harmonization and strengthening of the European internal market for medical devices, the European Community also pursue a goal to facilitate the innovation and ensure the competitiveness of the medical device industry in the EU. The MDR aimsto achieve this by introducing stricter regulatory requirements for medical devices, including increased testing of clinical data, stricter requirements for manufacturers' quality management systems and more transparency in the supply chain.[46]

- **United States (US)**

The majority of medical devices subject to FDA regulation progress to market via one of three pathways: Premarket Notification (commonly known as 510(k) Clearance), Premarket Approval (PMA), and Humanitarian Device Exemption (HDE). There are other pathways, such as the Breakthrough, Expedited Access, De Novo, and Investigational Device Exemption, however these areless frequently used.[15] Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA their intent to market a medical device. This is knownas Premarket Notification (PMN) or 510(k). Under 510(k), before a manufacturer can market a medical device in the United States, they must demonstrate to FDA's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market. If FDA rules the device is "substantially

equivalent," the manufacturer can market the device. If the device you are researching has been in commercial distribution before 1976 or is substantially equivalent to a device already on the market, you should search FDA's 510(k) releasable database.[25]

- **Australia**

In 2022, U.S. exports of medical equipment and supplies to Australia totaled US$1.5 billion, representing 3% of total medical equipment and supplies exports. Approximately 85% of domestic demand for medical devices and diagnostics is met by imports while nearly all medical technology products manufactured in Australia are exported. The three major suppliers of medical imports are the United States, China, and Germany. The United States is the largest supplier of medical products, accounting for 31% Australia's imports. Australia has a high per capita income, and there is demand for a full range of medical equipment. U.S. medical equipment is traditionally well received due to its perceived high quality. The market is sophisticated, mature, and quick to adopt new healthcare technologies.[47]

- **Africa**

Half of all COSECSA countries are currently developing regulatory processes for medical devices (Level 2) while the remaining half do not have a formal regulatory process in place for medical devices (Level 3). South Africa has an established, formal regulatory process for medical devices that includes all essential regulatory components as recommended by the WHO (Level 1). Levels of medical device regulation were examined with respect to GDP and GDP per capita as these metrics are descriptive of the size of the economy and income per person. GDP was found to have a strong positive association with the level of medical device regulation, yielding a Spearman correlation coefficient of 0.90. South Africa, with the highest GDP of $349 billion, has the greatest establishment of medical device regulation. All countries with a GDP between $20 and $120 billion fell under Level 2. All countries with a GDP lower than $20 billion fell under Level 3.[48]

Challenges

- **India** :- 1. Import Centric.
2. Inadequate Distributions.
3. Limited Funding.
4. Proper Training and Education.
5. Weak Technology Transfer Process.[49]

- **European Union (EU)**

1. Training and education.
2. Technical documentation.
3. Monitoring of suppliers.
4. Traceability and identification.
5. Review of Existing Medical Devices.
6. Bottlenecks in product availability.
7. Delays in introducing new technologies.[50]

- **United States (US)**

1. Financial Challenges and Healthcare Reform.
2. Patient Safety and Quality.
3. Government Mandate.[51]

- **Australia**

1. Gaps in the current framework.
2. Variable levels of consumer health literacy.
3. "Off-label use" of medical-device-like consumer goods.
4. Interpretation of 'intended purpose' to determine regulatory status.
5. New industry players unfamiliar with medical device regulation.[52]

- **Africa**

1. Regulatory inefficiencies.
2. Policy incoherence across government ministries.
3. The continent's well-documented infrastructure gap.
4. The lack of adequately skilled human capital in the country.[53,54]

CONCLUSION

This study shows the current scenario of the medical device in various countries. After study realizing that the production and use of the medical device is in primary stage. Some developed countries are making a lot of innovations in this but the underdeveloped countries are yet to move towards it as desired. Harmonization need to improvements in awareness and education programs about the medical devices. Manufacturers need to balancing device effectiveness with safety of patients. Regulatory agencies of particular country should establish an online adverse event reporting system and recall system to promote smooth

transaction between manufacturers and hospitals/patients. Medical devices are all set for a new era in the medical field.

REFERENCES

1. Information document concerning the definition of the term "Medical Device". 2005. May, [Accessed 2009 Oct 14].
2. World Health Organization (WHO). Medical device – full definition. Accessed March 4, 2021.
3. Sanjana P, Kirti H, Sajeli Begum A. Medical Devices and their approval procedure in India. International Jornal of Drug Regulatory Affairs, 2016; 4(3): 19-29.
4. Robert Shulman, Stuart Alan Weinzimer, William Tamborlane. Medical devices and technology across the years. [Cited 2023 Apr 30].
5. Privitera, M.B., M. Design, and D.L. Murray. Applied ergonomics: Determining user needs in medical device design. In Engineering in Medicine and Biology Society, 2009. EMBC 2009. Annual International Conference of the IEEE, 2009.
6. Hegde, V. Role of human factors / usability engineering in medical device design. in Reliability and Maintainability Symposium (RAMS), 2013 Proceedings – Annual, 2013.
7. Lucke, L.E., A. Mickelson, and D. Anderson. Proving experience speeds medical device time to market. in Engineeringin Medicine and Biology Society, 2009. EMBC 2009. Annual International Conference of the IEEE, 2009.
8. Guidelines for import and manufacture of medical devices. [Accessed 2009 Sep 18].
9. Markan S, Verma Y. Indian medical device sector: Insights from patent filing trends. BMJ Innov, 2017; 3: 167–75.
10. Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare. 2016. [Lastaccessed on 2021 Mar 04].
11. European Commission. Medical devices – sector. 2022. Accessed 9 May, 2022.
12. European Commission. Contact Points of National Authorities: December 2021.
13. Bianchini E, Mayer CC. Medical device regulation: should we care about it? Artery Res, 2022; 28(2): 55–60. doi: 10.1007/s44200-022-00014-0.
14. Makower J, Meer A, Denend L. FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies, November 2010.
15. U.S. Food and Drug Administration Overview of Device Regulation.
16. Australian Government Department of Health and Ageing. Review of health technology assessment in Australia, December 2009. Canberra: DoHA, 2009.

17. Australian Government Department of Health and Ageing Therapeutic Goods Administration. Australian regulatory guidelines for medical devices (ARGMD). Canberra: TGA, 2011.
18. Wilkinson B, van Boxtel R. The medical device regulation of the European Union intensifies focus on clinical benefits of devices. Ther Innov Regul Sci. 2019; 2168479019870732. 10.1177/2168479019870732.
19. Sastry A. Overview of the US FDA medical device approval process. Curr Cardiol Rep, 2014; 16(6): 494. 10.1007/s11886-014-0494-3.
20. Lissel A, Ottenberg F, Bracio BR, et al.. Status and solutions to medical device regulations for improving the healthcare landscape in Africa. Annu Int Conf IEEE Eng Med Biol Soc, 2016; 2016: 4329–4332. 10.1109/embc.2016.7591685.
21. World Health Organization (WHO). WHO Global Model Regulatory Framework for Medical Devices Including in vitro Diagnostic Medical Devices. WHO; 2017. Accessed March 4, 2021.
22. The Indian Medical Device Industry, Regulatory Legal and Tax Overview.
23. European Parliament and the Council. Regulation (EU) 2017/745 on medical devices. April 5., 2017.
24. European Commission. MDCG 2021-24 - Guidance on classification of medical devices, October 2021.
25. U.S. Food and Drug Administration Learn if a Medical Device Has Been Cleared by FDA for Marketing.
26. Australian Medical Device Guidance Document Number 25: classification of medical device. 2005. Jan, [Accessed 2009 Aug 12].
27. Medical devices and equipment. [Accessed Cited 2009 Dec 16].
28. Clarification with regard to control of various medical devices. 2009. Mar, [Accessed 2009 Dec 12].
29. Medical Device Rules, 2017: Ministry of Health and Family Welfare, Government of India. Available via CDSCO. [Last accessed on 2020 Jun 08].
30. Medical Devices (Amendment) Rules, 2020: Ministry of Health and Family Welfare, Governmentof India. Available via CDSCO. [Last accessed on 2020 Jun 08].
31. European Commission. New regulations, 2022.
32. European Commission. EUDAMED, European database on medical devices, 2022.
33. Finnish Medicines Agency (Fimea). Medical devices, 2022.
34. Meier B. 2013. FDA to tighten regulation of all-metal hip implants. New York Times.

January 16.

35. Brolin S. Global Regulatory Requirements for Medical Devices. 2008. Available from: URL: http://mdh.diva-portal.org/smash/get/diva2: 121327/FULLTEXT01.pdf on 10 April 2014.
36. Australian regulatory guidelines for medical devices (ARGMD). Version 1.1 May 2011. TGA Health Safety Regulation. Available from: URL: http: //www.tga.gov.au/pdf/devices-argmd-01.pdf on19th June 2014.
37. WHO. 2017. Global atlas of medical devices: WHO medical devices technical series.
38. NAFDAC. 2005. Guidelines for registration of imported drug products in Nigeria NAFDAC/RR/002/00.
39. Gad, M., Kriza, C., Fidler, A. & Kolominsky-Rabas, P. 2016. Accessing the medical devices market in Egypt and Saudi Arabia: a systematic review of policies and regulations. Expert Review of Medical Devices, 13(7): 683–696.
40. Samadi, F. 2015. Regulatory requirements of medical devices in MENA countries.
41. Thumm, M., Gaparayi, P., Goredema, W. & Tjipura, D. 2013. Assessment of the medicines regulatory system in Angola: report. submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program.
42. Lissel, A., Ottenberg, F., Bracio, B.R., Ravizza, A., De Maria, C., Ahluwalia, A., Di Pietro, L. & Trommler, P., 2016, August. Status and solutions to medical device regulations for improving the healthcare landscape in Africa. In 2016 38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC) 4329–4332.
43. Gebreab, S. & Wolyei, A.R. 2014. Regulatory overview: Ethiopia.
44. Kirby, N. 2017. A new regulatory regime for medicines comes into force in SA.
45. World Health Organization. Medical devices, 2022.
46. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) Text with EEA relevance.
47. Australia medical devices country commercial guide.
48. GDP (current US$). The World Bank; 2020. Accessed March 4, 2021.
49. Smita Sahu, Saikat Panja, 2017. Current Status and Challenges of Medical Device Innovations- Indian Perspective.
50. The new European Medical Device Regulation: Friend or foe for hospitals and patients?

October 2023.

51. American College of Healthcare Executives (2011).
52. The challenges of regulating direct to consumer digital medical devices (2019).
53. Hubner S, Maloney C, Phillips SD, Doshi P, Mugaga J, Ssekitoleko RT, et al. The Evolving Landscape of Medical Device Regula-tion in East, Central, and Southern Africa. Glob Health Sci Pract, 2021; 9(1): 136-48. [PubMed ID:33764886]. [PubMed Central ID:8087432]. https://doi.org/10.9745/GHSP-D-20-00578.
54. Gwaradzimba E, Shumba A. The nature, extent and impact of the brain drain in Zimbabwe and South Africa. Acta Acad, 2010; 42(1): 209-41. https://doi.org/doi:10.10520/EJC15473.